Study of a primary care depression relapse prevention program: “Keeping the blues away”

Dr Cate A. Howell CSM
November, 2009

Supervisors:
Professor Justin J. Beilby
Professor Deborah A. Turnbull

The Discipline of General Practice
School of Population Health and Clinical Practice
Faculty of Health Sciences
The University of Adelaide
Abstract

Depression is a serious and often relapsing problem, and the primary care relapse rate is reported to be 37-44.5%. The majority of patients with depression will present to their general practitioner (GP), who will often continue to play a central management role. It is therefore important that GPs are able to access to effective long-term management programs aiming to prevent relapse. However, practical well-researched models for delivering long-term care in the primary care setting are limited. The desire to develop an evidence-based depression relapse prevention program (RPP) stemmed from caring for individuals with depression in primary care settings. A scholarship provided the opportunity to go overseas in the year 2000 to investigate the management of depression, and to speak with a number of leaders in the primary care mental health field. There was consensus that depression relapse was an important area to research.

This combination of thesis and publications is the summation of eight years of work, related to the conceptualisation, development, and study of a primary care depression RPP called ‘Keeping the Blues Away’ (KBA). The overall aim of this research was to develop and implement a primary care depression RPP and to evaluate its acceptability and effectiveness. An action research approach involving enquiry, intervention and evaluation was adopted, and the research involved a number of phases, based on a framework by Campbell and Fitzpatrick (2000). The phases included pre-clinical and modeling (or development) phases carried out in 2001-2 (literature review, development of the KBA program and resources); an exploratory phase carried out in 2003 to assess the feasibility of studying the program in the general practice setting; and finally the intervention phase involving a randomised controlled trial (RCT). Ethics approval for this research was gained from the University of Adelaide Human Ethics Committee in 2001. The RCT was carried out in 2003-5. However, as insufficient numbers of participants were recruited to the intervention phase, the RCT is viewed as a large pilot study.

The initial literature review highlighted a paucity of literature relating to primary care and relapse prevention. One American study of a primary care RPP by Katon in 2001 was identified, and as the intervention in this study did not result in a significant reduction in relapse rates, it was concluded that a more intensive RPP might be
needed. In designing KBA, the researcher also drew on the recommendations of Segal (2003), who suggested that it might be possible to take ingredients of proven treatments and design novel preventive treatment. Subsequent literature reviews identified limited additional work on primary care depression RPPs in the Netherlands, including a thesis on a RCT of a RPP which did not produce significant results and an economic evaluation of the RPP.

KBA is a unique and multifaceted program aiming to reduce the severity of depression and prevent relapse, and drawing on a number of evidence-based therapies, such as Cognitive-behavioural Therapy (CBT) and Interpersonal Therapy (IPT). KBA is an holistic program (addressing the needs of the whole person), an approach consistent with bio-psychosocial model of the causation and treatment of depression. KBA addresses risk factors for depression, and is primarily a skills-based program. As depression is viewed as a chronic illness, the KBA program incorporates chronic disease management (CDM) principles such as self-management and adhering to treatment regimes. The literature and rationale for the development of the KBA program are summarized in the first publication from the British Primary Care Mental Health Journal. KBA is presented as a treatment manual, written over eighteen months, and an accompanying relaxation recording. The program is comprised of 10 Steps, with each step covering key areas of depression management and relapse prevention, and including information and practical exercises. The GP guides the person through the 10 Steps of the program.

The exploratory phase of this research involved trialling the program and its associated training and resources over a three month period with eight GPs and 15 patients. The GPs worked through the program with their patients during six to eight sessions. This phase provided useful insights related to the acceptability of the program, the suitability of the KBA resources, psychological assessment tools and GP training for the pilot RCT. Some challenges in implementing the KBA program were identified, such as GPs keeping contact with patients to ensure completion of all 10 Steps of the program. However, it was believed that the challenges identified in the exploratory phase could be managed through more extensive training and refinement of the study protocol. A key finding was that additional (up to 12) sessions for GPs to deliver the KBA program were required. The KBA materials were generally well received, however in this phase a relaxation tape was provided with words and no music, and suggestions were received to provide a relaxation CD with words and
Delivered by a GP and Clinical Psychologist over 20 hours, the KBA training program for GPs participating in the pilot RCT included information on the assessment and management of depression, psychological approaches and relapse prevention strategies. The training program was evaluated by pre-test and post-test questionnaires, and an evaluation form. The pre-test involved a series of questions related to depression and its management, and also several questions on GPs perceived confidence in managing depression. There was sound pre-training knowledge, and significant improvement occurred in almost a quarter of the questions post-training. Self-perceived confidence in depression management also improved. The evaluation found that the training was well-received by the GPs, who reported that their knowledge of depression, appreciation and awareness of the various treatments and skills improved.

A number of research questions were identified for the pilot RCT, relating to whether there would be a reduction in relapse rates of depression when patients diagnosed with major depression were managed by GPs utilising the KBA program, when compared to usual general practice care. Secondary hypotheses related to clinical outcomes (reduced severity of the depression, clinical improvement, and enhanced quality of life) and improved process of care. A cluster randomised trial design was chosen with randomisation by individual general practices. A range of urban and rural South Australian Divisions of General Practice were contacted and GPs were to participate in the RCT. A total of 45 GPs agreed to participate and 23 practices were randomised to intervention and control. GPs were asked to identify patients aged 18 years or older, who had been diagnosed with a depressive disorder. A total of 110 participants were recruited, with 62 randomised to the intervention group and 48 to the control group. GPs and patients in the intervention arm of the study were provided with the KBA resources.

During the pilot RCT, quantitative measures of depression severity (DASS-21), quality of life (WHOQOL) and the Clinical Global Improvement (CGI) Scale were collected, and at the end of the study a series of telephone interviews were undertaken to gather qualitative information about experiences with KBA. Analysis looked at relapse rates and was completed on an ‘intention to treat’ basis, and from background music. These suggestions were acted on for the pilot RCT and a CD was recorded by the researcher.
the semi-structured interviews were analysed using content analysis. The results of the pilot RCT were published in the Medical Journal of Australia.(2)

Some interesting and promising findings occurred in the pilot RCT. Although no statistically significant differences were found between the intervention and control groups in terms of their relapse rates, a tendency was noted towards relapse rates being reduced in the intervention group. Younger people in either group tended to show similar probability of relapse, while older people in the intervention group showed a much lower probability of relapse than those in the control group. This was statistically significant ($P = 0.018$). A general decrease in depression scores was also found over time, and participants in the KBA group who had experienced depressive symptoms for more than six months had reductions in depression scores approaching significance ($P = 0.06$). GP and participant interview results indicated that the content of KBA was viewed as highly/extremely relevant, and the majority of participants were highly/extremely satisfied with the program. In regards to the KBA resources, the treatment manual and relaxation CD were well received, and psychoeducation and skills-based strategies were viewed as particularly relevant.

The key strengths of the pilot RCT were that it addressed an important area and that it involved the development of a novel clinical intervention with a manualised format. The research involved a multi-phase approach, which resulted in comprehensive KBA resources being developed. The RCT was undertaken in a number of varied general practices, suggesting that the results may be generalisable across a range of practices. The major limitations of the study were the recruitment of patients, and the potential lack of standardisation of clinical data collected via the retrospective case note review. Further studies of KBA are suggested, in particular exploring the use of the program in older patients and the use of other program formats (such as computer-assisted format) in younger people. The KBA manual and relaxation CD should continue to be improved, and the GP training program should continue to be offered as part of post-graduate education. A number of recommendations regarding future study design can be made, and in particular patient participant recruitment issues need to be addressed and longer-term follow-up of patients, such as two-year follow-up, should be carried out. The use of structured interviews carried out by blinded assessors should be considered in future studies, and health economic data would provide valuable information.
Over the past eight years there have been many developments in the Australian primary care mental health system. Notable changes since completion of the pilot RCT have been further emphasis on mental health care planning, including relapse prevention, and improved access to mental health professionals (MHPs) through government funding of their services in late 2006. These changes are outlined in the final publication from the Australian Family Physician journal. (3) The KBA program is now being used by a number of primary care mental health programs and MHPs in Australia, assisted by its manualised format, and there is potential to carry out research incorporating such programs and professionals in the future. A computer-assisted version of KBA has been developed, and this version is now being used in some primary care settings in Australia. In addition, there has been further editing and publication in October, 2009 of the KBA resources across the English-speaking world by Radcliffe Publishers.
Declaration

NAME: Dr Catherine A Howell
PROGRAM: Doctor of Philosophy (Medicine)

This work contains no material that has been accepted for the award of any other degree or diploma in any university or other tertiary institution, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

I give consent to this copy of my thesis, when deposited in the University Library, being available for loan and photocopying, subject to the provisions of the Copyright act 1968.

I also give permission for the digital version of my thesis to be made available on the web, via the University's digital research repository, the Library catalogue, the Australasian Digital Theses Program (ADTP) and also through web search engines, unless permission has been granted by the University to restrict access for a period of time.

SIGNATURE: ..........................................................

DATE: 14th July, 2010
List of Manuscripts Contributing to This Thesis

1. Preventing depression relapse: a primary care approach
   Primary Care Mental Health Journal 2004; 2: 151-156

2. Preventing relapse of depression in primary care: a pilot study of the “Keeping the blues away” programs

3. Management of recurrent depression
   Australian Family Physician, 2008; 37(9):704-708.
Acknowledgements

This thesis is entirely the work of the author including conception and study design, seeking of grant funds, supervision of data collection and writing. The contribution of colleagues and agencies who provided assistance is gratefully acknowledged.

Funding for this research was provided by the Discipline of General Practice, University of Adelaide, Primary Health Care Research Evaluation and Development Program, beyondblue: the national depression initiative, Royal Australian College of General Practitioners, and Spencer Gulf Rural Health School.

Advice and support was received from:

1. Dr Nancy Briggs, who assisted with the statistical analysis.
2. Wendy Newbury, Project Officer, who assisted with general project administration and organisation, data entry and cleaning, and telephone interviews.
3. Catherine Leahy and Andrew Holton who assisted by developing KBA data-bases.
4. Melissa Opolski, who carried out the retrospective case note reviews, and later contributed to the third paper and proof-read various thesis chapters.
5. Charlotte Marshall, who contributed to two of the papers.
6. Dr Michele Murphy, who co-facilitated the KBA education program, and Michelle Sexton for her support.
7. Gemma, Jessie and Ashleigh who assisted with proof-reading and technical assistance in the preparation of maps, tables and graphs.
8. Christina Sougleris, Project Officer, who entered data from the KBA education program into a data-base.
9. Nicky Bennett, administration officer, who assisted with formatting.
The academic supervision for this doctorate thesis at Adelaide University has been provided by:

Professor Justin Beilby, Executive Dean, Faculty of Health Science, University of Adelaide.

Professor Deborah Turnbull, Head of the School of Psychology, University of Adelaide.

I am extremely grateful to my supervisors for their guidance and wisdom during the past eight years.

Thank you also to my family (especially Alex) and friends who have supported me during this work.
Contents

Abstract................................................................................................................................. i
Declaration............................................................................................................................ vi
List of Manuscripts Contributing to This Thesis................................................................. vii
Acknowledgements........................................................................................................ viii
Contents............................................................................................................................... x
List of Tables and Figures................................................................................................. xvi
Glossary of Acronyms...................................................................................................... xix
Chapter 1. Exegesis.............................................................................................................. 1
  1.1 Combination thesis and publication format.............................................................. 1
  1.2 Background to this work.......................................................................................... 1
  1.3 The KBA program.................................................................................................. 2
  1.4 Research into the KBA program............................................................................. 3
  1.5 Chapter summaries............................................................................................... 5
  1.6 Summary............................................................................................................... 9
Chapter 2. Introduction and Literature Review................................................................. 10
  PART ONE.................................................................................................................... 10
  2.1 Research aims & hypotheses................................................................................. 10
  2.2 Depression background....................................................................................... 12
    2.2.1 Definitions of depression, relapse and recurrence......................................... 12
    2.2.2 Epidemiology................................................................................................ 14
    2.2.3 Depression illness burden............................................................................ 16
    2.2.4 Depression – a chronic disease.................................................................... 17
    2.2.5 Depression aetiology & co-morbidities....................................................... 17
    2.2.6 Depression severity, course and complications (including suicide)............. 21
  2.3 Management of Depression.................................................................................... 22
    2.3.1 Diagnosis and assessment............................................................................. 22
    2.3.2 Treatment phases......................................................................................... 24
    2.3.4 Management plans....................................................................................... 25
    2.3.5 Bio-psycho-social management of depression.............................................. 25
    2.3.6 Treatment guidelines.................................................................................... 29
    2.3.7 Treatment adherence.................................................................................... 31
    2.3.8 Management of self harm and suicide risk Assessment................................ 33
    2.3.9 Chronic disease management (CDM)............................................................. 35
  2.4 Relapse and Recurrence of Depression.................................................................. 37
4.3.6 Use of the KBA program ................................................................. 87
4.3.7 Assessment tools ........................................................................... 89
4.3.8 Interviews ...................................................................................... 92
4.4 Results .............................................................................................. 93
4.4.1 Feasibility of implementing and studying the KBA program in the general practice setting ................................................................. 93
4.4.2 Acceptability of the KBA program, suitability of the KBA resources and remaining study forms ................................................................. 105
4.4.3 Appropriateness of the psychological assessment tools ...................... 106
4.4.4 Evaluation of the GP training program to determine its adequacy ........ 107
4.5 Discussion .......................................................................................... 109
4.5.1 Feasibility of implementing and studying the KBA program in the general practice setting ................................................................. 110
4.5.2 Program acceptability ..................................................................... 111
4.5.3 Appropriateness of the psychological assessment tools ...................... 112
4.5.4 Adequacy of training ..................................................................... 113
4.6 Summary and recommendations .......................................................... 114
Chapter 5. Pilot Study GP Training Program: Methods and Results ............ 117
5.1 Introduction ....................................................................................... 117
5.2 Background ...................................................................................... 117
5.2.1 Positive outcomes from GP mental health training ............................ 118
5.2.2 Less positive outcomes from GP mental health training .................... 119
5.2.3 Australian GP mental health training initiatives ............................... 119
5.3 The pilot study training programs ......................................................... 120
5.3.1 The intervention (KBA) group training program ............................... 120
5.3.2 The control group training program ............................................... 129
5.4 Evaluation methods .......................................................................... 130
5.4.1 Sample and attendance ................................................................... 130
5.5 Evaluation results ............................................................................. 131
5.5.1 Pre-tests and post-tests ................................................................... 131
5.5.2 GP satisfaction ............................................................................... 134
5.6 Discussion ......................................................................................... 143
5.7 Summary ......................................................................................... 145
Chapter 6. Pilot RCT: Background and Method ........................................... 146
6.1 Introduction ....................................................................................... 146
6.2 Background ...................................................................................... 146
8.8.3 Helpful and unhelpful aspects of KBA .......................................................... 190
8.8.4 The KBA resources ..................................................................................... 190
8.8.5 Reasons for non-completion ......................................................................... 190
8.8.6 Overall perceptions ..................................................................................... 190
8.9 Summary ......................................................................................................... 191
Chapter 9. Pilot RCT - discussion .......................................................................... 193
9.1 Introduction ..................................................................................................... 193
9.2 Overview of the aims of the pilot RCT ............................................................. 193
  9.2.1 Internal validity ........................................................................................ 193
9.2.2 Issues related to GPs involved in the study and measurement of outcomes ................................................................. 195
9.3 Discussion of the findings in relation to the study aims ................................... 197
  9.3.1 Aim 1 - reduction in depression relapse ................................................... 197
  9.3.2 Aim 2 - reduction in depression severity .................................................. 198
  9.3.3 Aim 3 – enhancement of quality of life and production of greater clinical improvement ................................................................. 199
  9.3.4 Aim 4 – satisfaction with the KBA program ............................................. 200
9.4 Pilot RCT strengths and limitations................................................................ 200
  9.4.1 Study strengths ....................................................................................... 200
  9.4.2 Limitations of the study .......................................................................... 201
9.5 Interpretation of the pilot RCT in relation to comparable literature ............... 203
  9.6 Summary ..................................................................................................... 206
Chapter 10. Conclusion .......................................................................................... 207
10.1 Introduction ................................................................................................... 207
10.2 Pilot RCT implications and recommendations ............................................. 207
  10.2.1 GPs ........................................................................................................ 207
  10.2.2 Measurement Tools .............................................................................. 208
  10.2.3 Study design ......................................................................................... 208
  10.2.4 KBA and depression relapse and severity ............................................. 208
  10.2.5 KBA resources ..................................................................................... 209
10.3 The Australian primary mental health care system ...................................... 209
10.4 Potential modifications and additions to the KBA program ......................... 211
  10.4.1 Influence of new therapies and thinking .............................................. 211
  10.4.2 The development of computer-assisted therapy ................................... 213
10.5 Conclusion ................................................................................................... 213
Chapter 11. Closing Statements: Publication .......................................................... 217
List of Tables and Figures

Tables

Table 1.1 Summary of this work........................................................................................................ 4
Table 2.1 Risk factors for depression relapse/chronicity................................................................. 38
Table 2.3 KBA program outline........................................................................................................ 56
Table 4.2 Exploratory phase GPs: mean age and gender by practice location............................... 94
Table 4.3 Exploratory phase participants: demographic information.................................................. 95
Table 4.4 Exploratory phase participants: depression history............................................................... 96
Table 4.5 Exploratory phase participants: co-morbidities................................................................. 97
Table 4.6 Exploratory phase participants: depression treatment...................................................... 98
Table 4.7 Summary of KBA steps completed by participants............................................................ 99
Table 4.8 0-10 Depression rating scale results.................................................................................. 100
Table 4.9 DASS results...................................................................................................................... 101
Table 4.10 Quality of Life results........................................................................................................ 103
Table 4.11 Clinical Global Improvement results.................................................................................. 104
Table 4.11. Completion of assessment tools ....................................................................................... 107
Table 4.12 Adequacy of GP training – evaluation findings................................................................... 108
Table 4.13 General evaluation questions (on presentation and content).......................................... 109
Table 5.1 Learning outcomes for each step of the KBA intervention group training......................... 124
Table 5.2 Content of KBA intervention group training....................................................................... 127
Table 5.3 Number of intervention group urban and rural GPs who attended each GP training session.......................................................................................................................... 131
Table 5.4 Comparison pre- and post-test results (Wilcoxon Signed Rank test)................................. 133
Table 5.5 GP training program session 1 evaluation results............................................................... 135
Table 5.6 GP training program session 2 evaluation results............................................................... 137
Table 5.7 GP training program session 3 evaluation results............................................................... 138
Table 5.8 GP training program session 4 evaluation results............................................................... 139
Table 5.9 GP training program session 5 evaluation results............................................................... 140
Table 5.10 GP training program learning outcomes results................................................................. 141
Table 6.1 Summary of participant inclusion and exclusion criteria................................................... 152
Table 8.1 Practice location – urban and rural...................................................................................... 169
Table 8.2 Characteristics of GPs randomised to intervention (KBA) group and control group.............. 171
Table 8.3 Characteristics of participants randomised to intervention (KBA) group and control group........................................................................................................................................ 172
Table 8.4 Mental health training undertaken by GPs in the study...................................................... 173
Table 8.5 Usual GP assessment and management .................................................. 174
Table 8.6 Depression relapse data by group ........................................................ 177
Table 8.8 Depression relapse data by past relapse ............................................. 178
Table 8.9 Interactions between groups and length of time ................................ 181
Table 8.10 Mean DASS scores in KBA and control groups ............................. 182
Table 8.11 Interactions between groups and length of time .............................. 183
Table 8.12 Interactions between groups and length of time .............................. 184
Table 8.13 Interactions between groups and length of time .............................. 185
Table 8.14 Interactions between groups and length of time .............................. 186
Table 8.15 CGI results ...................................................................................... 188
Figures

Figure 2.1 Depression severity, relapse, recurrence and remission ......................... 14
Figure 2.2 Prevalence of mental health disorders in Australia .............................. 15
Figure 2.3 Prevalence of anxiety and depression in Australia .............................. 16
Figure 4.1 Graphs showing DASS results ............................................................. 102
Figure 4.2 Graph of Quality of Life results ......................................................... 104
Figure 4.3 Graph of Clinical Global Improvement results .................................... 105
Figure 8.1 Practice locations - urban and hills practices ................................... 169
Figure 8.2 Further practice locations - including rural practices ...................... 170
Figures 8.4 Depression scores over time ............................................................. 180
Figure 8.4 Quality of life score – physical - over time ......................................... 184
Figure 8.5 Quality of life score – psychological - over time ................................. 184
Figure 8.6 Quality of life score – social - over time ............................................ 186
Figure 8.7 Quality of life score – environmental - over time .............................. 187
Glossary of Acronyms

ACT – Acceptance and Commitment Therapy
ATAPS – Access to Allied Psychological Services
BOMHC – ‘Better Outcomes in Mental Health Care’
CBT – Cognitive Behavioural Therapy
CGI – Clinical Global Improvement
CPD – Continuing Professional Development
DALYs - Disability Adjusted Life Years
DASS – Depression, Anxiety and Stress Scale
DSM-IV – Diagnostic and Statistical Manual of Psychiatric Disorders
ECT – Electroconvulsive Therapy
FPS – Focused Psychological Strategies
GP – General Practitioner
GPMHSC – General Practice Mental Health Standards Collaboration
IPT – Interpersonal Therapy
KBA – Keeping the Blues Away
LIDO – Longitudinal Investigation of Depression Outcomes
LIFE – Longitudinal Interval Follow-up Evaluation
MBCT – Mindfulness-Based Cognitive Behaviour Therapy
MHP – Mental Health Professionals
MJA – Medical Journal of Australia
MBS – Medicare Benefits Schedule
MI – Myocardial Infarction
QOL – Quality of Life
RACGP – Royal Australian College of General Practitioners
RCTs – Randomised Controlled Trials
RPP – Relapse Prevention Program
SA – South Australia
SD – Standard Deviation
SNRIIs – Selective Serotonin and Noradrenaline Reuptake Inhibitors
SSRIIs – Selective Serotonin Reuptake Inhibitors
United States of America - USA
VVS - Victorian Validation Study
WHO – World Health Organisation: WHO-QOL – WHO Quality of Life
Chapter 1. Exegesis

This work details the basis and development of a unique primary care treatment program, the KBA program, which aims to reduce the severity and relapse of depression. It also describes the research undertaken to evaluate the program’s effectiveness, and the implications of this research. This chapter provides a brief summary to this work, including the various phases of the research and how the work will be presented.

1.1 Combination thesis and publication format

This work utilises a combination of written text and publications. The research has been carried out in several phases (described below), over eight years. Several publications have resulted. The written chapters and the publications together provide a comprehensive summary of the research.

1.2 Background to this work

The desire to develop an evidence-based depression RPP stemmed from the researcher’s work in caring for individuals with depression in the primary care setting over many years. Primary care is the first level care provided to patients by suitably trained personnel. It is supported by referral systems in a way that maximises patient self-reliance and participation. (4) Patients with depression are most often managed by health care providers in this setting. (5) Working in general practice, it became apparent that individuals with depression commonly re-presented at a later time with relapses and recurrences of the illness. This observation was supported in a study by Vuorilehto et al (2004) which reported that the majority of primary care patients with depression suffer from recurrent major depression. (6) It also seemed that there was limited information on relapse prevention strategies suitable for the primary care setting, making clinical management challenging.

A Churchill Fellowship in the year 2000 provided the opportunity to travel overseas to study the primary care management of depression and anxiety with a number of
leaders in the primary care mental health field. Professors of General Practice and Psychiatry with an interest and research background in primary care mental health were visited, and discussion with these experts identified that little work had been done in the area of relapse prevention in primary care. There was also a distinct consensus amongst these professionals that depression relapse was a significant issue which required further research.

The key outcome of the Fellowship was the decision to undertake research in the area of primary care depression relapse prevention. The literature review (detailed in Chapter 2) identified the view that depression should be managed as a chronic illness.(7) It also highlighted the paucity of literature relating to primary care and relapse prevention. Only one American study of a primary care RPP was initially identified, and as the intervention in this study did not result in a significant reduction in relapse rates, it was concluded that a more intensive RPP might be needed.(8)

1.3 The KBA program

As a result of the Fellowship and the literature review, a comprehensive and evidence-based treatment program was developed. Called KBA, it aims to reduce the severity of depression and prevent relapse. Consistent with the primary care setting, it is also a holistic program; in other words, it addresses the needs of the whole person including biological, psycho-social and spiritual facets.(9) The rationale for this approach will be justified in Chapter 2. Given that the majority of patients with depression will present to their GP, and the GP generally continues to play a central management role, it is important that GPs are able to utilise effective long-term management programs aiming to prevent relapse.(10) Hence the KBA program was designed to be delivered by in the general practice setting.

In designing KBA, the researcher drew on the work of Segal (2003), who suggested that it might be possible to take the active ingredients of proven treatments and design novel preventive treatments that are skills based.(11) KBA is designed to be a novel, multifaceted program, that draws on a number of evidence-based therapies, such as Cognitive Behavioural Therapy (CBT) and Interpersonal Therapy (IPT). With any new or novel program, there will be reliance on established approaches, but new ideas will also be involved. In developing the KBA program, a range of information and knowledge sources were utilised, including research literature,
published books on depression treatment, current expert thinking on depression and relapse prevention, and clinical and teaching experience. The KBA program also incorporates CDM principles such as self-management (12), which involves engaging in health promotion activities, monitoring/managing symptoms of illness, managing the impacts of illness on functioning, emotion and relationships, and adhering to treatment regimes.(13) KBA is presented as a treatment manual, comprised of 10 Steps, with each one covering key areas in depression management and relapse prevention. The clinician can guide the person through each step of the program. KBA incorporates assessment, treatment planning, and regular follow-up of patients. It provides information and exercises to teach practical skills and relapse prevention strategies.

**1.4 Research into the KBA program**

This thesis presents research related to the development of the KBA program and its implementation and evaluation in the primary care setting. The research is based on the ‘action research’ model, which is a ‘community-based model’, undertaken to improve practices and understanding of practices in social systems. Action based research has frequently been undertaken in range of settings, such as health clinics and schools.(14) An action research approach involving enquiry, intervention and evaluation was adopted.(15)

Randomised controlled trials or RCTs are accepted as a reliable method of testing the effectiveness of a therapeutic intervention.(16) However, complex interventions, such as CBT for individuals with depression, or a multifaceted program such as KBA, which are made up of multiple components, are more difficult to study due to problems of developing, identifying and reproducing the intervention.(16) In this research, a framework for studying the development and evaluation of such interventions developed by Campbell and Fitzpatrick (2000) was utilised. As applied to KBA, it involved:

1. A pre-clinical phase, including identification and review of relevant theory evidence.
2. A modeling or developmental phase involving design of the program and preparation of the KBA program resources.
3. An exploratory phase to assess the feasibility and acceptability of studying the program in the general practice setting.
4. An intervention study to evaluate the effectiveness of the program. An RCT was carried out, but due to time/funding constraints, and some recruitment challenges, the intervention study described in this work is a pilot study.

The various phases are detailed in the 12 chapters of this work. Table 1.1 (below) provides a summary of the research phases and how they relate to the thesis chapters and publications. A descriptive summary of the chapters follows.

**Table 1.1 Summary of this work**

<table>
<thead>
<tr>
<th>Research phase</th>
<th>Time-line</th>
<th>Chapter</th>
<th>Chapter title</th>
<th>Focus of chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exegesis</td>
<td>1</td>
<td>1</td>
<td>Exegesis</td>
<td>Description of the KBA research, thesis and publications.</td>
</tr>
<tr>
<td>Pre-clinical &amp; modeling phases</td>
<td>2001-2002</td>
<td>2</td>
<td>Introduction and literature review.</td>
<td>Literature supporting the KBA program. Development of the KBA resources.</td>
</tr>
<tr>
<td>Above phases</td>
<td>2004</td>
<td>3</td>
<td>Preventing depression relapse: <em>publication</em>.</td>
<td>Summary of treatment strategies to prevent relapse; development of the KBA program.</td>
</tr>
<tr>
<td>Pilot RCT</td>
<td>Mar-May 2004</td>
<td>5</td>
<td>Pilot study GP training program: method and results.</td>
<td>Description and roll-out of the KBA training program for GPs participating in the KBA pilot study.</td>
</tr>
<tr>
<td>Pilot RCT</td>
<td>May 2004 – Dec 2005</td>
<td>6</td>
<td>Pilot study: background and method.</td>
<td>Background to the pilot phase and the methodology used.</td>
</tr>
<tr>
<td>Pilot RCT</td>
<td>2008</td>
<td>7</td>
<td>Pilot RCT: <em>publication</em>: of results.</td>
<td>Published results of the pilot study.</td>
</tr>
<tr>
<td>Pilot RCT</td>
<td>2006</td>
<td>8</td>
<td>Pilot study:</td>
<td>Additional and</td>
</tr>
</tbody>
</table>
1.5 Chapter summaries

The current chapter provides a summary of the work, as a way of introducing the phases of this research and the format of the thesis.

Chapter 2 then describes the pre-clinical and modelling (or developmental) phases of the research. It provides a summary and review of the relevant literature on depression and its treatment, as well as depression relapse and relapse prevention. The modeling of the KBA program and development of the KBA resources are also described in Chapter 2. The modeling phase in this research was lengthy as a new program and resources had to be developed. This phase involved review of research and other literature, and the development of frameworks and ideas. It lasted 18 months, and resulted in a 237-page treatment manual and relaxation recording.

The literature review identified that most depression treatment studies have been undertaken in specialist rather than primary care settings, and practical well-researched models for delivering long-term care in the primary care setting are limited. The general literature on depression relapse prevention supported a range of treatment strategies (adherence to medication, psychological treatments such as CBT and IPT) that help prevent depression relapse. Initially only one American study of a primary care RPP was identified, and as the intervention in this
study did not result in a significant reduction in relapse rates, it was concluded that a more intensive RPP might be needed. Subsequent work in the Netherlands has looked at a RPP, but did not have significant findings.

Chapter 3 is a publication in the Primary Care Mental Health Journal which summarises the background to the KBA program, providing an outline of the rationale for the KBA program. Chapter 4 outlines the methodology and results of the exploratory phase of this work, which aimed to determine the acceptability of the KBA program and its associated resources in a small sample of GPs and patients, and the feasibility of carrying out a larger intervention study or pilot RCT. A ‘utilisation-focused’ evaluation methodology was used. The GPs worked through the KBA program with their patients during six to eight sessions, providing useful insights related to the acceptability of the program, the suitability of the KBA resources, psychological assessment tools and GP training.

Some challenges in implementing the KBA program were identified, such as GPs keeping contact with patients to ensure completion of all 10 Steps of the program. However, it was believed that the challenges identified in the exploratory phase could be managed through more extensive training and refinement of the study protocol. A key finding was that additional (up to 12) sessions for GPs to deliver the KBA program were required. The KBA materials were generally well received. This phase informed modifications to the KBA program, resources and associated training and the subsequent pilot RCT.

The development and evaluation of the KBA training program for GPs participating in the larger pilot study is presented in Chapter 5. Extensive time was taken to develop this 20-hour training package, and to have it accredited with the Royal Australian College of General Practitioners (RACGP). Delivered by a GP and Clinical Psychologist in 2004, the program was run three times (60 hours in total), in urban and rural areas, to enable all GP participants to conveniently attend. The training included information on the assessment and management of depression, psychological approaches and relapse prevention strategies. The training program was evaluated by pre-test and post-test questionnaires, and an evaluation form. Sound pre-training knowledge was demonstrated, with significant improvement in a number of questions post-training. Self-perceived confidence also improved. The evaluation found that the training was well-received by the GPs, who reported that
their knowledge of depression, appreciation and awareness of the various treatments and skills improved.

The background and methodology of the pilot RCT is presented in Chapter 6. A number of research questions were identified for this phase, relating to reduction in relapse rates and severity of depression in patients receiving the KBA program, compared to patients receiving usual general practice care. Issues such as acceptability of the KBA program to GP and patient participants were also considered. A cluster randomised trial was deemed the appropriate research model for such an intervention trial, and this phase was carried out over 20 months.

The results of the pilot study are presented in Chapter 7, a publication in the Medical Journal of Australia (MJA). Additional or expanded results are provided in Chapter 8. These chapters provide information on the sample, the pathway of participants through the study and the outcomes. Participant recruitment began in May 2004 and the study ended in December 2005. Quantitative measures of depression severity (DASS-21), quality of life (WHOQOL) and the Clinical Global Improvement (CGI) Scale were collected, and at the end of the study a series of telephone interviews were undertaken to gather qualitative information about GP and participant experiences.

23 practices were recruited (45 GPs) and randomized in the pilot RCT. A total of 110 participants joined the study, with 62 randomised to the intervention group and 48 to the control group. Although no statistically significant differences were found between the intervention and control groups in terms of their relapse rates, a tendency was noted towards relapse rates being reduced in the intervention group. Younger people in either group tended to show similar probability of relapse, while older people in the intervention group showed a much lower probability of relapse than those in the control group. This was statistically significant ($P = 0.018$). Also, a general decrease in depression scores was found over time. Participants in the KBA group who had experienced depressive symptoms for more than six months had reductions in depression scores approaching significance ($P = 0.06$). GP and participant interview results indicated that the amount of information and the content of KBA were viewed as highly/extremely relevant. In regards to the KBA resources, the treatment manual and relaxation CD were well received. Psycho-education and skills-based strategies were viewed as particularly relevant.
Chapter 9 discusses the pilot RCT findings in relation to the study aims, together with the limitations of the study and an interpretation of this study in relation to comparable literature. The key strengths of the pilot RCT were that it addressed an important area, namely depression relapse, and that it involved the development of a novel clinical intervention with a manualised format. The research also involved a careful multi-phase approach, which resulted in comprehensive KBA resources being developed. The RCT was undertaken in a number of varied general practices, suggesting that the results may be generalisable across a range of practices. The major limitation of the study was recruitment of patients, and another limitation was the potential lack of standardisation of clinical data collection via the retrospective case note review. A stronger methodological approach would have involved regular collection of basic clinical measures by unblinded GPs, and the use of structured interviews performed by external, blinded research assessors.

The implications and recommendations from the research are presented in Chapter 10, highlighting that as a proportion of GPs were able to participate and be involved in a clinical intervention study that involves a relatively intensive program, research involving GPs in the study of primary care mental health intervention programs should continue to be pursued. However, it is also recommended that measurement tools should be chosen carefully in relation to studies carried out in the general practice setting. The pilot RCT experienced limitations in study design, and in subsequent research, possible solutions to patient recruitment should be explored, the use of structured interviews carried out by blinded assessors should be considered, and future studies into RPPs should adopt two-year patient follow-up and incorporate the collection of health economic data.

There is possible merit in the KBA program with respect to relapse prevention (particularly in older patients), and with respect to depression severity (particularly in patients with more severe depression), warranting further investigation. Given the findings and implications of the KBA pilot, and that no other RPP trialled in the primary care setting has yet had significant results, further studies of the KBA program should be carried out. The KBA manual and relaxation CD are useful resources, and they should continue to be improved and included in further studies. The journal component of the KBA program is not considered useful. The GP training
A number of recommendations regarding future study design are also made, in particular patient participant recruitment issues need to be addressed. Longer-term follow-up of patients is desirable, and in future studies, two-year follow-up should be adopted. The use of structured interviews carried out by blinded assessors should be considered in future studies and health economic data would also provide valuable information.

Over the past eight years there have been many developments in the Australian primary care mental health system. Notable changes since completion of the pilot RCT have been further emphasis on mental health care planning, including relapse prevention, and improved access to mental health professionals (MHPs) through government funding of their services in late 2006. These changes are outlined in the final publication from the Australian Family Physician journal (3), which is provided in Chapter 11. This paper considers the management of recurrent depression, and in particular management in the Australian context. It highlights the potential place of programs such as KBA in the primary care setting. The KBA program is now being used by a number of primary care mental health programs and MHPs in Australia, assisted by its manualised format, and there is potential to carry out research incorporating such programs and professionals in the future.

1.6 Summary

This combination thesis and publication document details the basis and development of the KBA program, which aims to reduce the severity and relapse of depression. It describes the research undertaken to evaluate the effectiveness of this primary care program. The research involved a number of phases, including a cluster randomised pilot study. The implications of this research and the recommendations arising from it are presented. In particular, the place of primary care depression relapse prevention strategies and programs such as KBA in the Australian context are described.
Chapter 2. Introduction and Literature Review

This chapter describes the pre-clinical and modelling (or developmental) phases (16) of this research and provides a summary and review of the relevant literature on depression and its treatment. The concepts of relapse and recurrence of depression are explained, and the literature on treatment strategies to prevent relapse of depression are critically reviewed in the first part of the chapter. Management of depression in the Australian primary care setting is described, with the aim of setting the scene for current depression management in Australia. In the second part of the chapter, the development of the KBA program and its rationale including relevant literature are described.

PART ONE

2.1 Research aims & hypotheses

The overall aim of this research was to develop and implement a primary care depression RPP and to evaluate its acceptability and effectiveness. A program called KBA was developed during the modelling phase of the study. KBA was designed with the aim of improving clinical outcomes for patients with depression, in terms of reduced severity of depression symptoms and reduced rates of depression relapse. Initially a brief education program to train GPs in using KBA was also developed, and trialled during the exploratory phase.

Several research questions were identified for the exploratory phase:

1. Is it feasible to use the KBA program in the general practice setting?
2. Is the program acceptable to GPs and patients?
3. Are the resources suitable?
4. Is the GP training adequate?

These questions will be addressed in Chapters 3.

Several research questions were then identified for the larger pilot intervention study (RCT), namely:

1. Is there a larger reduction in relapse rates of depression when patients diagnosed with major depression are managed in general practice by GPs
trained in and utilising the KBA program, when compared to patients managed with usual general practice care?

2. Is there a greater reduction in the severity of depression in patients receiving the KBA program, compared to those receiving usual general practice care?

3. Comparing KBA to usual practice, is there greater clinical improvement (GP perceived) or improved quality of life.

4. Are the GPs and patients satisfied with the KBA program?

5. Is the GP training in using the KBA program adequate and effective?

These questions will be addressed in Chapters 5 to 9.

The primary hypothesis of this research is that the KBA program will reduce relapse rates of depression in patients with major depression, by one half, when compared with usual general practice care.

Secondary hypotheses related to clinical outcomes include the following hypotheses; that, in patients with major depression treated by their GPs, the KBA program will:

1. Reduce severity of the depression symptoms.
2. Produce greater clinical improvement.
3. Enhance patient quality of life.

Secondary hypotheses related to the process of care are that there will be:

1. GP satisfaction with the KBA (education and treatment) program and the related resources.
2. Patient satisfaction with the KBA program and the related resources.
2.2 Depression background

2.2.1 Definitions of depression, relapse and recurrence
In this section, the diagnostic criteria for Major Depressive disorder, Depression and Minor Depression are outlined. The definitions of relapse and recurrence of depression then follow.

Major Depressive Disorder

According to the Diagnostic and Statistical Manual of Psychiatric Disorders (DSM-IV), a Major Depressive Disorder or depression is characterised by persistent depressed mood and/or loss of pleasure or interest in almost all activities.(21) The diagnosis of a major depressive episode is based on one of these primary symptoms being present for at least two weeks. In addition, four or more of a range of other symptoms must be present.

These symptoms include:
1. Changes in appetite, weight.
2. Sleep disturbance.
3. Changes in energy levels.
4. Feelings of worthlessness or guilt.
5. Difficulty thinking and concentrating.
6. Recurrent thoughts about death or suicidal thoughts.

Psychomotor agitation or retardation may also be observed, and there must be significant distress or impairment in functioning.(21)

Dysthymia

Dysthymia is a chronic disorder comprising a depressed mood that lasts most of the day and is present on most days.(9)
Minor Depression

Minor depression is a mood disturbance where at least two (but less than five) of the symptoms of major depression are present for at least two weeks, and at least one of the symptoms is a persistently depressed mood or loss of interest or pleasure in activities.(9) The criteria for major depression are not met in minor depression.

Subthreshold syndromes

Subthreshold syndromes are syndromes that, for some reason, do not fulfil all the required criteria of threshold definitions, such as the definition of depression above. These syndromes occur frequently at all ages, and it is often questioned whether these disorders are significant clinical problems or not.(22) It has been suggested, however, that it is important to characterise the continuum of symptoms, rather than adhering to strict diagnostic thresholds.(23) Subthreshold syndromes may also represent a prodromal phase, that is with forerunner symptoms and signs, or a residual phase of a depressive illness.(24)

Relapse and recurrence

Depression is a relapsing and recurring disorder.(7, 25) Relapse is defined as an early return of symptoms, while recurrence is a later return of symptoms after a period of remission.(26) Remission has been defined as at least a two-week period below a cut-off point on depression symptoms measures, and recovery as beginning after two continuous months below that cut-off point.(27) In other words, a recurrence is a new episode of depression that occurs during remission, while a relapse is the resurgence of an episode that had gone into remission, or temporarily subsided.(28) The nature of relapse, recurrence are shown below in Figure 2.1.
Definitions relating to length of time vary between researchers, but there is general agreement in the literature that relapse refers to a time frame of less than six months of remission, and recurrence applies to a time frame of greater than six months of remission. (29) For the purpose of this study conducted over a 12 month time period, and for ease of explanation, the single term ‘relapse’ will be adopted.

2.2.2 Epidemiology

Mental health disorders

According to the 2007 National Survey of Mental Health and Wellbeing (30), of the 16 million Australians aged 16-85 years, almost half (45%) had a mental health disorder at some point in their life. One in five (20% or 3.2 million) Australians are affected by a mental illness in any 12 month period, and 10% of Australians report a long term mental health problem. (30) Women experience higher rates of mental disorders in any 12 month period than men (22% vs. 18%). (30)
Figure 2.2 Prevalence of mental health disorders in Australia

NOTE:
This figure is included on page 15 of the print copy of the thesis held in the University of Adelaide Library.

(From AIHW, 2007)

Specific disorders

Of the 3.2 million Australians who had a 12-month mental disorder, 14.4% had an anxiety disorder, 6.2% had an affective disorder, and 5.1% had a substance use disorder. (30) Women experienced higher rates of anxiety (18% vs. 11%) and affective disorders (7.1% vs. 5.3%) than men. However, men had twice the rate of substance use disorders (7.0% vs. 3.3% for women). (30)

Depression is a highly prevalent disorder, with a one in five lifetime risk (30), and is the fourth most common problem managed in general practice. (31) Depression is predicted to be the second largest cause of disease burden worldwide by 2020 (32). It is reported that 77.5% of individuals who experience a major depressive episode will have at least one more episode during their lifetime. (7, 33, 34) The primary care relapse rate of depression has been found to be 37 - 44.5%. (8, 34, 35) A higher rate (64%) has recently been reported by Yiend et al (2009). This British study followed patients in general practice over 23 years. (36) As highlighted in the exegesis, it has also been reported that, from a lifetime perspective, the majority of primary care
patients with depression suffer from recurrent major depressive disorder, although they are often in prodromal or residual phases.(6)

Figure 2.3 Prevalence of anxiety and depression in Australia

NOTE:
This figure is included on page 16 of the print copy of the thesis held in the University of Adelaide Library.

(From AIHW, 2007)

### 2.2.3 Depression illness burden

The Global Burden of Disease Study (37) predicts that by the year 2020, depression will be the second leading cause of disease-burden worldwide.(37) An Australian community survey calculated that mental illness contributes 13% to the ‘total burden of disease’ in terms of disability-adjusted life years (DALYs).(38) It is also the most common cause of disability.(39) The negative effects of depression on quality of life and daily function are said to be equivalent to those of heart disease, and exceed those of diabetes.(40) Depression often impairs social and occupational functioning, and has a significant impact on relationships and the individual’s productivity.

It was reported in 2005 that 6% of the total Australian health care budget was spent on mental health service,(31) and the economic cost of depression has been estimated at five billion dollars per annum.(41) Over the coming decades mental health disorders are likely to become an even greater health burden on the Australian community, making the need for efficacious and cost-effective treatments an ongoing challenge in modern health care.(31, 39, 41)
2.2.4 Depression – a chronic disease

Depression, because of its relapsing nature, has in recent years been viewed as a chronic illness.(7) Chronic illness is characterised by gradual onset and long-term duration.(42) Hence depression has been described as ‘more like asthma than appendicitis’ (that is, more a chronic illness than an acute illness), and as a chronic condition characterised by the clinical parameters of severity and co-morbidity (43), where co-morbidity is defined as a co-occurring condition or disease in a patient with an existing disease.(44)

Up to 20% of individuals with depression will have a chronic course.(8, 34) Professor Gavin Andrews, an eminent Australian psychiatrist and researcher, carried out a longitudinal study in which patients with depression were followed for 15 years (from 1970-1985). He found that in his cohort, 20% recovered and remained continuously well, 60% recovered but had further episodes and 20% committed suicide or were always incapacitated.(7) Hence depression is described as a potentially chronic, recurring disorder and a long-term approach to care is recommended.(7)

2.2.5 Depression aetiology & co-morbidities

The cause of depression is not fully understood, but a ‘bio-psycho-social’ model of causation has been proposed. In other words, causation is the result of the interplay of biological, psychological and social factors.(45, 46) Some authors have suggested that this model should also include spiritual factors as these can be highly significant for some individuals.(46, 47)

There are a number of theories related to the biological aetiology of depression, including there being an inherited tendency to develop depression. This is supported by family and twin studies. There is an increased risk of depression in first-degree relatives of individuals with depression. For major depression the concordance rate in monozygotic twins is about 50 per cent.(9) In recent years there has been progress in the understanding of the role of genes in serotonin production and transportation.(48) According to the ‘neurotransmitter theory’, a disturbance in neurotransmitters in the brain (the biogenic amines namely serotonin, noradrenaline and dopamine) is related to the depressive symptoms.(9) Infections such as
glandular fever, anaemia, low thyroid function or diabetes can also produce symptoms of depression. An individual may be more prone to low mood at times of hormonal changes, such as in the postnatal period or at menopause. Some prescribed medications have depression as a side effect (for example, corticosteroids and beta-blockers), and substance abuse can also be associated with depression.(49)

It is also established that stressful life events (personal tragedies, relationship breakdown or unemployment) are likely to play a role in the onset or relapse of depression. Loss and grief may also be a trigger.(50) Depression occurs more commonly at transitional stages in life, such as adolescence, middle age, retirement age and in the elderly. Traumatic early life experiences, such as childhood emotional or sexual abuse, can be associated with later depression. Other reported risk factors include a past history of depression, being female and adolescent or experiencing anxiety.(51)

An individual's personality may play a role in depression. Some people have a tendency to be pessimistic or view things negatively, and such negative thought patterns are suggested to be risk factors for depression.(51) Optimistic individuals tend to have a style of thinking that helps them persevere and embrace challenges. When faced with problems they do not automatically blame themselves or others for the problem, or see the problem as unsolvable. However, adults diagnosed with depression tend to use permanent and universal thinking styles to explain bad events.(52) A prospective study of college students identified students as high risk or low risk for depression based on their thinking styles (pessimistic or optimistic). The study found that those students at high risk had odds of minor and major depression up to 6.8 times more than the low risk group.(53)

Early life traumas may influence personality and vulnerability to depression, and parental mental illness and lack of social supports are known to be risk factors for depression.(51) Social and economic factors can increase stress and decrease opportunities to look after health and well-being.(54) Hegarty and Gunn (2004) have explored the association between depression and abuse by partners of women attending general practice and found that physical, emotional and sexual abuse are strongly associated with depression.(56, 57)
Therefore, the literature suggests that a number of social factors including good interpersonal relationships, parenting skills, social support, family cohesion and social connectedness are protective against depression. A history of academic or sporting achievements and an easy-going temperament are viewed as helpful. In particular, optimistic thought patterns and effective coping skills (for example, stress management, social skills and problem-solving skills) are considered protective. (51, 54, 55)

In relation to problems co-existing with depression, it is reported that more than 40% of patients with depression meet the diagnostic criteria for another psychiatric disorder. (58) Co-morbidities of depression include anxiety disorders, schizophrenia, eating disorders including anorexia and bulimia, substance abuse and suicide. (59) Depression is also associated with chronic medical conditions, including cardiovascular disease, neurological disorders, cancer and chronic lung disease. (60)

The co-existence of depression and anxiety is common in general practice. The Australian National Survey of Mental Health and Wellbeing found that the 12-month prevalence of depression was 5.8% and of anxiety was 9.7%. Depression alone, however, accounted for only 1.4% and for anxiety 2.9%, while over 3% reported mixed anxiety and depression. A study of functioning after a major depressive episode found that having a co-morbid anxiety disorder was a predictor of worsened functioning after recovery from the depression. (61) Such co-morbidity is generally associated with more severe illness where there is greater functional impairment, such as days lost from work, less treatment responsiveness and a higher risk of suicide. (62)

Co-morbidity between depression and somatic symptoms is also highly prevalent (6), and patients with depression use health care services three times as frequently as non-depressed patients. (63, 64) Co-morbidity between mental health issues and substance use is well documented. (65) One Australian study to determine the extent of co-morbidity of mental health disorders with alcohol or other substance misuse found co-morbid substance misuse in 12% of general practice patients. (66) At this time, there is no consensus on the reasons for the frequent co-morbidity of substance use and mental health problems, but there are a number of theories as to why co-morbidity may occur.
There are four main hypotheses for the co-occurrence of substance use and mental health issues, and it is possible that a combination of factors is responsible. The hypotheses are as follows:

1. Drug use as a way of coping with mental health problems.
2. Drugs potentially leading to mental health problems, or influencing/exacerbating mental health problems.
3. A combination of genetic and environmental factors (such as socio-economic disadvantage or emotional deprivation) interplay to increase the likelihood of co-morbidity.
4. Berkson’s paradox or high rates of co-morbidity being reflective of the treatment setting being studied, such as hospital and treatment service settings which may have a greater than average proportion of attendees who experience co-morbidities.(67)

Mental illness & physical disease are risk factors for each other, and individuals with co-morbidity are at increased risk of adverse health and social outcomes.(68) Depression is a significant co-morbidity with chronic physical health problems, such as cardiac disease. Prevalence rates in hospitalised patients after an acute myocardial infarction (MI) or heart attack are as high as 40%. (69) As many as 60% of individuals post-MI experience depression in the year after cardiac hospitalisation. (70) Also, depression has a major impact on compliance with cardiac medication and participation in rehabilitation programs and is associated with a two to two-point-five fold increased risk of impaired cardiovascular outcome. (71-74)
2.2.6 Depression severity, course and complications (including suicide)

Depression is often graded as mild, moderate or severe. According to the World Health Organisation Collaborating Centre for Mental Health and Substance Abuse, in mild depression there is minor impairment of social and occupational functioning; whereas moderate depression interferes with the ability to function socially or at work and there are no psychotic features; while severe depression results in severe impairment in functioning and may involve psychotic symptoms, such as delusions.(59)

If left untreated a major depressive episode may last between six and 24 months, but will most likely continue for three to 11 months, with 20-30% having persistent residual symptoms.(8, 58) In one study of the course of depression, even with appropriate treatment, 12% of patients had not recovered after five years.(75) The course of severe depression is reported to be progressive in nature, even with treatment.(76)

The most serious complications of depression are self-harming behaviours and suicide (deliberately taking one’s own life).(77) Self-harm includes poisoning by taking pills and cutting, and can lead to disability and death. These behaviours can occur in both males and females and are more common in the teens to the middle aged. Individuals with mental health disorders, alcohol or drug use disorders, or those with a history of childhood sexual abuse are more at risk. Between 16% and 48% of people who self harm do so again within three months, and between two to seven percent of those who self harm die by suicide within the first year, rising to 24% within five years of the initial attempt.(77)

There are several models related to the causality of suicide.(78) The ‘Stress Diathesis Model’ identifies that the risk of suicide is determined not only by the triggers, such as the onset or acute worsening of a psychiatric illness or a psychosocial crisis (such as interpersonal loss), but also by a diathesis or combination of factors. The diathesis may include gender, religion, familial and genetic components, childhood experiences, psychosocial support system and availability of highly lethal suicide methods.(78) Another model focuses on the neurochemistry of suicide, with particular emphasis on the role of serotonin because reduced levels of serotonin have been found in the central nervous systems of...
suicide victims. This model hypothesises that low serotonin is linked with depression and auto-aggression (aggression directed towards self).(78, 79)

It is generally concluded that suicide results from an accumulation of risk factors, and is influenced by problems across society (such as mental health, drugs and alcohol, family issues, employment, cultural identity, law enforcement, education and poverty).(80) However, the presence of a mental health disorder is an extremely important risk factor in suicide.(65) A meta-analysis of the literature relating to suicide and mental disorders by Harris (1997) concluded that virtually all mental health disorders (apart from intellectual disability and dementia) relate to an increased risk of suicide.(81) Psychological autopsy studies, which examine the factors contributing to suicide, have been carried out in many countries, and have demonstrated that up to 90% of individuals who suicided had a mental health disorder at the time of their death.(82)

Mann (78) reported that 60% of suicides occur in people with a mood disorder, and that suicide is generally a complication of a psychiatric disorder. Major depression exists in 60-70% of suicides in the under 35 age group.(65). Alcohol and substance dependence (often co-morbid with other mental health problems) are associated with an increased risk of suicide, as are personality disorders (borderline, antisocial, avoidant and dependent).(65, 83) The lifetime suicide risk in depression is estimated to be 3-4% in the general population and even higher in the discharged hospital population.(58, 65, 78)

2.3 Management of Depression

2.3.1 Diagnosis and assessment

Management of depression begins with establishing rapport with the individual and developing a therapeutic relationship. The relationship is established through communication skills, such as carefully listening to the person’s story and reflecting and clarifying the content of the information to check accuracy and to demonstrate interest and understanding. This is central to the success of other aspects of treatments.(84)
The early phase of treatment involves accurate diagnosis and assessment. Diagnosis is based on the DSM-IV criteria as previously outlined.(21) Assessment includes taking a comprehensive history of the presenting symptoms and concerns, their social and occupational situation and supports, past history of physical health problems, depression or other mental health issues (including suicide attempts), family history of depression or mental health disorders (including suicide), past and current drug and alcohol use, and any treatments already tried.

A mental state examination should be conducted to assess the person’s appearance, behaviour, attitude, speech, mood, affect, appropriateness, perceptual disturbances, thought processes and content, cognition, judgement, insight and reliability.(9) It is important to assess the individual for underlying or co-existent medical problems, such as thyroid disorders or diabetes. This will involve appropriate examination and laboratory tests.(9) This careful assessment of the individual, their situation and needs, is vital to the development of an appropriate management plan.(85)

A number of assessment tools are available to assist diagnosis, to grade the severity of the depression and assist in monitoring progress. Standardised measures permit the determination of the benefits achieved by interventions, involve the patient in monitoring their own condition and enhance clinical record keeping.(5) Many of the available assessment tools were developed for research purposes but have been validated in community settings. One example is the Depression, Anxiety and Stress Scale (DASS), developed by Lovibond and Lovibond (86), which provides quantitative scores for depression, anxiety and stress in outpatient populations. It is reliably correlated with other psychological scales and uses Australian norms.(86)

The assessment process also involves a formulation of the biological, psychological and physical factors, which assists in understanding why the depression has developed in that individual, and also identifies any precipitating or maintaining factors and relevant personality factors. Protective factors should be noted and issues of risk addressed.(85) Given that the lifetime mortality from suicide is 15% (of persons with major depression in discharged hospital populations), the assessment of suicide risk is vital.(87) There is universal agreement that asking questions about suicidal ideation does not trigger suicidal behaviour and that encouraging the patient to confide in another person is of therapeutic value.(88) The assessment should
include the person’s sense of hopelessness or degree of impulsivity, as well as risk factors such as past attempts, social isolation and access to weapons.(89)

Direct questions can be used to explore the factors related to suicidal intent such as degree of planning, communication of suicidal ideation, purpose of attempt, ambivalence regarding life/death, knowledge of lethality of the particular method, precautions against discovery, presence and content of a suicide note, and acts in anticipation of death.(90) Suicidal thoughts often revolve around interpersonal issues, and so the presence of these in the person’s life should be explored. Assessment tools, such as the Modified Scale for Suicidal Ideation, which determine degree of risk (from low to high) are available.(91)

2.3.2 Treatment phases

The acute or initial treatment phase aims to stabilise and relieve symptoms. The initial aims of treatment are to reduce and ultimately to remove all signs and symptoms of the depressive syndrome, to restore occupational and psychosocial function to that of the asymptomatic state and to reduce the likelihood of relapse and recurrence.(92) The initial treatment phase is followed by a stage of continuation of treatment to stabilise remission and prevent the return of acute symptoms.

The maintenance phase of treatment aims to prevent relapse or recurrence of subsequent episodes of depression.(92) The most important aspect to this phase is maintaining adherence to treatment (10), and the length of the maintenance treatment phase depends on the history of depression and the individual’s risk of developing a new episode.(50) There is growing evidence that longer-term maintenance drug or psychological treatment strategies are required to have a significant impact on the large disease burden associated with major depression.(93)

In view of the recurrent nature of depression, a long-term approach to care is recommended.(7) The long-term approach should aim to provide education about the possible recurrent nature of depression and to implement positive strategies to help prevent recurrences.(10, 50)
2.3.4 Management plans

In recent years there has been emphasis on developing management plans in collaboration with the patient after the comprehensive assessment is completed.(94) The plan involves listing issues or problems to be addressed, and strategies to be adopted, such as psycho-education, medication recommendations, psychological treatments, social measures and plans for referral and longer-term management.(85) Johnson (95) reports that there is “a dearth of published research examining what impact these plans might have on the care of patients with mental health disorders in the general practice setting”, (2007, p.204) however, it is important is that there is an understanding of treatment plans and a clear written treatment summary.

Having a plan for managing early relapse symptoms assists the person to identify their particular symptoms at an early stage, and to identify potential high risk situations (such as during times of stress).(59) The plan involves recording what the patient should do and who they might contact if symptoms appear.

2.3.5 Bio-psycho-social management of depression

The bio-psycho-social model of the causation of depression was introduced earlier in this chapter. The general management of depression is based on this bio-psycho-social model, and aims to provide an integrated approach to treatment by addressing biological and psycho-social factors.(9, 45, 96)

Psycho-education

Central to treatment is educating the patient, and their family/carers where appropriate, about depression and its management, including lifestyle changes that will assist recovery.(84) Many Australians have limited knowledge about depression. There are also myths in the community, such as depression being a weakness in the individual, and these can be related to stigma. Improving ‘literacy’ or knowledge and understanding about depression is therefore viewed as important in management.(97)
One study by Highet (98) identified a number of important themes in the experience of carers and families of individuals with depression. It identified that the role of carers and families was made more difficult by the lack of community awareness about depression and sometimes the unwillingness of others to assist with support of the person with depression. This resulted in a sense of isolation, which was also heightened by feeling excluded from treatment and decisions.

A meta-analysis integrating the results of four studies evaluating the effectiveness of passive psycho-educational interventions in reducing depression was published in 2009. It found that brief interventions, such as providing information, educational materials such as leaflets and internet material reduced depression symptoms, were easy to implement and inexpensive.(99)

**Medication**

Depression management may involve treatment with medication. Antidepressant medications include tricyclic antidepressants and monoamine oxidase inhibitors. Two of the most frequently prescribed classes of antidepressants are the selective serotonin reuptake inhibitors (SSRIs) such as sertraline or escitalopram and selective serotonin and noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine. Other newer agents include mirtazapine and reboxetine. SSRIs are better tolerated by individuals due to a reduced side effect profile, and are safer drugs in overdose than the older tricyclics. Choice of antidepressant depends on the individual’s clinical presentation including severity of the depression, past response to medication and co-morbid problems, and dosage depends on severity of the depression and response to treatment.(58)

Antidepressants are indicated in moderate and severe depression.(84) A general guideline is that antidepressants are useful when there is significant depression, when there has been a previous positive response to medication or a poor response to psychotherapy, or when several of the physical changes of depression (such as altered sleep or low energy), agitation or suicidal ideas are present.(100)

Medication may be used in the acute treatment phase or in the continuation phase, to suppress symptoms during a current depressive episode. Maintenance therapy with medication aims to prevent the development of a new episode. Individuals who have
achieved remission of symptoms and who have had two or more episodes of depression in their lifetime (especially if there are co-morbid disorders, ongoing psycho-social stressors, poor symptom control or severe depression episodes) are candidates for maintenance therapy. The data on maintenance therapy supports the continued use of the drug dosage that helped the patient achieve remission.(101)

It is established that medication is effective in managing depression.(10) Systematic reviews in people aged 16 years and over have found that antidepressant drugs are effective in the acute treatment of all grades of depressive disorders.(102) Antidepressant drugs and electroconvulsive therapy (ECT) were the only treatment for which there is good evidence of effectiveness in severe and psychotic depressive disorders.(102) A recent meta-analysis assessed the effects of newer antidepressants (such as SSRIs, mirtazepine and reboxetine) on major depression. It found that a number were more efficacious than others. In particular two SSRIs (sertraline and escitalopram) were found to be efficient and had good acceptability profiles (low side effect and discontinuation rates).(103)

**Psychological treatment**

A range of psychological therapies are utilised in the management of depression. In particular, a number of studies have provided Level I or II evidence (that is, evidence based on systematic reviews or meta-analyses of all relevant RCTs or evidence obtained from at least one properly designed RCT)(104) for the effectiveness of Cognitive Behaviour Therapy (CBT) as a depression treatment.(105, 106) CBT refers to a set of principles and practices based on the view that cognitions and cognitive processes (thoughts and beliefs) affect behaviour, and that these processes can be changed through cognitive and behavioural techniques.(107) In CBT, the therapist works collaboratively with the patient to guide them through cognitive strategies such as identifying unhelpful cognitions, challenging and correcting them. Underlying beliefs are identified and tested in a similar way. CBT also utilises behavioural techniques such as behavioural activation (engaging in activities), relaxation and assertiveness training.(108, 109)

Problem–Solving approaches commonly used in CBT have evolved into a therapy in their own right. Problem-Solving Therapy involves defining the problems faced by an individual, and looking at logical, practical ways of dealing with them.(49, 110, 111)
There have been several RCTs of Problem-Solving Therapy.(112, 113) A study by Mynors-Wallis (114) found that Problem-Solving Therapy for depression in primary care was effective and acceptable. Problem-solving Therapy emphasizes the development of a new skill, in which the patient identifies possible solutions to their problems, rather than solutions being suggested by the therapist and thus empowering them to solve future problems.(115) There is also Level II evidence that problem-solving treatment by a GP is no less effective than antidepressant treatment for depression, psychological symptoms and social functioning.(116)

Interpersonal Therapy (IPT), which addresses interpersonal functioning (interactions with others, such as family or a partner) and loss and grief issues and their relationship with the depression, is well supported in the literature.(49, 117) A systematic review of studies of the effectiveness of treating depression (in 883 outpatients) with psychotherapy (CBT and IPT) found symptoms of depression were improved and the improvements were similar to those with medication.(118)

Counselling from trained counsellors is available in the primary care setting in the United Kingdom. Counselling is a general term and may involve crisis or general support and guidance or psychotherapeutic work. Systematic reviews regarding counselling in primary care have been carried out. A review by Brettle (2008) synthesising evidence from 26 studies related to counselling with a number of psychological issues presenting in general practice concluded that counselling is a valid approach. Another review looked at eight studies comparing usual general practice care to general practice plus counselling and found that people who receive counselling are more likely to feel better immediately after treatment and be more satisfied than those who receive care from their GP. However, in the long run counselling is not any better than GP care.(119, 120)

Addressing lifestyle factors including exercise, developing the sense of well-being (Well-being Therapy) and bibliotherapy (working through a treatment book, such as one based on CBT) have also been reported by leading researchers or in national guidelines to be useful strategies.(24, 50, 121) Well-being Therapy focuses on developing a sense of well-being rather than relieving symptoms of illness, and aims to increase personal effectiveness.(24) Befriending of individuals with depression by volunteers has also been shown in a RCT to lead to a higher frequency of remission in women with chronic depression.(122)
The relatively new Mindfulness-based CBT (MBCT) approach teaches patients cognitive-behavioural skills and meditation, often in the group setting. An exploratory mixed methods study of the acceptability and effectiveness of this approach for patients with depression and anxiety in primary care (n=13) was carried out, with the majority of patients finding mindfulness training to be an acceptable form of therapy. The group setting was perceived by patients to be a positive experience (normalising and validating). There were also reductions in depression and anxiety scores.

Combination or sequential therapy

In many instances, a combination of medication and psychological therapy, such as SSRIs and CBT, are used in the treatment of depression. This combined approach is reported to be more effective, especially in moderate to severe depression. A number of RCTs support the combination or sequential use of different treatments to address different phases of depression, such as achieving remission through pharmacological measures, followed by psychological treatment. There is Level II evidence demonstrating that combined CBT and medication are effective for patients with residual symptoms, and in recurrent depression, CBT in combination with medication has been found to be effective in preserving recovery.

In addition, the use of medication and psychological therapy in sequence (sequential therapy) for depression has been found to be clinically useful, and is supported by a review of the evidence from meta-analysis and general reviews. This is consistent with Australian depression treatment guidelines which incorporate a range of combination therapies, including antidepressant medication, CBT, IPT and social support. The guidelines are outlined below.

2.3.6 Treatment guidelines

A number of the treatments already described have been incorporated into depression treatment guidelines, which are based on evidence and expert opinion. The 2002 Australian beyondblue guidelines outlined evidence-based treatments for different severities of depression, and identified first, second or third-line and continuation treatments. More recent guidelines from the Royal Australian and New Zealand College of Psychiatry (2004) recommend maintaining a
treatment regime for as long as is necessary to allow the person to stabilise. The guidelines state that this will be at least one year, and where there is a history or significant risk of recurrence the person should be monitored and treated proactively for three years. (84)

These guidelines also state that mild depression can ideally be managed within primary care, and that the management should include education about depression, lifestyle changes and the use of strategies such as problem-solving. Relationships with significant others should be considered and any other necessary assistance should be organised, and supportive monitoring provided. According to the guidelines, there is no evidence for the use of pharmacological or psychological treatment for this group unless the symptoms persist beyond eight weeks, then brief CBT or IPT or SSRIs should be used in addition to supportive management. (84)

For moderately severe depression and dysthymia, the guidelines recommend either an antidepressant or one of the brief psychological therapies (8-12 sessions of CBT or IPT). Regular monitoring of side-effects, treatment benefits, changes in stresses and encouraging compliance should be provided and treatment should be reviewed at the end of a reasonable trial period. The guidelines state that primary care services will manage the long-term care of the person with limited input from specialist services. (84)

The guidelines recommend that severe depression is treated with an antidepressant and once there has been a response, psychological therapy may be added. For recurrent depression or failure to respond to a first-line treatment with an SSRI or psychological therapy, swapping to a tricyclic antidepressant or an SNRI, or combination therapy should be considered. Psychotic depression or severe depression with suicide risk should be managed by specialist mental services. (84) Addition of CBT or IPT to the continuing and maintenance treatment phases has been associated with lower depression relapse rates, and ongoing relapse prevention and early intervention in any recurrence is essential. (84)

Importantly, evidence suggests that only a minority of primary care patients with chronic illnesses such as depression are receiving treatment according to guidelines. (127) Trivedi and Lin (2007) reported that in the United States of America (USA), while 51.6% of individuals with major depression received treatment, only
21.7% received minimal guideline-level treatment. (128) The researchers suggest there is potential for the primary care setting to be pivotal in the early diagnosis and treatment of depression, and in another paper Trivedi (129) suggests the use of electronic treatment decision support systems as a potential means to improve adherence to guidelines.

A study by Hegarty and Gunn (2009) assessed the relevance of depression guidelines to Australian primary care. Significant limitations in relation to rigour in the development and applicability of depression guidelines were found, in addition to lack of attention to addressing associated risk factors or sufficient attention to different types of psychological therapies. (130) A further study by Rollman et al (2005) in the USA suggested strategies such as engaging local health care providers, providing training and fostering collaboration between providers as being effective in ensuring guidelines are adopted. (131)

### 2.3.7 Treatment adherence

An important factor in the management of depression is to maintain compliance with an effective treatment. (84) However, significant non-compliance to prescribed medication regimens is a prevalent problem in the treatment of depression. (132) Sherbourne (133) examined the characteristics of depressed primary care patients who receive at least minimal standards (at least four specialty counselling visits and/or at least two month use of antidepressants) of evidence-based treatment. The main predictors of non-response to treatment included suicidal ideation, unemployment and non-adherence to medication.

Studies have shown that average length of treatment with antidepressant medication is shorter than recommended in evidence-based treatment guidelines, and that medications are often stopped after three to six months. (34, 134) Factors leading to discontinuation of therapy are not well understood. However, a study by Demyttenaere examining why patients stopped their medication, found the most common reason given was “feeling better” (2001, p.31), and 24% of patients did not tell their doctor about stopping. (134)

It has also been found that stable use of antidepressant medication over a long period of time is associated with lower relapse rates than either titration of dosage,
early discontinuation or switching of medication and augmentation.\(^{(135)}\) Melfi \(^{(136)}\) examined a database of over 4,000 adults who filled an antidepressant prescription at the time of initial diagnosis with depression, and followed them for up to two years. The aim of this study was to determine whether adherence to recommendations in evidence-based guidelines for medication use reduced the likelihood of relapse. The study confirmed that the group with continuous use of antidepressants were less likely to experience relapse compared with the group who discontinued early.

A follow-up study of out-patients with depression found that those who dropped out of treatment within one year were more likely to have a recurrence in the future than patients who continued antidepressant treatment for more than one year.\(^{(137)}\) A further study of 835 primary care patients over two years showed superior long-term recovery in patients who were adherent to antidepressant medication compared to non-adherent patients.\(^{(138)}\)

A group of researchers from the USA \(^{(139)}\) examined the effects of several primary care-based quality improvement programs on medication management for depression via a RCT. Strategies used in these programs included training of local experts who collaborated with patients’ usual primary care providers and or patient education and follow-up by trained nurses. The program involving collaboration resulted in increased rates of antidepressant treatment, and the program involving follow-up was associated with longer term antidepressant use than in usual care groups.\(^{(139)}\) Peveler and colleagues \(^{(140)}\) also evaluated different methods of improving adherence to antidepressant drugs, and found that counselling about drug treatment improved adherence in patients with moderate levels of depression.

An intervention involving mailing an education flyer to primary care patients prescribed antidepressant medications and an informational letter to the doctor was studied by Azocar and Branstrom \((2006)\). A total of 972 patients were involved in the cohort study. Patients filling a prescription over the first two months of the study were allocated to the control group (receiving usual care) and over subsequent months to the intervention group. Soon after filling their prescription, the intervention group were emailed a flyer which emphasized the importance of continuing to consult with the doctor, the increased risk of relapse of depression following early discontinuation of medication and the value of self help strategies such as exercise. Claims on health services (medication and psychotherapy) were assessed, and improved consistency
in the use of treatments was found (such as less gaps in medication use) and adherence to medications. This study was limited by the lack of randomized design, but produced some encouraging results.(141)

2.3.8 Management of self harm and suicide risk Assessment

It is important to carefully assess risk of self-harm and suicide and carry out appropriate management. Michel (2000) describes the importance of GPs understanding their role, the early detection of serious emotional problems which might lead to suicide, the detection of high-risk clients with acute risk of suicide and the development of meaningful communication skills.(88) GPs need to be mindful of the somatic symptoms of depression, symptoms of current depression, hopelessness, and suicidal ideation.(78)

Successful communication between suicidal clients and health professionals is fundamental to appropriate management, and is not an easy task. In a psychological autopsy study of 571 suicides in Finland in which a health care professional had been contacted by the patient prior to suicide, Isometsa and colleagues (1995) found that on the occasion of the last visit, the issue of suicide had been discussed in only 22% of cases.(142)

Management of self-harm

Treatments for self-harm aim to:
1. Prevent future self harm and improve coping skills.
2. Reduce distress leading to or as a result of self harm.
3. Treat associated mental health disorders.
4. Detect life stress that may benefit from professional help.
5. Reduce the likelihood of suicide.
Medication may be indicated, or psychological treatments including CBT and problem solving.(143)

Management of the suicidal patient

There are three major components in the management of a suicidal patient, namely the diagnosis and treatment of existing psychiatric disorders, the assessment of
suicide risk and removal of the means for suicide, and specific treatment to reduce the patient’s propensity to attempt suicide.(78)

Intervention focuses on reducing the immediate danger and accessing assistance and resources. A crisis intervention model which incorporates the following measures is appropriate:

1. Defining the problem (risk assessment).
2. Ensuring safety.
3. Providing support.
4. Examining alternatives (depending on available support).
5. Making a management or action plan.
6. Obtaining commitment to the plan.(144)

Treatment of a suicidal patient involves ensuring their safety and addressing the underlying problems and diagnoses, including co-morbidities.(145) Depending on the level of suicidal risk, treatment may involve the following:

1. Hospitalisation.(65)
2. Referral to psychiatrist.(65)
3. Outpatient or primary care treatment.(49)
4. Removal of lethal drugs or firearms.(49)
5. Antidepressants or other medication if indicated.(65)
6. Psychosocial interventions (such as problem-solving or dealing with interpersonal issues, mobilisation of support).(49, 145)
7. Aftercare/longer term care.(65)

For those with severe psychiatric illness and marked suicidal ideation, hospitalisation will be necessary. For those at serious risk, immediate further assessment or hospitalisation may be appropriate. For those at lower risk, the opportunity to ventilate concerns, receive support and begin treatment may be enough.(65) It is important for the person to have an emergency plan, with telephone numbers of people/agencies to contact in the event of intensification of suicidal thoughts.

There is an absence of evidence about the effectiveness of specific psychological strategies in the management of the suicidal person.(146) A number of potential interventions have been utilised including CBT, Problem-Solving Therapy, Interpersonal and Family Therapy, outreach therapy and crisis support.(147) It is
suggested in the literature that risk factors for suicide such as social isolation, and substance use need to be addressed, with strategies including involving family and carers, frequent appointments and reduction of substance use.(148)

2.3.9 Chronic disease management (CDM)

CDM principles

The management of chronic conditions is one of the most significant health challenges facing Australia today, and the current literature suggests that the principles of managing chronic disease should be applied to depression.(7, 64, 149) Patients affected by chronic disease present with different needs to patients with acute medical problems. Chronic disease is characterised by gradual onset, long-term duration, multiple causes, and commonly co-morbid conditions.(42) Chronic conditions therefore require a different response than acute care. It has been suggested that deficiencies in current western systems of care for chronic disease include rushed practitioners not following established practice guidelines, lack of care coordination, lack of active follow-up to ensure the best outcomes and patients being inadequately trained to manage their illnesses.(42, 150)

Evidence has accumulated that in depression, using approaches that comprehensively and systematically assist patients to manage their chronic disease are more effective than those based on a more acute model of care.(150-152) Also, chronic care models recognise that CDM does not just take place in the GP setting - the influence of the wider community, the healthcare system, and the patient themselves need to be considered.

CDM and depression

Clinical trials between 1992 and 2006 evaluating CDM models for depression in primary care were reviewed by Kates (2007), with evidence found for the benefits of changing systems of care delivery to support the more effective management of depression in primary care. It was reported that most studies demonstrated improved outcomes in terms of symptom reduction, functioning in the community, adherence to treatment, community and workplace involvement and satisfaction with care.(94)
The following components of chronic care were recommended by Kates (2007) - case registries, case managers or coordinators, treatment algorithms, follow-up and monitoring after a depression episode, care and relapse prevention plans, visits by psychiatrist and training for all providers. (94) Other CDM strategies include GP and practice staff training and referral and shared care practices (between GPs and other health professionals). (153)

Studies have highlighted strategies to help educate and motivate patients to become knowledgeable partners in the care of their chronic illness, and to also ensure there is access to allied health professionals to support, educate and follow up patients. (154) For example, a CDM approach to depression was utilised in a study of managed care by practice nurses (telephone monitoring and summaries to GPs) resulting in increased remission rates and level of functioning. (155)

RCTs have shown that education, collaborative models of care, ongoing monitoring and adherence to treatment are effective. (25, 154, 156) A model of care in which patients are followed-up systematically is recommended (such as regular visits or telephone reviews), and treatment guidelines reinforce the importance of continuation of treatment and follow-up. (25, 134, 157)

The Australian Family Physician article (3), which forms Chapter 11, highlights key issues related to managing depression as a chronic illness.

**Self-management**

Self-management is central to the chronic care model and can be seen as covering a range of behaviours, knowledge and attitudes. (12) Self-management involves the individual playing an active role by engaging in activities that protect and promote health, monitoring and managing symptoms and signs of illness, managing the impacts of illness on functioning, emotion and interpersonal relationships, and adhering to treatment regimes. (13) Self-management also involves developing a collaborative treatment plan, written by the individual with depression, involved health professionals, and possibly family members or carers. The term ‘self-management support’ is used to describe the involvement of other services or individuals supporting the person to self-manage. (158) The strategies required by a patient to
maximise their self-management skills will depend on the stage of chronic illness being experienced.\(^{(159)}\)

It is suggested that traditional models of care – where the GP plays a more active role in telling the patient what to do to try and motivate them to change – tend to be less effective in managing chronic disease.\(^{(160)}\) The literature on self-management suggests that if patients are encouraged to be more active in the health care process, they have better outcomes. Also, evidence supporting specific self-management interventions and practices in the health field is reported to be well documented in the literature.\(^{(12, 160)}\)

It is also argued that the decisions that patients make on a daily basis can have significant impact on their health and their chronic condition – this makes it even more important that the patient is an active and informed participant in the health care process.\(^{(160)}\) Another important aspect of self-management is producing a better informed patient who is equipped with the skills to deal with any new problems that they encounter, to engage in newly acquired health behaviours and to regulate their own emotional state. If the patient can apply these principles, then the results may include improvement in health status or slowed deterioration of health status, leading to reduced use of healthcare services as a secondary outcome.\(^{(161, 162)}\)

### 2.4 Relapse and Recurrence of Depression

#### 2.4.1 Relapse risk factors

A review by Bercusa (2007) of studies on specific risk factors for recurrent depression identified an underlying vulnerability that is seen as largely genetic.\(^{(163)}\) Reported risk factors for depression relapse included residual (including sub-threshold) symptoms, and a past history of dysthymia or previous episodes of depression.\(^{(35, 164, 165)}\) Hospitalisation in the period prior to relapse, benzodiazepine use, psychiatric co-morbidities (including substance use and panic disorder) and early discontinuation of antidepressants are also reported to be risk factors.\(^{(34, 136, 166)}\)
The risk of early discontinuation of antidepressants is supported by Melfi (1998), who carried out a study of 4,000 adult patients diagnosed with depression. The patients were followed for two years and those who continued therapy with their initial antidepressant were least likely to experience relapse or recurrence. Those who discontinued their antidepressant early were most likely to relapse.(136)

Long-term outcome has also been found to relate to remission status at three months after initiating treatment, and a longer duration of illness is predictive of poor recovery.(155, 167) Shorter time to full remission is protective against relapse, supporting the need for early and adequate treatment. Early onset or severe depression at diagnosis and childhood experience of loss or adversity are risk factors for chronicity.(35, 137, 168) The risk factors are summarised in Table 2 below.

Table 2.1 Risk factors for depression relapse/chronicity

| 1. Genetic vulnerability.(163) |
| 2. Continued symptoms, including subthreshold symptoms.(35, 164, 165) |
| 3. Past history of dysthymia or depression.(35, 164, 165) |
| 4. Hospitalisation prior to diagnosis, psychiatric co-morbidities or benzodiazepine use.(34, 136, 166) |
| 5. Early discontinuation of antidepressants.(136) |
| 6. Early onset of depression, long duration of illness or severe depression.(35, 137, 155, 167) |
| 7. Negative thinking styles.(169) |
| 8. Childhood experience of loss, adversity or trauma.(155, 170) |
| 10. Lower self-efficacy in managing depression.(170) |

The literature highlights the potential role of cognitive, psychological and social (psychosocial) factors in depression relapse.(169, 173, 174) There is evidence for initial depressive episodes being precipitated by stressful life experiences, subsequent episodes by negative thinking styles, and for protracted psychosocial stressors having a role in maintaining depression.(169, 175) It may be that patients who have had depression become sensitised to subsequent episodes.(176) It is also proposed that cognitions that affect intra and interpersonal communication, or those related to unrealistic goals, perceived lack of control or self-focus influence the chronic nature of depression.(177)
A recent study by Gopinath (2007) retrospectively examined data from primary care patients with recurrent or chronic depression who had been involved in a clinical trial of a primary care depression intervention, with the aim of identifying predictors of relapse.(170) Factors found to be associated with significantly higher risk of relapse included:

1. Poorer medication adherence in the 30 days prior to the original trial.
2. Lower self-efficacy to manage depression (such as using a written relapse prevention plan to identify early symptoms of depression and to seek help early).
3. Higher scores on a questionnaire identifying childhood trauma.

Limitations of the study were its use of a sample of limited diversity and the use of retrospective data.

2.4.2 Prevention of depression relapse and recurrence

Relapse prevention theory

Relapse prevention is often defined as medication adherence or recognition of early warning signs. However, Rickwood (178) suggests that its meaning is broader than this. Relapse prevention also means putting in place supports to remain as healthy as possible, thereby reducing the likelihood and severity of future illness symptoms. It includes developing personal strategies to cope with stressors and recognising early warning signs of illness and responding to them, that is, having a relapse prevention plan.(178)

Treatment guidelines and relapse

Depression treatment guidelines support early vigorous treatment to prevent chronicity.(179) Duration of therapy will depend on the patient’s history, and further studies are needed in this area to establish optimum lengths of therapy.(180) Continued therapy after the acute phase is critical in the prevention of relapse.(10, 148)

Depression treatment guidelines recommend maintaining a treatment regimen for as long as is necessary to allow the person to stabilise. This will be at least one year,
and where there is a history of recurrence or significant risk of recurrence, the person should be monitored and treated actively for three years. For recurrent depression, the guidelines recommend maintenance antidepressant therapy and/or a CBT booster and regular monitoring. If there has been no prior psychological therapy it is advised that CBT or IPT sessions are added, with regular booster sessions.

**Identifying and minimising risk factors**

As in the management of other chronic illnesses, the literature recommends identifying risk factors for relapse and minimising them. Reported risk factors for depression relapse included residual symptoms and hence it is important to treat the depression adequately such as not discontinuing antidepressants too early. Shorter time to full remission is protective against relapse, supporting the need for early and adequate treatment.

Gopinath highlights the importance of self-efficacy in managing depression. Strategies that enhance self-efficacy, such as using a written relapse prevention plan to identify early symptoms of depression and to seek help early, are seen as helpful in reducing the risk of relapse. The general literature also emphasises the role of psychosocial difficulties in depression, and it follows that it is important to reduce such difficulties. One study of women suffering from chronic depression found that a reduction in the score for ongoing life difficulties, the presence of social support and a sense of hope for a better future preceded improvement. As outlined earlier, there is evidence for depression relapse being influenced by negative thinking styles. Thus, it is important to tackle negative thinking early if there are signs of relapse.

**Enhancing protective factors**

The literature suggests that management should also involve the enhancement of protective factors to help reduce the risk of relapse. Protective factors are reported to include good interpersonal relationships and social support, family cohesion and social connectedness, academic or sporting achievements, an easy-going temperament and optimistic thought patterns.
The beyondblue guidelines (10) recommend considering increasing social support (housing, befriending). Teaching problem-solving, stress management and having a plan for managing early relapse symptoms are also advised.(10) In addition, psycho-social treatments are reported confer protective effects beyond active treatment. CBT may be particularly valuable in providing effective protection beyond the period of active treatment.(28) The role of these therapies in relapse prevention will be discussed later in this chapter.

Studies on relapse prevention in specialist settings

In this section, the literature on prevention of depression relapse and recurrence based on studies of different treatment approaches in specialist settings, such as in psychiatric units or hospital outpatient clinics, will be described. A systematic review of the literature on depression relapse prevention with antidepressant drug treatment pooling 31 RCTs (4410 patients), found continuing treatment with antidepressants reduced the odds of relapse by 70% compared with treatment discontinuation.(180) The importance of continuation of drug treatment has been addressed in the section on treatment adherence.

There is Level II evidence in the literature for the effectiveness of CBT and IPT in preventing depression relapse in specialist settings.(125, 182, 183) There is evidence that CBT has an enduring effect that extends beyond the end of treatment and assists in preventing recurrence.(184) An early study by Paykel (1999) involved 158 patients who were treated with medication and management sessions and followed over 48 weeks. Of the 50% of patients who received 18 sessions of CBT, only 20% relapsed, compared with 47% relapse in the group that only received only medication and management sessions.(106)

A well designed study of depression relapse rates among psychiatry outpatients who received continuation phase CBT after having received CBT in the acute phase of treatment, found a significantly lower risk of relapse compared to those patients who received no further therapy.(183) In this study, 84 hospital outpatients aged 18 to 65 years with recurrent depression were randomised to have either 10 sessions of continuation phase CBT over eight months (intervention), or no CBT (control). The findings were that over the eight month period, the CBT group showed significantly lower relapse rates (10% relapse) than the control group (31% relapse). At 24
months, patients with depression, who were treated with CBT showed relapse rates of 16%, compared to 67% in the controls.

Another RCT of 187 patients examined the use of CBT compared with usual care, and found a significant protective effect of CBT which intensified with the number of previous episodes.(185) Tang (2007) also reports that CBT may have significant advantages over antidepressants in preventing depression relapses. The existence of ‘sudden gains’ or large symptom improvement between sessions is suggested to reduce depression relapse and recurrence. Sixty patients received CBT and only one third of sudden-gain responders relapsed in two years. They had a 74% lower relapse risk than non-sudden-gain-responders. The small sample size, and hence reliability of the findings, is a significant limiting factor of this study.(186)

An Austrian study by Vos and Haby (2004) found that existing episodic treatment of depression avert 9% of the disease burden related to major depression in adults, whereas the authors predicted that optimal episodic treatment with CBT could avert 28%. Furthermore, it was predicted that maintenance CBT could avert 52% of disease burden.(93)

One small study of 35 patients with depression being treated with CBT (109) examined the effectiveness of different components of the CBT and found that both CBT coping skills (behavioural activation, thought and belief work) and independent implementation (out of session) of CBT material predicted lower risk for relapse in the year following treatment. Even though this was a small study, and it is possible that there were other alternative explanations for the findings, the value of different aspects of the CBT was highlighted.(109)

Relapse prevention and combined/sequential treatments in specialist settings

Rafanelli and Fava (126) report that sequential treatment of recurrent depression derives from the awareness that one course of treatment with medication or psychological treatment is unlikely to provide the solution. Examples of sequential treatment include changes in medication, or addition of exercise or CBT. The aim or the sequential approach is, according to Rafanelli (2007, p.1726) to “add therapeutic ingredients as long as they are needed”.
There have been positive trends in the studies of sequential treatments in specialist settings.(187) For example, a study by Fava (1998) of preventing recurrent depression with CBT after pharmacotherapy resulted in lower relapse rates persisting for four years.(188) In this study, 40 outpatients with recurrent major depression who had been treated with antidepressant drugs were randomly assigned to either CBT or clinical management. Each group received ten clinical sessions and in both groups the antidepressant medication was tapered and discontinued. Two-year follow-up occurred.

Results of this study showed that the CBT group had a significantly lower level of residual symptoms after discontinuation of medication compared with the clinical management group. At two-year follow-up, CBT also resulted in a statistically significant lower relapse rate (25%) than clinical management (80%). It is noteworthy that the CBT was supplemented in this study by lifestyle modification and Well-Being Therapy. Also, these patients were followed for six years, and even after that length of time the protective effect of the CBT had persisted. Ninety percent of the patients receiving clinical management had relapsed at six years, compared to only 40% of the patients who had received CBT.(189)

Studies from specialist settings supporting the combination or sequential use of different treatments to address different phases of depression, suggest that multiple interventions may provide more long-term benefit to patients than a single treatment delivered on its own.(11) For patients with residual symptoms, combined CBT and medication have been shown to be effective,(106, 190) while IPT has been found to be effective in combination with medication in recurrent depression.(125) It is suggested that further work is needed to find ways of extending care across the different phases of the disorder, and to tailor treatments to the different needs of depressed patients, such as for those with a history of several episodes of depression.(11)

Psychotherapy is seen as having additional benefit even if pharmacological therapy has been successful. Therapy aiming to alleviate residual symptoms and increase the person’s feeling of well-being (Well-Being Therapy) is reported to be a promising area, though more studies are needed.(191)
Novel treatments and relapse prevention

Segal (2003) suggested that it might be possible to take the active ingredients of proven treatments and design novel preventive treatments that are skills-based. (192) For example, a mindfulness-based CBT (MBCT) approach that teaches patients cognitive-behavioural skills and meditation was developed that has been found to reduce relapse in patients who have had three or more episodes of depression. (123, 192)

In mindfulness meditation patients learn to be aware of their mood becoming more depressed, and to bring their thinking back to the present whenever they are diverted by negative thinking patterns. (192) A well-designed RCT by Teasdale (2000) evaluated MBCT in recovered and recurrently depressed patients (n=145), over 60 weeks, finding that in those participants who had had three or more previous episodes of depression, MBCT significantly reduced the risk of relapse and recurrence. (123)

Primary care treatment programs to prevent relapse

A review of the literature was carried out in 2001-2 (and updated in subsequent years) to identify studies of primary care treatment programs aiming to prevent relapse of depression. The following keywords were used – depressive disorder, family practice, primary health care, outcome, prognosis, prevention, relapse or recurrence. A range of electronic databases including Medline, PsycLit and Cochrane Library were searched for journals from 1990 onwards in the English language. Bibliographies of identified studies were reviewed and key journals were hand searched. The initial review located a total of 120 papers related to depression and primary care, but only one study from the USA specifically evaluating a primary care depression RPP. (8)

This study by Katon (2001) consisted of an RCT involving 386 patients between 18 and 80 years of age with recurrent depression or dysthymia. It was set in four large primary care clinics, and results were reported in the Archives of General Psychiatry Journal. Initially, 2699 letters were mailed to eligible patients from the clinics. A total of 2051 patients underwent a screening interview and 702 were found to be eligible for a baseline interview for the study. Of these a number were unable to be contacted
or refused the interview (all were accounted for), and of the 480 patients completing the baseline interviews, 386 were successfully randomised (approximately equal numbers to intervention and control groups). No sample size calculation was provided.\(^{(8)}\)

The intervention was of relatively low intensity, and sought to extend research on collaborative care. It included education, two primary care visits with a depression specialist (such as a psychologist), and three telephone consultations over a one-year period with feedback to the GP. At the initial visit, the depression specialist reviewed the course of the current depressive episode and undertook a bio-psycho-social history. The intervention had a number of self-treatment goals, namely to improve long-term adherence to medication, to increase awareness of prodromal symptoms, and to increase the use of self-monitoring strategies to identify recurrence and to increase proactive steps (for example, early help seeking in response to early warning signs of depression).

Further treatment goals included increasing the daily use of depression treatment techniques, such as increasing pleasant activities (such as walking), exercise and socialising, promoting problem-solving skills and self-efficacy for managing depression. Each patient had a written personal relapse prevention plan, which was shared with the primary care provider. Follow up telephone calls focused on monitoring progress and adherence to each patient’s treatment plan. The protocol utilised principles of motivational interviewing (helping patients clarify the potential rewards of engaging in self treatment behaviours) and cognitive behavioural theories of relapse prevention.

Each patient’s adherence to medication was assessed at three monthly intervals by a blinded interviewer, prescriptions were monitored and a depression assessment tool was used during the telephone interviews. The study was focused in terms of the group studied (adults with recurrent depression), the intervention given (specific number and types of visits and telephone follow up with feedback) and the outcomes measured (relapse and recurrence rates, reduction in symptoms and adherence to medication).

It was reported that individuals in the intervention group had significantly greater adherence to adequate dosages of medication and were more likely to refill
prescriptions during the 12-month follow-up. These individuals also had fewer depressive symptoms, but relapse rates were not reduced over the twelve-month follow-up period. One weakness in the study was the high level of missing data (20%). This was discussed by the authors and statistical methods attempted to take the missing data into account. Also any adverse events were not reported.

This study is specific to the American health system and in particular to a Health Maintenance Organisation, by which 78% of the participants were employed. The study participants were also highly educated. It is possible in this group that there would be less psychosocial risk factors than in groups with participants from lower socio-economic groups. Hence, the generalisability of these findings to other groups or health systems is questionable.

This study concluded that primary care requires systematic change to improve chronic illness management, and that strategies such as education and activation (such as scheduling pleasant daily activities), monitoring of adherence and outcomes of treatment, and referral of treatment resistant patients (that is, those not responding to standard depression treatments) are important. The researchers concluded that a more intensive RPP might be needed to decrease relapse rates.(8)

2.5 Depression and the Australian primary care setting

Mental health care is an integral part of primary health care.(193) It has been suggested that the general practice setting is ideal for the delivery of long-term mental health care because of the continuous medical care provided by GPs to their patients.(7) However, past evidence has suggested that the recognition of depression among primary care patients by GPs is lower than it should be, ranging from 23-75%, with the most commonly accepted figure being 50%.(194) A study of GPs’ knowledge about diagnosis and treatment of depression found that the majority relied on somatic symptoms rather than the key diagnostic criteria related to mood changes.(195). A range of barriers have been identified which may contribute to difficulty in diagnosing depression, such as stigma about mental health issues, the existence of co-morbidities, inadequate GP skills or consultation times, or systems within practices (for example, to recall patients with depression for follow-up) and
insufficient access to specialist consultations.\(64, 196\) The important role of GPs is acknowledged in the literature, but there is also agreement that there is a need for GPs to improve their care of patients with recurrent and chronic psychiatric illness and to provide longer-term depression care including relapse prevention.\(8, 10, 148\)

Australian Government policy addresses important mental health care issues, and in particular the increasing role of the primary health care sector.\(197\) In 2001/02 the Commonwealth Government allocated $120 million to establish the ‘Better Outcomes in Mental Health Care’ initiative (BOMHC) with further funding committed in the 2005 Federal Budget.

BOMHC consisted of five components:

1. Education and training to enhance GPs’ mental health skills.
2. Three step mental health process (undertaking an assessment, management plan and review) requiring what was called ‘Level One’ or 6 hours of training.
3. Focused psychological strategies (FPS), evidence-based such as CBT, requiring ‘Level Two’ training (20 hours of training).
4. Access to allied psychological services (ATAPS) via Divisions of General Practice (local GP support organisations).
5. Access to psychiatric support, via telephone or email through a national hotline.\(198\)

GPs undertaking Level One and Two training were able to utilize additional Medicare item numbers for providing the assessment and FPS services.

There have been further developments in relation to Australian primary care mental health subsequent to the KBA study. These developments and their implications will be outlined in Chapters 10-11.
PART TWO:

2.6 Development of the KBA program

Subsequent to the literature review, and in response to conclusions by researchers such as Katon (8) and Segal (11), a multifaceted treatment program incorporating a range of psychological therapies and aiming to reduce the severity of depression and prevent relapse was developed. Called KBA, it was designed especially for the primary care setting, taking into account several limitations of the setting, including time constraints, the need for training and the necessity of having readily accessible information about depression for patients.(64)

With any new program, there will be reliance on what is already known and proven, but such programs will also involve new ideas and approaches. In developing the KBA program, the following sources of information, knowledge and understanding were utilised:

1. Evidence in the research literature.
2. Information from published books on depression treatment.
3. Current expert thinking on depression and relapse prevention from the literature, clinical guidelines and from speaking with experts in the field.
4. Clinical and teaching experience, which assisted in maximising clinical relevance of the KBA program.

Experts in the field were consulted by the researcher as part of a Churchill Fellowship. Primary Mental Health Care Professors, C. Dowrick and A. Kendrick, were visited in the United Kingdom. The Institute of Psychiatry in London, the Depression Care Training Centre, Professor G. Goodwin, Dr C. Williams and Dr C. Smith (psychiatrists), and Primary Care Psychiatry Professor L. Gask, were also visited. Discussions included the need for long-term management of depression in primary care, the place of relapse prevention and the lack of research and resources in this area.

The KBA manual was written over 18 months, but the conceptualization of the program was based on over 20 years of clinical and teaching experience. The need for clear and concise patient information, presented in the one manual, became evident during these years. Experience teaching GPs in both rural and urban areas
during these years also suggested that GPs wanted further training in mental health and access to useful resources both for themselves and their patients. Access to training and resources seemed particularly to rural practitioners, probably due to more limited access to mental health services and practitioners. A manualised format was also seen as enabling patients to do take-home tasks between consultations.

### 2.6.1 KBA treatment strategies

As outlined earlier in this chapter, support was found in the literature and treatment guidelines for a range of treatment strategies that have been shown to be useful in depression management and relapse prevention. These were incorporated into the KBA program, and included the following strategies:

1. The assessment and treatment of co-morbid problems. (62)
2. Early vigorous treatment. (179)
3. Long-term management based on a CDM model. (155)
4. Education about depression and relapse. (84)
5. Encouragement of adherence to medication. (136)
6. Strategies to address risk factors for relapse. (85, 170)
7. The development of coping skills such as stress management and problem-solving skills. (51, 113, 148)
8. The development of cognitive-behavioural and interpersonal skills. (106, 125, 183, 186)
9. Combined or sequential treatments, such as medication followed by psychological therapies. (96, 126)
10. Continuation of drug therapy after the acute phase. (50)
11. Addressing psychosocial/interpersonal difficulties. (169)
12. Addressing lifestyle and well-being issues. (181)
13. Counselling that fosters hope for a better future. (172)
14. Bibliotherapy. (50, 121, 190, 199);
15. More intensive follow-up, monitoring and a plan for managing early relapse symptoms. (10)

### 2.6.2 KBA underlying treatment approaches

An important step in the process of designing the KBA program, was determining which psychosocial treatment approaches and models of therapy would underpin the
10 Step program. Evidence of their effectiveness in treating depression and preventing relapse, and their suitability for use in the primary care setting was considered. Factors such as the time necessary to deliver the therapy and the capabilities of practitioners were also considered.

Consequently, the following approaches were incorporated into KBA:

1. Psycho-education (providing information) for the individual and family on depression and its management.(59)
2. Strategies to minimise the risk factors for relapse and enhance the protective factors.(10, 55)
3. An holistic approach, addressing physical, psychological, social and spiritual aspects of causation and treatment, and encouraging return to functioning in all areas of life.(9)
4. A self-management approach involving teaching practical skills (such as goal setting and problem-solving), to enable the individual to manage the depression currently and in the future.(11, 151)
5. An approach enabling combination or sequential therapy.(96)
6. An eclectic approach, enabling a multi-faceted but integrated approach.(107)
7. A range of psychological therapies that can be tailored to the individual patient, including CBT, IPT, Problem Solving, Multimodal Therapy, Narrative Therapy and Well-being Therapy.(107, 200, 201)

These approaches will now be explained in more detail.

Psycho-education

Psycho-education involves assisting the individual and their families/carers to understand the nature of depression and treatment strategies. This enables the individual and their family/carer both to work collaboratively with the GP or health professional in deciding the most appropriate treatment approaches to be taken. Psycho-education is recognised as an important part of treatment, and is also a key element of CBT.(105, 106, 114)

According to Rickwood (178), families and carers also regard relapse prevention as a learning process, involving coming to understand if, when and how to act. Recognising early warning signs of illness and responding to them relies on the
patient having good relationships with others, and upon their understanding of the illness. Having a written relapse prevention plan can assist.(10, 202). This strategy is incorporated into the KBA program in Step 9.

**Reducing risk factors and enhancing protective factors**

The risk factors for depression relapse/chronicity have been outlined. The literature recommends identifying risk factors for relapse and minimising them.(10, 55) Also, the presence of two coexisting risk factors, rather than one alone, is considered important in identifying high risk individuals.(183) The KBA program addresses key risk factors for depression relapse including early discontinuation of medication, psychiatric co-morbidities and psychosocial difficulties.(136, 169, 175)

According to clinical guidelines, adequate depression treatment using medication and/or psychological treatments is important in reducing the risk of relapse. Adherence to treatment for the guideline-prescribed length of time is an important part of this.(84) The KBA program provides information about treatments for the individual and their family/carer, including details about length of treatment and advice not to discontinue treatment without speaking with the individual’s GP. The KBA program involves regular monitoring and follow-up of the person with depression for a 12-month period, to monitor progress and ensuring that treatment is continued.(10)

The KBA program begins with an assessment of the individual, including co-morbidities such as anxiety or substance use (alcohol, smoking or illicit drugs). Strategies to manage anxiety are incorporated into the program, with information on anxiety provided and stress management strategies (including relaxation) covered in the early KBA steps. The program also addresses alcohol and other substance use, with advice to seek assistance from specialist agencies if needed.

The literature on depression emphasises the role of psychosocial difficulties as a risk factor in depression, with psychosocial stressors believed to play a role in maintaining depression.(169, 175) It follows therefore that reducing such difficulties will also be important in relapse prevention.(167, 169) Depression treatment guidelines recommends teaching problem-solving and considering increasing social support (for employment and housing, befriending by volunteers).(10) The KBA
program incorporates strategies to carefully address psychosocial difficulties such as loneliness and unemployment.

Consistent with the approach of enhancing protective factors, the KBA program provides information on the importance of connectedness and teaches social skills such as assertiveness. A number of the protective factors for depression are addressed in the different psychological therapies, such as working on interpersonal relationships and family cohesion in IPT, and developing optimistic thought patterns in CBT. A range of CBT and IPT strategies are utilised, addressing coping skills such as stress management and problem-solving (in Steps 3, 4, 5 and 8).

Holistic approach

The literature recommends that the bio-psycho-social-spiritual causality of depression be taken into account in treatment.(9) To address this recommendation, the KBA program aims to take a holistic approach (addressing the needs of the whole person), recognising that the various aspects of a person’s life are important.

The program incorporates skills development, as well as focusing on the individual’s levels of functioning and quality of life. It has been noted that from the patient’s perspective, a vital part of recovery is often the individual’s return to their usual level of functioning.(203) The KBA program therefore focuses on the return to optimum levels of functioning in all areas of life: physical (through treatment of co-existing physical problems and addressing lifestyle issues), and psychological, social and spiritual (through a range of psychosocial therapies and strategies). Occupational issues are also discussed in Steps 6 and 8.

Self-management approach

As highlighted earlier in this chapter, Gopinath (170) found lower self-efficacy to manage depression to be associated with significantly higher risk of relapse. To address this risk factor, and consistent with a CDM approach, self-management is incorporated into the KBA program. The aim of incorporating the self-management approach is to enable the individual to be best able to manage the depression both in
the present and in the future, and to assist in relapse prevention.(11, 151). KBA provides information and guidance on depression and its management for the individual and their family/carers, and encourages a healthy lifestyle as well as teaching practical skills.

**Combination and sequential therapy**

Current management guidelines pertain to both pharmacological and psychosocial treatment approaches, and support the use of evidence-based, combination therapies.(10) Adequate treatment of depression with medication and/or psychological treatments is important in reducing risk of relapse. Consistent with the literature, the KBA program is designed to be used in combination with medication, where clinically indicated for the individual patient.

**Eclectic approach**

Whilst recognising the evidence supporting the use of certain individual therapies in managing depression (such as CBT and IPT), one distinct approach is also highlighted in the literature. The ‘eclectic approach’ involves utilising concepts and methods from a number of therapy styles, and given the wide range of risk factors for relapse, seems to lend itself to depression management.(204)

Also, in the primary care setting GPs and other health professionals tend to utilise a range of therapeutic approaches, and will often use multiple approaches with one individual. The eclectic approach is also consistent with Katon’s (205) suggestion of taking a multi-faceted approach to preventing depression relapse. In this way, co-morbidities and lifestyle factors can be addressed alongside psychosocial issues.(11, 205, 206)

**Psychological therapies**

A range of psychological therapies are utilised in the management of depression. These can be grouped into counselling/supportive psychotherapies, and structured therapies. Counselling involves listening, empathy and advice, whereas structured
therapies involve specific techniques including problem-solving and relaxation.(207) The following structured therapies are well supported in the literature:

1. CBT.(125, 182, 183)
2. IPT.(117)
3. Problem-Solving Therapy.(105, 106, 114)
4. Well-being Therapy.(199)
5. Mindfulness and mindfulness-based cognitive therapy.(11, 123)

These therapies involve teaching the patient with depression a range of practical skills that can be utilised with the present episode or any future episodes of depression. This evidence-based, practical approach was congruent with the KBA program.

An eclectic model of psychological therapy called Multimodal Therapy was developed by Arnold Lazarus, who recognised that individuals are unique, having different biological make-ups and different dimensions to their personality.(107, 200, 201) In this model, clinicians choose strategies or skills from several therapy models when working with their patients, depending on the issues of the individual patient. In other words, the therapist considers what is best for that particular individual.(204) The KBA program is consistent with Multimodal Therapy by incorporating supportive therapy, CBT, Problem-Solving Therapy, and elements of IPT and Well-being Therapy, while at the same time allowing tailoring of the program to the individual. For example, more emphasis can be placed on the issues or related steps in the KBA program of most relevance to the individual at the time.

KBA also draws on several other psychological approaches to fully address the psycho-social-spiritual model of treatment; namely, narrative and existential therapies. Narrative therapy involves the therapist and the individual patient working together to identify what the individual wants in their own life, and how best to utilise their own knowledge and skills to achieve that.(208) Existentialism recognises the importance of the physical aspects of oneself (such as physical health and fitness), as well as the social, psychological and spiritual.(201) The literature suggests that spiritual approaches which address meaning and purpose in life, can sometimes help the individual cope, even when facing suffering.(209)
2.7 Outline of the program and KBA resources

The KBA program is based on evidence in the literature on depression outlined earlier in this chapter, and on clinical experience. It also involves new approaches, and is designed to provide an engaging and easy-to-use presentation and delivery model.

2.7.1 10 Steps of the KBA program

A 10-step treatment outline is utilised in the KBA program. It focuses on developing an understanding of depression and anxiety (the most common co-morbidity to depression).(59) In the KBA program, one step builds onto the next step. For example, Step 2 of the KBA program describes anxiety, and then in Steps 3 and 4 there are specific skills for dealing with stress and anxiety such as relaxation strategies. Also, the earlier steps cover more general skills, while later steps move on to more complex skills, such as those involved in CBT. This enables the individual working through the program to gradually acquire knowledge and skills, and build confidence in managing the depression. The KBA steps are summarised in Table 2 below.

Table 2.2 10 steps of the KBA program

<table>
<thead>
<tr>
<th>'Keeping the Blues Away': 10 step relapse prevention program</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Medical and psychosocial assessment, goal-setting, monitoring progress.</td>
</tr>
<tr>
<td>2. Information about depression and anxiety and relapse prevention.</td>
</tr>
<tr>
<td>3. Healthy lifestyle issues (nutrition, exercise, sleep, managing stress).</td>
</tr>
<tr>
<td>4. Useful coping skills (mood diary, problem-solving, relaxation techniques).</td>
</tr>
<tr>
<td>5. Helpful thinking or cognitive strategies (thought monitoring, analysis and challenging).</td>
</tr>
<tr>
<td>7. The benefits of activity (activity scheduling, laughter and humour).</td>
</tr>
<tr>
<td>8. Fostering social support and skills, dealing with relationship issues and unemployment.</td>
</tr>
<tr>
<td>9. Developing a plan to manage early symptoms of relapse.</td>
</tr>
<tr>
<td>10. Reassessment, review and helpful resources.</td>
</tr>
</tbody>
</table>
2.7.2 KBA program time-frame

The KBA program is to be commenced once the patient’s depression is stabilised by initial treatment, and is designed to continue for 12 months. It is suggested that the 10 steps of the program should be delivered by the same GP during appointments scheduled every one to two weeks, over approximately three months (see Table 4). The appointments should be at least 30 to 45 minutes in duration. The intense period of delivery of the KBA program is then followed by regular patient reviews preferably by the same GP (at least monthly for the remainder of 12 months), for monitoring of progress and reinforcement and maintenance of skills.

Decisions about the frequency and number of initial KBA sessions was based on clinical guidelines related to delivering psychological therapies for depression, research literature and also practical considerations. For moderately severe depression, the guidelines recommend either an antidepressant or one of the brief psychological therapies (8-12 sessions of CBT or IPT). One research study involving a RCT comparing two treatments in outpatients with major depression utilised 8 or 16 sessions of psychotherapy in combination with pharmacotherapy. The briefer version achieved faster remission of the depression, and most of the improvement occurred during the first 8 weeks, although the results were similar at the end of treatment in both groups. As general practice is more time limited than specialist settings, approximately six to eight sessions were deemed to be more realistic for the delivery of the KBA program.

Table 2.3 KBA program outline

<table>
<thead>
<tr>
<th>Steps</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient provided with KBA manual, journal</td>
<td>At outset of program</td>
</tr>
<tr>
<td>and relaxation CD</td>
<td></td>
</tr>
<tr>
<td>Step 1 - assessment and goal-setting</td>
<td>Steps 1-10 delivered over 6-8 sessions</td>
</tr>
<tr>
<td>(assessment tools)</td>
<td>during next 3 months</td>
</tr>
<tr>
<td>Step 2 - psycho-education</td>
<td></td>
</tr>
<tr>
<td>Step 3 - healthy lifestyle issues</td>
<td></td>
</tr>
<tr>
<td>Step 4 - useful coping skills, including</td>
<td></td>
</tr>
<tr>
<td>relaxation</td>
<td></td>
</tr>
<tr>
<td>Step 5 - helpful cognitive strategies</td>
<td></td>
</tr>
</tbody>
</table>
## 2.7.3 Resources

As outlined earlier in this chapter, bibliotherapy or working through a treatment book, has been reported to be a useful treatment strategy.\(^{(50, 121)}\) Also, the KBA program needed to be reproducible across a number of practices and delivered by a number of GPs. Hence, bibliotherapy was adopted as an important part of the KBA program.

The KBA treatment manual aims to serve a number of purposes, as:

1. A guide for the GP.
2. A workbook for the individual with depression.
3. A resource for patients to use into the future.

The manual is provided to patients along with a journal, or a blank exercise book to enable patients to record their thoughts as they work through the program, to document their progress or record questions for their GP. The KBA manual contains repetition of key strategies and key points, most easily seen in the ‘Points to Remember’ summary tables at the ends of each section in the steps. This is to emphasise important issues, and to accommodate the loss of concentration and memory that can occur in depression.\(^{(21)}\) Individual steps can also be revisited as part of the KBA program, consistent with treatment guidelines which advocate ‘booster CBT sessions’ in the treatment of depression.\(^{(10)}\)

| Step 6 - dealing with psychological issues |  |
| Step 7 - the benefits of activity |  |
| Step 8 - fostering social support and skills |  |
| Step 9 - managing early relapse symptoms |  |
| Step 10 - review and repeat assessment tools | Approximately 3 months |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Review and repeat assessment tools | 12 months |

### Table

| Step 6 - dealing with psychological issues |  |
| Step 7 - the benefits of activity |  |
| Step 8 - fostering social support and skills |  |
| Step 9 - managing early relapse symptoms |  |
| Step 10 - review and repeat assessment tools | Approximately 3 months |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Follow-up |  |
| Review and repeat assessment tools | 12 months |
Also, a recording of a relaxation script (written by the researcher, who is trained in hypnotherapy) was made especially for the KBA program. The recording mirrors the relaxation techniques described in Step 4 of the program, namely physical relaxation, breathing techniques and visualisation. A meditation based on a colour visualisation is included as it focuses on relaxation and enhancing self-confidence, a topic covered in Step 6 of the program. A mindfulness-based meditation is incorporated as it offers another form of relaxation, and also reinforces some of the cognitive strategies outlined in Step 5 of the KBA program.

2.7.4 KBA training for GPs

A training or education program was written to accompany the KBA program. The training program associated with the exploratory phase of the study will be outlined in Chapter 4, and the program associated with the pilot phase will be described in Chapter 5.

2.8 The KBA program in detail

2.8.1 Step 1 - Getting started: assessment and goal setting

Step 1 in the KBA program addresses the need for assessment, both medical and psychological, of the individual with depression and forms the basis of developing a treatment plan. Part of this process is collaboratively identifying the main issues for the individual with depression, and then determining actions to address these issues. Hence Step 1 in the KBA program involves goal setting, which is carried out jointly by the patient and GP.

In Step 1 in the patient is encouraged to define and prioritise their own goals with the assistance of the GP. These goals then assist in directing treatment, and enable the GP to place emphasis on relevant strategies from the KBA program (such as lifestyle or cognitive strategies) for the individual. The severely depressed person may only be able to consider how they direct their attention and activity for an hour at a time, but as the person improves, they will be able to consider a day at a time, increasing
Step 2 of the KBA program also requests that GPs and their patients regularly review the goals and monitor progress.

### 2.8.2 Step 2 – information about depression and relapse prevention

This step provides psycho-education about depression, which has already been highlighted a fundamental part of depression management and is particularly central to CBT. Step 2 provides patients with information about the prevalence of depression, and it is differentiated from normal feelings of sadness. The DSM-IV criteria for depression and characteristic symptoms are outlined. The debilitating effect of the low mood and other symptoms of depression is outlined, as are the effects on the ability to cope and function. The fact that many patients with depression present to their GP with physical complaints is stated, and the common co-morbidity of anxiety with depression is also discussed.

Step 2 of the KBA program explains the ‘bio-psycho-social’ model of depression. The role of loss and grief as a potential trigger for depression is introduced, and followed up later in the KBA program. The program incorporates the view that spiritual factors may also be important. The term ‘spiritual’ refers to personal views that express a sense of something greater than one-self, such as a Creator. Hence, the program discusses spiritual factors where appropriate and utilises existential concepts related to meaning in life.

Risk factors for depression, such as difficult life events, substance misuse and negative thinking, are noted, along with the need to address them in the treatment of depression. The importance of enhancing protective factors, such as supportive social networks and coping strategies, is also highlighted. The risks of depression are outlined, with the most significant risk being suicide. In Step 2, the individual is encouraged to talk to their family, friends, GP, or mental health professional if they have suicidal thoughts. Relationship breakdown and the link between alcohol or drug use and depression are also discussed.

This step outlines the benefits of treating depression early and highlights the range of treatment strategies available. The KBA program may be used alongside medication for depression; hence, the use of antidepressant medication is discussed in Step 2. Information on psychological therapies is also provided, including
counselling, CBT, IPT, Narrative Therapy and Well-Being Therapy. The main focus in this step, however, is on providing non-judgmental support so that people can talk over their problems. Having support during a very difficult time in life is really important.(110)

Some of the concepts of CBT, such as the person with depression possibly viewing themselves, their future or the world negatively, are introduced early in the program.(212) The aim of CBT, to provide the person with the tools to deal with negative thinking, feeling and behaviour, is also outlined.(213) The CBT approach is covered in detail in Step 2.

The psycho-education process is continued with information on working with the GP, and ways to help oneself and involve family and friends. The terms relapse and recurrence of depression are explained, and the rate of relapse in primary care is provided. The aims of the KBA program are presented, and the fact that many people remain well is highlighted to emphasise the importance of maintaining a sense of hope and perspective.(214)

2.8.3 Step 3 – Healthy lifestyle issues

The literature on depression management supports addressing lifestyle issues in treatment.(50, 121, 188) Step 3 of the KBA program addresses key lifestyle issues, and related issues such as drug use and gambling. Sections include:

1. Healthy eating.
2. Becoming more active and exercising.
3. Sleeping better.
5. Avoiding alcohol, cigarettes and other drugs.
6. Addressing gambling.

The section on healthy eating is based on the Dietary Guidelines for Australian Adults.(215) Information on exercise follows. It is well-established that exercise has a positive effect on mood, results in increased physical fitness, promotes a sense of well-being and aids sleep.(216, 217) A study of 156 patients with depression were randomly assigned to a four-month course of exercise, sertraline or a combination of the two. After four months all patients had improved. After 10 months however,
participants in the exercise group had lower relapse rates. The researchers concluded that exercise therapy is feasible and is associated with significant benefit, especially if continued over time.(218)

A range of different mechanisms for these effects have been proposed, such as increasing endorphin or neurotransmitter release, and the reduction of muscle tension and meditative state associated with exercise.(219) Pollock (220) notes the benefits of exercise in depression, suggesting that treatment include a collaborative exercise plan.(220) Simple ways to incorporate more exercise into the day are discussed in KBA and patients are reminded to utilise the goal setting approach when planning exercise.

Because sleep disturbance is common and often very troubling in depression, tips around to minimise sleep problems, often called ‘sleep hygiene’ are outlined.(21) The individual is encouraged to keep a sleep record or diary, including a record of the day’s activities and sleep patterns. A number of sleep hygiene tips based on grey literature (books, lay publications), such as establishing a sleep routine, and taking time to relax before going to bed, are provided.(221-226)

A clinical observation is that stress is often associated with anxiety and depression. Psycho-education about stress is provided, including information on stress triggers (such as financial or work worries) and the stress response (often called the ‘fight or flight response’).(227, 228) Understanding the stress response is useful in reducing anxiety related to the physical symptoms, such as rapid heart rate and sweating, that it can produce.(110) A series of exercises are provided to assist the individual to identify both their own stress triggers, and strategies to manage their stress.

Limited information is also provided regarding the relationship between depression and drug and alcohol use, and the individual is encouraged to talk about drug and alcohol-related issues and any gambling-related concerns with their GP or to seek specialist assistance.

2.8.4 Step 4 – Useful coping skills

This step provides information on a range of coping skills, including:

1. Keeping a mood diary.
2. Problem solving.
3. Getting on with things and not procrastinating.
4. Relaxation techniques.
5. Dealing with panic episodes.

The first coping skill, ‘keeping a mood diary’, was included because various forms of recording information (such as mood or thoughts) in a diary format have been advocated in depression management. It enables the patient to record their mood on a scale of 0 to 10 (where 0 refers to no depression, and 10 to the most severe depression), as well as commenting on, the length and quality of their sleep, their eating patterns, and significant events or activities each day.

A mood diary is useful for raising the individual’s awareness about their mood and related events and activities, and provides a good basis for discussion with the GP about these key issues. As time goes on, the patient is encouraged to focus on positive feelings and events, such as what has helped their mood to improve or what positive events happened in a day, such as the individual sleeping better or having a more positive day. This approach is drawn from Well-being Therapy.

Step 4 states that when an individual is feeling stressed or depressed, negative thoughts can seem overwhelming and it can be harder to think through a problem clearly. Hence structured problem-solving, is presented in KBA to assist the individual to work through their problems. The technique involves defining the problems being experienced and looking at logical, practical ways of dealing with each of them, with the aim of deciding on the best possible solution. The general rules for problem solving and tasks involved are outlined.

As activity has the potential to improve mood, the skill of ‘daily activity scheduling’ is explained in Step 4. This skill also fosters a sense of normal routine and satisfaction. Guidelines for planning activities, including planning one day at a time and carrying out activities which provide pleasure, and a scheduling chart are provided.

The importance of dealing with stress was outlined in Step 3, with relaxation techniques mentioned as one stress-management technique. A range of relaxation techniques are discussed in Step 4. There are established physical and mental
benefits from learning to relax, including improved sleep and reduced anxiety. \(232, 233\) Relaxation techniques are also part of an holistic approach to health, fitting with the philosophy of the KBA program.

A range of basic techniques are presented, as one technique may suit an individual better than another. Physical relaxation or progressive muscle relaxation is outlined in Step 4 and included on the specially prepared relaxation CD. \(49\) Breathing techniques are also important in learning to relax, because, for example, in times of stress an individual’s breathing rate may increase and breathing can become shallow. The usual resting breathing rate in an adult is about 12 breaths per minute, but when anxious, may go up to 25 breaths per minute. Breathing techniques can be used to slow the breathing rate and lessen shallow breathing. \(47, 110\) The third technique presented is a visualisation of a peaceful and safe place, which can be a positive and relaxing experience for many individuals.

A number of other relaxation ideas are then discussed. Meditation techniques focus on quietening the mind, and when the mind is quiet the body may also relax. It refers to learning to direct our attention and energy to where it is most needed, resulting in being ‘in the moment’ (being mindful) and not struggling with unnecessary mental activity. \(123, 234\) can be applied to meditation or to any simple daily task. \(235\) There is mention that different forms of meditation are used by people with different spiritual beliefs. For example, Buddhist teaching includes meditation. Physical practices which incorporate relaxation, such as yoga, are also highlighted.

The specially produced KBA relaxation CD contains three tracks, each incorporating different techniques:

1. Physical relaxation, breathing techniques, visualising a pleasant place.
2. Meditation based on a colour visualisation.
3. A mindfulness meditation incorporating cognitive strategies.

The author wrote the script for the relaxation recording based on hypnotherapy training, clinical experience and related literature. \(234, 236\)

The current literature emphasises that anxiety commonly coexists with depression. \(110\) Also, it has been shown that experiencing symptoms of panic predicts a poorer response to therapy in women with recurrent depression. \(166\) A section on managing panic attacks is therefore included in the KBA program,
beginning with psycho-education. A panic attack is defined as a discrete period of intense fear or discomfort, developing abruptly and reaching a peak within 10 minutes.(110)

Treatment of panic attacks involves providing information about panic and reassurance. It is important for the individual to be aware that the physical symptoms are part of the body’s normal reaction to danger or threat, but that in anxiety the symptoms can be out of proportion to the situation. Panic is an extreme form of anxiety, which is frightening but not dangerous.(49, 110) Management involves support, learning coping strategies for dealing with panic attacks such as breathing techniques, relaxation techniques, cognitive strategies and taking medication if appropriate.(110, 237)

2.8.5 Step 5 – Helpful thinking or cognitive strategies

The basic concept of CBT was introduced in Step 2, and is further explored in this step. CBT is an effective means of tackling symptoms of anxiety and depression, and involves making changes in behaviour and patterns of thinking.(212, 213) Thinking in depression is negative, and is often self-blaming and self-critical.(213) There can also be a negative view of the world and the future.(213) Feelings of sadness can trigger automatic negative thinking styles, and a vicious cycle occurs in which the sad feelings and negative thoughts reinforce each other.(187) CBT incorporates behavioural techniques, in which depression-reinforcing habits are discouraged and more active and social behaviours are encouraged.(207) Several behavioural strategies were outlined in previous steps, including relaxation techniques, behavioural activation (encouraging and planning engagement in daily activities) and graded exposure (Step 4).(207)

Learning how thinking and feeling interact, and how to develop different ways of thinking is the basis of the cognitive part of CBT. Specific cognitions are targeted for change through practices such as monitoring, identifying and challenging unhelpful thoughts and replacing unhelpful thinking patterns with more helpful ones.(107, 207) The KBA program describes these practices as five steps, with the aim of presenting key strategies in an easy-to-follow format. Step 5 incorporates a thought diary, with columns gradually added in relation to each of the five CBT steps. The five steps are as follow:
1. Keeping a thought diary to raise awareness of thoughts that occur in depression.
2. Understanding thinking errors. In CBT, thoughts are seen to be rational or irrational (the wording ‘helpful’ or ‘unhelpful’ is used in KBA). There are a number of common thinking errors, including ‘all-or-nothing’ thinking, in which situations are seen as black and white with no middle ground.
3. Identifying thinking errors.
4. Challenging unhelpful thinking. Strategies, such as looking for evidence and putting thinking into perspective, are provided.
5. Developing more helpful thoughts.

Towards the end of Step 5, several important issues related to CBT for depression and the origin of thinking errors are covered. It is explained that individuals may develop assumptions and beliefs about the world, others and themselves. Beliefs operate at an unconscious level, and come into play when responding to situations.(213) In depression the beliefs tend to be negative, and may include the unhelpful beliefs of needing to be loved by and approved of by significant people in one’s life, or always being competent and achieving in life.(230, 240) In anxiety, negative beliefs often relate to a sense of being threatened and lacking the ability to deal with threats.(213, 230, 240) Strategies are then provided to assist the individual to develop more helpful beliefs.(229)

A section on mindfulness completes this step, as it assists the individual to address negative thinking styles in depression. Through paying purposeful attention to the present moment, mindfulness provides a way of raising awareness of one’s thinking.(123, 192) This mindfulness principle has been incorporated into therapies known as mindfulness-based CBT (MBCT).(192, 241) MBCT combines cognitive and meditation techniques, and is associated with a number of positive outcomes.(242) In traditional CBT, the patient is engaged in challenging unhelpful thoughts, whereas in mindfulness CBT, the thoughts are allowed and accepted, rather than engaging with them.

Increased awareness of negative thoughts allows a person with depression to realise when they are about to undergo a downward mood swing. It has been suggested that being aware of this weakens the depressed thought, making it possible for the
individual to halt the vicious cycle between negative thoughts and negative feelings. Once aware of thoughts linked with depression relapse, it is suggested that the individual can challenge them using the learned strategies or by doing a pleasant activity. (123, 192) One other positive aspect of MBCT is its association with increased awareness of pleasant events and feelings that occur during the day. A brief mindfulness-based meditation is provided on the KBA relaxation CD.

2.8.6 Step 6 – Dealing with psychological issues

Individuals with depression will each have their own personal and psychological issues to work through. Step 6 addresses a number of psychological issues, identified from literature and clinical experience, that may be experienced by individuals with depression, namely:

1. Low self-esteem.
2. Loss and grief.
3. The ‘negative’ emotions and the need to ‘let go’.
4. Loneliness.
5. Hopelessness and suicidal thoughts.
6. Trying to find hope and meaning.

Self-esteem

Many patients with depression express low self-confidence, self-dislike or self-loathing. The founder of CBT, Dr. A. Beck, found that 80% of people with depression expressed self-dislike. (243) It is therefore essential to address the issue of self-esteem in depression management. (107) Self-esteem is defined as one’s sense of self-worth – how an individual sees and judges oneself, often in comparison to others. Self-esteem relates to our underlying attitudes and beliefs, including self-confidence (beliefs about one’s ability). One’s sense of self-worth affects general functioning and how an individual relates to other people, and low self-esteem can contribute to an individual with depression withdrawing from other people. (244)

The literature suggests that unhelpful thinking, discussed in Step 5, is a major influence on self-esteem. (212) Such thinking, for example, can lead the individual to label themselves as a failure, which can be self-defeating. (212) Strategies to challenge unhelpful thinking in relation to self-esteem are outlined in the KBA
manual, along with a number of useful techniques used by therapists to help individuals raise their self-esteem.

**Loss and grief**

It is recognised that depression may be triggered by loss and grief.(50) Loss is defined as a perceived negative change by an individual, which may be related to the loss of a person, object, state or opportunity of value. Grief is the response to this perceived loss.(245) Loss may be death-related or non-death related.(246) For example, an individual may grieve the death of a person or pet, while a non-death related loss could be divorce or the loss of one’s job. Many aspects of the individual are affected by grief – physical, emotional, behavioural, cognitive (such as memory and concentration), social and spiritual.(247, 248) Sometimes individuals can become stuck in their grief and an intense grief reaction continues.(249) This can be related to unresolved feelings such as guilt. Ongoing or long-term grief is known as ‘chronic grief’. (250, 251)

Many of the symptoms experienced in normal grief, such as sadness, crying, feeling low, loss of appetite, disturbed sleep and poor concentration, overlap with the symptoms of depression. These symptoms will usually diminish over time. However, on some occasions a depressive illness may develop out of grief. This is when depressive symptoms are both prolonged (more than two months) and more severe than expected.(21, 49) Depression itself may cause losses, such as loss of health, interests, social contacts or ability to work. These losses in turn may add feelings of grief to the depression.

Adjusting to loss takes time and effort, and there are a number of different approaches to grief therapy. Several approaches are highlighted in this step, as they provide an holistic approach to dealing with loss and grief. Grief therapy may involve understanding the process of grief, sharing thoughts and feelings about the loss and reviewing what it means to the individual, identifying and expressing negative emotions associated with the loss, such as self-blame or anger, and problem-solving ways of coping with the troublesome feelings resulting from the loss, practical problems, or new ways of coping in life.(245, 252, 253)
There are also a number of strategies for dealing with the negative thinking that can occur in grief. Fear, guilt, anger, sadness, self-blame or blaming others can all occur in grief. The principles of CBT as outlined in Step 5 can also be applied in the context of loss and grief. A number of factors that help individuals adjust to loss have been identified. At some stage, achieving a sense of closure is important. This refers to closure with the physical body after a death, but does not include closure to the love and influence of the person who died. Letting go of the lost person or object can be difficult, and tends to happen gradually. Sometimes there are still things that need to be said to the deceased, and it can help to say these at the graveside or in a poem or letter. Approaches used in Narrative Therapy are highlighted in this step.

The negative emotions

Humans experience a range of emotions, some of which are referred to as ‘negative’ emotions, including anger, guilt, shame, jealousy and hate. The aim described in the KBA manual is to learn to express these emotions in helpful or constructive ways. The first step in dealing with any of these emotions is acknowledging its existence, which involves learning to recognise and name the emotion. Further strategies for managing these emotions are described in Step 6, including CBT strategies and the use of rituals (ceremonies) to let go of emotions that may have been preventing recovery.

Loneliness

The next section of the KBA program addresses the loneliness that may be felt by individuals with depression. In depression there is a tendency to withdraw from people, and feeling lonely can be an issue. One may feel lonely because of loss associated with death or divorce. In terms of loneliness resulting from being disconnected from people, it can be useful to utilise cognitive strategies. For example, an individual might think that ‘no one cares’, though people have actually been helpful in the past and are perhaps unaware of the current problems. The individual is encouraged to revisit goal-setting (as outlined in Step 1). A goal might be to become more active and involved with other people.
Hopelessness, suicidal thoughts

The issue of suicide in depression has already been highlighted in this chapter, and is discussed in Step 6 of the KBA program. There is greater risk of suicide in someone who is feeling severely depressed and feeling hopeless, has made plans for suicide, or who has a family history or past history of suicide attempts. (78) The individual is advised to talk with someone, such as a family member, friend, their GP or a mental health professional, if they are experiencing suicidal thoughts. GPs are trained to assess the level of risk of suicide and work out the best treatment. (259)

The cognitive therapeutic approach can be helpful with regard to suicidal thoughts. In particular, it is valuable in identifying associated thoughts and feelings, such as feelings of guilt or thoughts about punishing oneself. It is important to convey hope and emphasise both that there are options besides suicide, and there are valuable reasons for living. (212) It is useful for the individual to stay in close contact with their GP and other health professionals and to have a list of people/agencies to contact in the event of worsening suicidal thoughts. (260) A list of emergency numbers is included in the KBA manual (in the Resources section) for this purpose.

Counselling that fosters a sense of hope for a better future has been cited in the literature as important in the recovery from depression. (172) For example, a study by Brown (1998) found that in women with longer-term depression (for 12 months or longer), the occurrence of an event related to a sense of making a ‘fresh start’ often preceded recovery. (172) Based on this participants in the KBA program are provided with hopeful reassurance during the program. Life does have difficult times and times of suffering, and it is suggested that how one responds to these challenges that is important. (261)

Finding meaning

The next section looks at the concept of meaning, drawing on Existential Therapy, which is concerned with what it means to the individual to be alive. The existential model recognises the importance of the physical, as well as the social, psychological and spiritual, aspects of oneself. (201) Existential Therapy also considers the person
to be in a constant process of learning and change.(201) Victor Frankl, one of the founders of existential therapy, experienced Hitler’s concentration camps. He described three sources of meaning that allowed victims to survive: a purpose through work, existence of a love, or a sense of meaning through suffering. Frankl advocated the importance of creative values (what we achieve), experiential values (what we experience, including relationships) and attitudinal values (qualities that enable us to persist).(262) He believed that the search for meaning and purpose was central to human existence.(204)

The literature suggests that two approaches used in Narrative Therapy may be helpful in dealing with suffering and finding meaning.(208) One is externalising the problem – talking of how ‘the depression’ affects an individual, that is, that the individual is not the depression and therefore not the problem. Externalising the problem enables the person and potentially their family to consider how the problem (‘the depression’) is affecting that person and how they might deal with it. The other involves looking for alternative, positive experiences during negative experiences such as depression. Even during very difficult times, people find strength within themselves to cope. This approach aims to identify, use and build on these strengths to manage the depression.(208)

Inspirational quotes were included at the start of each step in the KBA manual to stimulate thought and to provide encouragement and inspiration. It is suggested that the individual look out for quotes, poems or pieces of writing that have meaning to them, as sometimes inspirational words can elicit hope and lift spirits.(245) A poem is included in the manual as an example of such writing.

2.8.7 Step 7 – The benefits of activity

Activity or occupation is central to life, as our daily routine, including work and leisure time, involves activities. Activity provides life with routine, and can give individuals a great sense of satisfaction and achievement.(263) Loss of motivation and lethargy occur in depression,(21) meaning that the individual with depression is less likely to do the activities that usually provide them with pleasure and/or meaning. A vicious cycle can result – the less active the individual becomes, the more depressed they feel and the less they do.(55, 230)
The literature suggests that activity can improve mood, and clinical experience also suggests that activity can greatly change people’s lives. However, the key to such improvement is finding activities that are meaningful to the person. In his book “The Noonday Demon, An Anatomy of Depression” (264), Andrew Solomon tells a story that demonstrates the power of activity. He writes about a Cambodian woman called Phaly Nuon, who helped many women during the time of the Khmer Rouge. Phaly found that many women were depressed and traumatised as a result of the war, and she developed her own way of helping these women. She found that the women were helped to manage the traumas by telling their story and listening to the stories of others and through the use of craft and music as a distraction. She would then involve them in activity or work – teaching them skills that they could use in later employment. Finally, Phaly taught the women to take care of themselves and each other.(264)

To assist individuals to identify activities to incorporate into their life, a list of enjoyable activities is included in Step 7. Activity scheduling was outlined earlier (in Step 4), and in this step individuals are asked to think about ways that they could include pleasant activities in their life. In keeping with addressing the social and spiritual aspects of health, the concept of ‘giving’ as being an important and rewarding part of life and recovery from depression is discussed. Buddhism views compassion as being an important part of recovery from depression.(265)

2.8.8 Step 8 – Fostering social support and skills

Having good social support is said to be a protective factor, while poor social support is said to be a risk factor.(51) Feeling connected with other people contributes toward a sense of belonging, and loneliness is a form of disconnectedness.(258) Individuals are encouraged in Step 8 to nurture relationships with their family, friends, and acquaintances. If there is a problem in a relationship, they are encouraged to look at options for dealing with the problem.

Developing assertiveness, that is, being able to express one’s needs and feelings more directly, is also discussed. The individual is asked whether they have difficulty expressing their opinion, find their needs are not being met, or if they unintentionally upset people by what they say. If the answer is yes to any of these questions, then working on being more assertive is important for that individual.(110, 266)
Assertiveness can be helpful in starting conversations, confronting others, dealing with annoyance, responding to criticism, turning down requests or asking for favours. (110)

Relationships are a central part of life, and dealing with relationship issues can be an important part of managing depression. A relationship breakdown may have contributed to the development of depression, or relationship problems (such as bullying or domestic violence) may be causing ongoing stress. IPT which addresses interpersonal functioning (interactions with others, such as family or a partner) and loss and grief issues and their relationship with the depression, is well supported as an effective depression treatment in the literature. (49, 117, 267)

Strategies in managing conflict are also outlined in this step, and individuals are encouraged to talk with their GP about any relationship concerns or to seek a referral to a mental health professional. Separation and divorce are associated with many challenges and stresses, cause loss and grief, and potentially lead to hurt feelings and anger. Again, individuals are encouraged to seek counselling, and the principles outlined in Step 6 on managing loss and grief can also be applied in this situation.

Being unemployed can have a variety of adverse effects on the individual – from withdrawing from friends and family and feeling lonely, to an impact on sleep and daily routine. Self-esteem often falls and there is also generally a financial strain related to being unemployed. A number of studies have been carried out to explore the effects of unemployment on mental health, finding that depression causes increased levels of stress and hinders recovery from mental health problems. (268, 269)

In this step, an exercise (drawing a ‘support map’) to help patients identify their social supports is included. Family or friends, acquaintances or local people may be part of a support network. Work, religious institutions, a community club or service may provide regular social contact with people. A pet, or an interest such as reading, might also be a ‘friend’ to the person. (270, 271)
2.8.9 Step 9 – Developing a plan for managing early relapse symptoms

In Step 9, three steps for developing a plan to manage relapse are outlined, and a table is provided for the individual to complete. The steps are as follows:

1. Identifying the early warning symptoms.
2. Identifying possible high-risk situations for relapse.
3. Preparing an emergency plan.(202)

Having a plan for managing early relapse symptoms assists the person to identify their particular symptoms early on (for example, sleep difficulties or irritability), and to identify potential high-risk situations for themself (such as during times of stress and fatigue related to work).(202) The emergency plan involves the individual recording what they should do if symptoms appear, such as taking some time out or restarting medication, and who to contact, such as their GP or mental health professional.(54, 110, 272)

2.8.10 Step 10 – Reassess, review and helpful resources

This step advises the GP and the patient to reassess the individual's progress and to review the previous nine steps. This review allows time for the key issues to be reinforced and to revisit the most important ones for that individual. The manual concludes by noting that KBA was developed with the aim of helping the individual recover from the depression and to stay well in the future, and has addressed the physical, psychological, social and spiritual aspect of mental health. Utilising a narrative approach, the program concludes by inviting the person to reflect on and note their own strengths and resources.

2.8.11 Resources – Where to go for help

A comprehensive list of resources, including books, websites, community resources, treatment services and emergency numbers is presented, to provide an accessible list of resources to be explored as part of the KBA program or in the future.
2.9 Conclusion and recommendations

This chapter has provided information related to the pre-clinical and modeling phases of this research, including a literature review pertaining to depression treatment and relapse prevention, and the development of the KBA program. Given that depression is for many individuals a relapsing problem, (25, 273) and it is now viewed as a chronic illness, (7, 64) it is important that GPs are able to access to effective long-term management programs aiming to prevent relapse. (10) Most depression treatment studies, however, have been undertaken in specialist rather than primary care settings, and practical well-researched models for delivering long-term care in the primary care setting are limited. (8, 17)

The current paucity of literature relating to primary care and relapse prevention emphasises the need to develop and research RPPs. Only one American study of a primary care RPP was initially identified, and as the intervention in this study did not result in a significant reduction in relapse rates, it was concluded that a more intensive RPP might be needed. (8) The general literature on depression relapse prevention supports a range of treatment strategies (adherence to medication, psychological treatments such as CBT and IPT) that help prevent depression relapse. There is particularly strong evidence for CBT. The literature also suggests that a primary care depression RPP needs to provide an intensive, multifaceted and integrative approach. (8)

In addition, Segal (11) suggested that it might be possible to take the active ingredients of proven treatments and design novel preventive treatments that are skills-based. Hence, the KBA program is an eclectic, multi-modal program, incorporating Supportive Therapy, Psycho-education, and elements of CBT, IPT, Narrative, Existential and Well-being Therapy. KBA addresses risk factors for depression and strategies to enhance protective factors, and is primarily a skills-based treatment approach.

The key implications of the early phases of this research are recommendations arising can be summarised as follows:
1. Depression is for many individuals a relapsing problem (7, 25), and many patients will be managed in primary care.(17) There has been little research carried out in the primary care prevention of depression relapse.

*Recommendation:* It is important to develop and research primary care depression RPPs.

2. A primary care depression RPP needs to provide an intensive, multifaceted and integrative approach, and might involve taking the active ingredients of proven treatments and designing a novel skills-based treatment.(11) Depression is viewed as a chronic illness, and the principles of managing chronic disease should be applied to depression.(7, 64, 94) There is support for bibliotherapy in the literature as a useful treatment strategy.(50, 121, 190, 199)

*Recommendation:* The KBA program should be a, multimodal, skills-based program, incorporating a range of treatment strategies. The principles of managing chronic disease, such as management/relapse prevention planning, follow-up and monitoring and self-management, should be incorporated into the program. The KBA resources should include a comprehensive treatment manual.

Chapter 3 is a publication which outlines the background to the KBA program, and is useful at this point as a summary, prior to the chapters describing the exploratory and intervention phases of this research work. Chapter 3 also touches on the Australian primary mental health care context, and the potential place of the KBA program in this context. The concluding chapters will return to this issue.
Chapter 3. Preventing Depression Relapse: Publication

This chapter comprises a publication which summarises the pre-clinical and modeling phases of this doctoral research. The article provides background information on the nature of depression and relapse, and outlines the limited literature on primary care relapse prevention. The management of depression and strategies for relapse prevention are discussed. The 10 steps of the KBA program are introduced, and the rationale for the program and its place in the Australian primary care mental health context briefly outlined.

This paper provides a useful summary at this point, prior to the chapters on the subsequent phases of this research.

Title: Preventing depression relapse: a primary care approach
Primary Care Mental Health Journal 2004; 2: 151-156

Authors: Dr C. A. Howell

Statement of Authorship

Dr C. A. Howell

conceived, conceptualised, and wrote the manuscript.

Signed……………………………………………………
Date……………………………….

NOTE: This publication is included on pages 77-82 in the print copy of the thesis held in the University of Adelaide Library.
Chapter 4. Exploratory Study: Methods and Results

4.1 Introduction

As outlined in Chapters 1 and 2, this research involved both pre-clinical and modelling phases, enabling a thorough literature review and development of the rationale for the KBA program along with the associated resources. The exploratory phase, aiming to assess the feasibility of implementing and studying the KBA program in the general practice setting, prior to carrying out the pilot RCT, will now be outlined. The relevant research questions are listed, followed by the methods used and the results. The implications and recommendations from this phase are then summarised.

4.2 Background

The exploratory phase was carried out in February to July of 2003. It involved implementing the KBA program with a small sample of GPs (n = 7) and their patients (n = 15) to test a number of initial research questions, and to identify any other unforeseen issues in the use of the program in a general practice setting. This phase provided a means of identifying and managing any factors that may have interfered with the effectiveness of the program, aiming to create a solid foundation prior to carrying out the larger pilot intervention study.

The exploratory phase aimed to address the following research questions:

1. Is it feasible to implement and study the KBA program in the general practice setting?
2. Is the program acceptable to participating GPs and patients?
3. Are the KBA resources suitable to rollout in the larger pilot study?
4. Are the data collection and other forms involved in the study managed by GPs/patients?
5. Are the chosen psychological assessment tools appropriate for the study?
6. Is the GP training provided in this phase adequate for the larger study?
4.3 Method

4.3.1 Ethics approval

Ethics approval was sought from the University of Adelaide Human Ethics Committee in November of 2001, for this Study of a primary care treatment program aiming to reduce the relapse of depression, which included this exploratory phase of the research and the larger pilot study (see Appendix A1). The Committee granted approval in December of 2001 (Appendix A2), and approval was reviewed annually from then.

4.3.2 Study design

In the exploratory phase, a small evaluation of the KBA program in the general practice setting was carried out, adopting a ‘utilisation-focused’ method. This method is flexible and calls on quantitative and qualitative data as appropriate.(15) In this phase it was important to gather feedback from GPs and participants to assess the feasibility and acceptability of implementing and studying the KBA program and its associated resources in a larger intervention study in the general practice setting. This phase also provided an opportunity to select and trial a number of psychological assessment tools with the program, to assist in determining which tools would be most suitable for use in the larger pilot study.

The exploratory phase involved recruiting a small sample of GPs in both urban and rural areas to trial the KBA program and its associated resources with a number of their patients. Experience in teaching rural GPs as outlined in Chapter 2 highlighted their desire for mental health training and resources, and the researcher was keen to address this need, especially given the large expanses of rural and remote areas in Australia. It was also thought that including rural practices would enhance the generalisability of the study findings.

The aim was for those GPs to recruit 10-15 patients to participate, as it was anticipated that this number would provide adequate information or a saturation of responses. A relatively short time frame was chosen (three months) for GPs to deliver the KBA program to each patient. While it was important to achieve the aims of this phase, it was also necessary for the remainder of the research to proceed in a
timely manner. Hence follow-up past three months was not carried out in this exploratory phase.

In addition to quantitative data, qualitative data were also gathered during this phase. The adequacy of the training provided to GPs was assessed via a questionnaire given to the participating GPs. At the end of this phase, brief semi-structured interviews were carried out with a sample of participating GPs and patients to gain their feedback on the program, the resources and study protocol. Data were recorded and tabulated manually during this phase as numbers were small.

4.3.3 GP recruitment

‘Convenience’ and ‘snow-balling’ sampling techniques were used in this phase. Several GPs known to the researcher were approached, as they were easy to access and likely to respond.(14) These GPs suggested several other GPs, not personally known to the researcher, but working in the same practices as the known GPs, and these GPs were invited to participate. As a result, three urban and 5 rural GPs were approached by the researcher over a two-week period and agreed to participate. After being provided with brief training on the KBA program, all three urban GPs, and four of the five rural GPs went on to participate in this phase. The rural GP who ceased participation in this phase withdrew due to the time commitment involved in taking part.

Participating GPs were asked to complete a questionnaire that gathered demographic information about the GP, including their age and practice location, and information about their training in mental health and usual practice, such as frequency of patient consults and use of different treatment strategies. It was anticipated that this type of questionnaire would be used in the larger study to gather baseline information about the GPs, and so it was important to trial the questionnaire itself. It was also thought that the results of this questionnaire might help inform the first research question of this phase, that is, the feasibility of implementing and studying the KBA program in a general practice setting.
4.3.4 GP training

Time frame and facilitator

Participating GPs completed a 4-hour training session, with urban GPs trained as a group in February of 2003 and rural GPs trained as a group in March of 2003. The GP researcher carried out the training.

Information provided

The GP training involved provision of the following information:

1. Introduction to this study of a primary care treatment program aiming to prevent the relapse of depression (see Appendix A3), with discussion on the nature of the exploratory phase and the three-month timeline.
2. Gaining consent and use of the patient information sheet.
3. Background information on depression, including relapse and recurrence.
4. Information on the development of the KBA program (rationale, related literature) and the 10 Step treatment manual.
5. Overview of the management of depression, including use of antidepressants and psychosocial treatment.
6. Use of the KBA program, including:
   a. Assessment, including use of specific assessment tools prior to Step 1 and after Steps 5 and 10.
   b. Overview of each step of the KBA program (Steps 1-10).
   c. Seeing patients regularly (every one to two weeks) initially whilst working through the 10 Steps of the program, and subsequent regular follow-up of patients for the remainder of the three months (at least monthly).
7. Resources list.
### Handouts provided

GPs were provided with the following handouts at the training session:

1. Learning outcomes and an outline of the training (Appendix A4).
2. A summary of the proposed KBA research.
4. Copies of the information and consent sheets (Appendices A5 and A6).
5. Copies GP and participant data collection sheets (Appendices A7 and A8).
6. Copies of assessment tools (Appendices A9), and guide to use of the tools.
7. Checklists (summarising the steps involved in the study and KBA program) for the GP to use with each participant (Appendix A10).
8. The KBA manual (A4 size).
10. KBA relaxation tape.

### 4.3.5 Participants

Subsequent to the training, each of the GPs recruited 1-4 patient participants with depression. The aim of 10-15 participants was achieved (n = 15). Participants were provided with an information sheet and their informed consent was gained by the GPs (Appendices A7 and A8). A data collection sheet given to patient participants at the outset of the study gathered demographic and baseline information.

### 4.3.6 Use of the KBA program

After recruiting and gaining a patient’s consent, GPs proceeded to utilise the KBA program with the patient in their clinical practice. GPs met with their patients regularly over three months to carry out assessments, to facilitate their progress through the KBA program, and to review the patient’s progress. It was suggested that the GPs would need to see their patients six to eight times over the three months of the study, to guide the patients through KBA and follow their progress. A checklist of activities involved in the study and KBA program was provided to the GPs to guide them through the study and program.

It highlighted when the assessment tools were to be used and when the KBA resources were to be provided to the participants. An abbreviated checklist is provided below, with a full copy provided in the appendices (Appendix A10).
Table 4.1 Exploratory study checklist for GPs

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
</table>
| Initial Phase | • Information sheet  
• Consent  
• Data sheet |
| Patient to complete assessment tools | • 0-10 depression rating scale  
• DASS  
• QOL scale  
Provide participant manual and journal |
| Step 1 - Assessment and goal-setting | |
| Step 2 - Psycho-education | |
| Step 3 - Healthy lifestyle issues | |
| Step 4 - Useful coping skills | Provide relaxation tape |
| Step 5 - Helpful cognitive strategies | Review and repeat 0-10 depression rating scale |
| Step 6 - Dealing with psychological issues | |
| Step 7 - The benefits of activity | |
| Step 8 - Fostering social support and skills | |
| Step 9 - Developing a plan to manage early symptoms of relapse | |
| Step 10 - Reassess and review, and resources | Repeat patient assessment tools:  
• 0-10 depression rating scale  
• DASS  
• QOL scale  
• CGI |
4.3.7 Assessment tools

A number of psychological assessment tools were selected and trialled. Tools were selected based on validity and clinical appropriateness. Several patient self-report measures were selected to assess depressed mood (0-10 scale, DASS) and quality of life (QOL scale). GPs were also asked to assess patient improvement using the Clinical Global Impressions Scale (CGI).

The following psychological assessments were utilised. They are described in detail in this section and copies are included in the appendices (A9):

1. 0-10 depression rating scale.
2. Depression, Anxiety and Stress Scale (DASS).
3. Quality of Life Scale.

It was intended that several of the tools (0-10 scale, DASS, QOL scale) would be used to assess participant status both at the beginning (prior to Step 1) and conclusion of the program (following Step 10). GPs were also directed to ask patients to complete the 0-10 scale after finishing Step 5. The Clinical Global Impressions Scale was to be completed by GPs only at the end of the program (after Step 10), in order to measure the GP’s impressions of the participant’s improvement.

0-10 depression rating scale

A 0-10 scale was selected as a simple but effective measure of mood. Scales are often used in clinical practice and are reported to be useful.(229) For this measure, participants were asked, “In the past week, how much have you suffered from
depression?”, responding on an 11-point scale where 0 means “no depression” and 10 means “most severe depression possible”. In the KBA manual, participants are asked to regularly complete a similar 0-10 mood scale, making the use of this scale in sessions with their GP consistent with the manual.

DASS

The Depression, Anxiety, Stress Scale (DASS; Lovibond & Lovibond, 1995) is a self-report instrument that measures depression, anxiety, and stress. There are two versions of the DASS: the 42-item version (DASS-42) and the brief 21-item version (DASS-21). The shorter version was chosen for this exploratory phase, as according to Henry and Crawford (2005), the DASS-21 has several advantages over the DASS-42. It is shorter and more acceptable for use in time-limited consultations. In addition, it does not contain items identified as problematic in the full DASS, and has a cleaner structure. Research has shown the DASS-21 to possess adequate construct validity, and high reliability.(274) The normative data set for the DASS was based on samples of 1044 males and 1870 females ranging in age from 17-69 years. Age and sex differences in the normative group were small. For example, the mean depression score for 20-29 year olds was 6.35, with standard deviation (SD) of 6.85, compared to 50-59 year olds with a mean of 5.28 and SD of 5.28. For males, the mean anxiety score was 4.6 (SD 4.8), and for females, the mean was 4.8 (SD 5.03).(86)

In the DASS-21, seven items are used to assess each state (depression, anxiety and stress). Depression scale items include statements such as “I felt down-hearted and blue”, anxiety items include “I experienced trembling, for example, in the hands”, and stress items are those such as “I felt that I was using a lot of nervous energy”.(86) In completing the DASS, the individual is asked to “read each statement and circle a number (0, 1, 2, or 3) which indicates how much the statement applied to you over the past week.” The answer rating scale is: 0 = did not apply to me at all; 1 = applied to me to some degree, or some of the time; 2 = applied to me a considerable degree, or a good part of the time; 3 = applied to me very much, or most of the time. Score ranges indicating normal, mild, moderate, severe, and extremely severe levels for each scale are available (Appendix A9).

According to Lovibond and Lovibond (86), people scoring highly on each DASS scale may display the following characteristics:
• Depression: dispirited, sad, blue, convinced that life has no meaning or value, pessimistic about the future, unable to experience enjoyment or satisfaction, unable to become interested or involved.
• Anxiety: apprehensive, panicky, trembly, shaky, awareness of dryness of the mouth, heart pounding, palms sweaty.
• Stress: over-aroused, tense, unable to relax, irritable, easily startled, intolerant of interruption or delay.(86)

Quality of Life Scale

Believing that existing quality of life scales would be too onerous use in the exploratory research, the researcher developed a brief quality of life scale. Based on work by Gill and Feinstein (275) and Marks (276), a series of statements about a variety of domains of quality of life were used for this measure. The domains were:

1. General quality of life.
2. Health-related quality of life.
3. Work.
5. Family relations.
6. Home duties (for example, shopping, cleaning, paying bills).(275, 276)

Participants were asked to rate each statement on a scale from 0-10, where 0 represented “no impairment” and 10 “most severe impairment”.

Clinical Global Impressions

The CGI scale (CGI; Guy, 1976) is a brief, easy-to-complete rating instrument developed to allow physicians to quantify their patient’s illness severity, and improvements due to therapy. It has been widely used in clinical research and especially in clinical trials of psychotropic treatments.(277) The CGI consists of three separate scales:

1. Severity of illness (the patient’s current symptom severity).
2. Global improvement.
3. Efficacy (comparison of the patient’s baseline condition with a ratio of the current therapeutic benefit to the severity of any side effects).

For this research phase, only the global improvement component of the CGI was utilised, as depression severity was being measured by the DASS and the third scale was not relevant to the study hypotheses. The CGI (improvement component) scale is a single seven-point measure that requires the clinician to assess how much the patient’s illness has improved or worsened relative to a baseline state at the beginning of the intervention. It asks, “Compared to the patient’s condition when first assessed, how much change has occurred?”), where 1 = very much improved, 2 = much improved, 3 = minimally improved, 4 = no change, 5 = minimally worse, 6 = much worse, and 7 = very much worse.(277)

4.3.8 Interviews

After the implementation of the KBA program in the general practice setting, brief structured interviews were carried out with a sample of participating GPs and patients. A number of GPs were interviewed. Saturation of information occurred by the fifth GP. These GPs were also asked to suggest a patient to be interviewed, to make contact with them and to ask permission for the researcher to make contact with them. The GP researcher subsequently conducted interviews three participants (two urban and one rural).

Semi-structured interviews were carried out. GPs were interviewed at face-to-face meetings taking about 20 minutes. Participants were interviewed by telephone and these interviews were more brief (about 10 minutes). The GP and participant interview questions are listed below.

GP interview questions

The GPs were asked the following open-ended questions:
1. How did you find the KBA training?
2. Is there additional training that you think would be helpful?
3. Were the assessment tools appropriate and easy to manage?
4. How did you find the remainder of the forms involved in the study?
5. Were you able to integrate the KBA program into your practice?
6. What were your views of the KBA resources (manual and tape)?

Participant interview questions

Participants were asked:
1. How did you find the KBA program?
2. Were the assessment tools easy to manage?
3. How did you find the rest of the forms (consent, information sheet, data collection) involved in the study?
4. What were your views of the KBA resources (manual and tape)?

4.4 Results

4.4.1 Feasibility of implementing and studying the KBA program in the general practice setting

Eight GPs and 15 participants in urban and rural areas were recruited to this phase over a short time frame, although one GP withdrew at the outset due to the time commitments required by the study.

GP demographics and mental health practice

Six of the seven GPs completed and returned an initial data collection form. Participating GPs were aged from 27-47 years old, with a mean age of 29 years in the rural GPs, and a much higher mean age of 44 years in the participating urban GPs. The sole male GP was from a rural location, while the six female GPs were evenly split between urban and rural practices. GP demographic results are summarised in Table 4.2.
### Table 4.2 Exploratory phase GPs: mean age and gender by practice location

<table>
<thead>
<tr>
<th></th>
<th>Rural</th>
<th>Urban</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean age</strong></td>
<td>29 years old</td>
<td>44 years old</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n)</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Female (n)</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>4</td>
<td>3</td>
<td>7</td>
</tr>
</tbody>
</table>

Participating GPs were asked a series of questions related to their use of psychological assessment tools in practice, and whether they had undertaken any previous mental health training. Half of the responding GPs indicated that they did not routinely use psychological assessment tools with their patients. All of the responding GPs had completed Level One BOMHC training, but only one GP had completed Level Two training (see Chapter 2, p.70, for information on this training).

Several questions on managing patients with depression were also asked. Most GPs indicated that on average, they saw patients with depression one to two times in the first month, and three to four times in the months following. Psycho-education (n = 4), counseling (n = 5) and CBT (n = 5) were the most frequently reported psychological approaches used by the GPs in managing patients with depression. Several other therapies were reported as also being used by GPs, including narrative therapy, existential therapy and mindfulness techniques. Information on these approaches has been provided in Chapter 2.

GPs cited a range of difficulties in managing mental health issues in their practice, including time-management, dealing with co-existing issues in their patients, accessing assistance, carrying out follow-up of their patients and encouraging medication compliance. A sense of isolation and lack of support in managing mental health issues was reported by several GPs.

**Participant demographics**

Results were available for 14 of the 15 participants. There was a small amount of extra missing data due to participants not completing all sections of the questionnaire. As shown in Table 4.3, the majority of participants (n = 10) were
female. Participants ranged in age from 18 to 63 years, with the mean age of female participants being slightly lower (36 years) than the mean age of male participants (39 years). Five participants were married, with the remainder being single, separated or divorced. Eight lived alone, and nine had family in Adelaide. Four participants were employed and 10 were not employed.

Table 4.3 Exploratory phase participants: demographic information

<table>
<thead>
<tr>
<th></th>
<th>Female</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of participants</td>
<td>n = 10 (data available for 9)</td>
<td>n = 5</td>
</tr>
<tr>
<td>Mean age</td>
<td>36 years old</td>
<td>39 years old</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Single</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Separated</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Divorced</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Live alone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Family in Adelaide</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Employed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>No</td>
<td>7</td>
<td>3</td>
</tr>
</tbody>
</table>

History of depression

All but one participant had a history of depression prior to the current episode, and the mean age for the onset of depression for women was 29 years old, while for men this was a little younger (25 years old). All participants reported having had more than one episode of depression and five reported that they had recovered between this episode and the last, but nine said that they had not recovered. For 11 participants, their most recent episode had lasted longer than six months, and the
mean depression severity (on a scale from 0-10) at the beginning of their most recent episode was 7.2 for women and 5.8 for males.

Table 4.4 Exploratory phase participants: depression history

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History of depression</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>Age at first depression</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>14 - 51 years</td>
<td>15 - 45 years</td>
</tr>
<tr>
<td>Mean</td>
<td>29.22 years old</td>
<td>25 years old</td>
</tr>
<tr>
<td><strong>Total no. of depression episodes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 episodes = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 episodes = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ongoing = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On and off = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Too many to count = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unsure = 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No response = 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>When last episode occurred</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within the past year</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>1-2 years ago</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>2-5 years ago</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5-10 years ago</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Recovered between this episode and last?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td><strong>Length of this depression episode</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 6 months</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>&gt; 6 months</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Missing data</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td><strong>Depression severity at beginning of this episode (0-10)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>5 - 9</td>
<td>0 - 9</td>
</tr>
<tr>
<td>Mean</td>
<td>7.2</td>
<td>5.8</td>
</tr>
</tbody>
</table>
Persistent depressed mood most of the day over last 2 years

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>

Other relevant history

Several questions were included in the questionnaire related to co-morbid medical problems and recreational drug use, including smoking and alcohol. Responses are summarised in Table 4.5. Five participants reported having other medical problems, and only two were smokers. Ten participants reported that they drank alcohol, and of these, five consumed less than two glasses per week, while four drank seven or more glasses of alcohol per week. Two participants reported using marijuana.

Table 4.5 Exploratory phase participants: co-morbidities

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other medical problems?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>8</td>
<td>1</td>
</tr>
<tr>
<td>Smoker?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Alcohol use?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Alcohol consumed per week (n = 6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not a regular drinker</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>1 per month</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>1-2 glasses</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3-4 glasses</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7-8 glasses</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>9+ glasses</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Use other drugs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>1 (marijuana)</td>
<td>1 (marijuana)</td>
</tr>
<tr>
<td>No</td>
<td>8</td>
<td>4</td>
</tr>
</tbody>
</table>
Depression treatment

11 participants responded that they were taking antidepressant medication, and 10 were being treated by their usual doctor. Six participants were seeing another health professional, such as a psychiatrist or counsellor.

Table 4.6 Exploratory phase participants: depression treatment

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>On antidepressant medication?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Depression treated by usual doctor?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>No response</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td><strong>Seeing another health professional?</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>(1 x psychiatrist, 4 x counsellor)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Completion of KBA steps by participants and time taken

Eight participants completed all 10 of the KBA program steps. Reasons for non-completion included being unable to continue because of a severe relapse of depression or life crises intervening. The average length of time to complete all 10 steps was 3.1 months, although some participants took as little as one month to work through the steps, and others took up to six months.
Table 4.7 Summary of KBA steps completed by participants

<table>
<thead>
<tr>
<th>KBA Step</th>
<th>No. of participants discontinuing (after completion of Step)</th>
<th>Reason for discontinuing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>n = 1</td>
<td>Lost to follow-up</td>
</tr>
<tr>
<td>3</td>
<td>n = 2</td>
<td>Did not attend; severe relapse</td>
</tr>
<tr>
<td>4</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>5</td>
<td>n = 1</td>
<td>Wished to continue, but ran out of time in trial</td>
</tr>
<tr>
<td>6</td>
<td>n = 1</td>
<td>Patient miscarriage</td>
</tr>
<tr>
<td>7</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>8</td>
<td>n = 1</td>
<td>-</td>
</tr>
<tr>
<td>9</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>10</td>
<td>n = 8</td>
<td>Program completed within 1-6 months (M = 3.1 months)</td>
</tr>
</tbody>
</table>

Psychological assessment tools

It was intended that the assessment tools (0-10 rating scale, DASS) be used to assess participant progress at the outset of the program and also at the end of the 10 Steps of the program. As outlined earlier, the CGI was to be completed by each GP at the completion of a patient’s program, to gauge the GP’s view of their patient’s improvement.

0-10 depression rating scale:

Results from participants’ 0-10 depression rating scales showed general improvements between their first and last KBA sessions. However, there were a number of missing results at the outset and with final scores. Only one scale was completed after Step 5. The results are given in Table 4.8.
Table 4.8 0-10 Depression rating scale results

<table>
<thead>
<tr>
<th></th>
<th>Initial 0-10 ratings</th>
<th>Post-Step 5 0-10 ratings</th>
<th>Final 0-10 ratings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed measure</td>
<td>n = 11</td>
<td>n=1</td>
<td>n = 9</td>
</tr>
<tr>
<td>Score range</td>
<td>0 - 10</td>
<td>7</td>
<td>1 – 7</td>
</tr>
<tr>
<td>Mean</td>
<td>4.7</td>
<td>7</td>
<td>3.4</td>
</tr>
<tr>
<td>Missing data</td>
<td>n = 4</td>
<td>n =14</td>
<td>n = 6</td>
</tr>
</tbody>
</table>

DASS:

Fourteen DASS results were obtained at the outset of the program, while only 9 completed DASS questionnaires had been collected by the end of the allotted study period. As shown in Table 4.9, initial session DASS results indicated that at the outset, the majority of participants had moderate or severe depression. However, at the end of the program DASS results showed that only one participant had moderate depression and one had mild depression. These results are demonstrated graphically in Figure 4.1. Table 4.9 also highlights the results from the DASS for anxiety. More participants had moderate to severe anxiety at the start of the program than at the end.
### Table 4.9 DASS results

<table>
<thead>
<tr>
<th>Measures completed</th>
<th>Initial DASS scores</th>
<th>Final DASS scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>n = 14</td>
<td></td>
<td>n = 9</td>
</tr>
<tr>
<td><strong>Depression</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>1 (7%)</td>
<td>4 (45%)</td>
</tr>
<tr>
<td>Mild</td>
<td>0</td>
<td>2 (22%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>6 (43%)</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Severe</td>
<td>7 (50%)</td>
<td>2 (22%)</td>
</tr>
<tr>
<td>Extremely severe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Anxiety</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>7 (50%)</td>
<td>7 (78%)</td>
</tr>
<tr>
<td>Mild</td>
<td>0</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>3 (21%)</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Severe</td>
<td>4 (29%)</td>
<td>0</td>
</tr>
<tr>
<td>Extremely severe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Stress</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>10 (71%)</td>
<td>6 (67%)</td>
</tr>
<tr>
<td>Mild</td>
<td>1 (7%)</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (7%)</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Severe</td>
<td>2 (15%)</td>
<td>1 (11%)</td>
</tr>
<tr>
<td>Extremely severe</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Missing data</strong></td>
<td>n = 2</td>
<td>n = 6</td>
</tr>
</tbody>
</table>

The graphs below demonstrate the results for the depression, anxiety and stress components of the DASS.
Figure 4.1 Graphs showing DASS results

- **DASS - Depression**
  - Initial and Final comparisons
  - Axes: 0-8
  - Categories: Normal, Mild, Moderate, Severe, Extremely Severe

- **DASS - Anxiety**
  - Initial and Final comparisons
  - Axes: 0-8
  - Categories: Normal, Mild, Moderate, Severe, Extremely Severe

- **DASS - Stress**
  - Initial and Final comparisons
  - Axes: 0-12
  - Categories: Normal, Mild, Moderate, Severe, Extremely Severe
Quality of Life:

Results from the quality of life-related questions answered by participants are summarised in Table 4.10. Figure 5 summarises these findings, and shows that overall participant improvements can be seen, with reduction in each of the assessed quality of life domains at the end of the study.

**Table 4.10 Quality of Life results**

<table>
<thead>
<tr>
<th>0-10 scale where 0 = no impairment and 10 = most severe impairment</th>
<th>Initial QOL ratings</th>
<th>Final QOL ratings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures completed</td>
<td>n = 9</td>
<td>n = 10</td>
</tr>
<tr>
<td>General</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rating</td>
<td>5.8</td>
<td>4</td>
</tr>
<tr>
<td>Score range</td>
<td>0-8</td>
<td>1-7</td>
</tr>
<tr>
<td>Health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rating</td>
<td>4.7</td>
<td>3.5</td>
</tr>
<tr>
<td>Score range</td>
<td>0-7</td>
<td>0-7</td>
</tr>
<tr>
<td>Work</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rating</td>
<td>5.4</td>
<td>3.2</td>
</tr>
<tr>
<td>Score range</td>
<td>0-9</td>
<td>0-8</td>
</tr>
<tr>
<td>Social</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rating</td>
<td>5.7</td>
<td>3.2</td>
</tr>
<tr>
<td>Score range</td>
<td>0-10</td>
<td>0-9</td>
</tr>
<tr>
<td>Family</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rating</td>
<td>5.3</td>
<td>2.6</td>
</tr>
<tr>
<td>Score range</td>
<td>0-9</td>
<td>1-9</td>
</tr>
<tr>
<td>Home duties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean rating</td>
<td>5.4</td>
<td>3.3</td>
</tr>
<tr>
<td>Score range</td>
<td>0-10</td>
<td>0-10</td>
</tr>
<tr>
<td>Missing data</td>
<td>n = 6</td>
<td>n = 5</td>
</tr>
</tbody>
</table>
Clinical Global Impressions:

Results of the CGI scale (improvement component) are given in Table 4.11. However, while these results appear promising, they are limited by a high proportion of missing data, and as such, are difficult to interpret. This is especially shown in Figure 4.3.

Table 4.11 Clinical Global Improvement results

<table>
<thead>
<tr>
<th>Final rating</th>
<th>No of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures completed</td>
<td>n = 7</td>
</tr>
<tr>
<td>GP-assessed improvement</td>
<td></td>
</tr>
<tr>
<td>Very much improved</td>
<td>3 (43%)</td>
</tr>
<tr>
<td>Very improved</td>
<td>0</td>
</tr>
<tr>
<td>Minimally improved</td>
<td>3 (43%)</td>
</tr>
<tr>
<td>No change</td>
<td>1 (14%)</td>
</tr>
<tr>
<td>Minimally worse</td>
<td>0</td>
</tr>
<tr>
<td>Much worse</td>
<td>0</td>
</tr>
<tr>
<td>Very much worse</td>
<td>0</td>
</tr>
<tr>
<td>Missing</td>
<td>n = 8</td>
</tr>
</tbody>
</table>
4.4.2 Acceptability of the KBA program, suitability of the KBA resources and remaining study forms

GPs and participants were also asked a series of questions during the post-program interviews to determine both the acceptability of the KBA program, and the suitability of the KBA resources (the manual and relaxation tape). GPs were asked whether they were able to integrate the KBA program into their practice, while participants were asked how they found the KBA program, and both GPs and participants were asked about their views of the KBA resources and the written forms used in the study.

Regarding GPs’ integration of KBA into their practice, one urban GP reported needing to “adjust to doing things differently - doing the normal consultation tasks plus the KBA program”, while another reported that they put off doing KBA at times because of more pressing management issues. Several GPs also noted that they needed more than the suggested six sessions to deliver the program. One GP commented that “chasing patients” to ensure follow-up was both different to their
usual practice, and challenging, and several GPs stated that their patients generally liked the KBA program.

All of the GPs said that they liked the materials, were positive about the written information in the manual, and noted that they could always find something in the manual that was relevant to their patients. They also reported that they liked the materials because the information was all in the one place, saving time. They found it helpful to be familiar with the materials, and one of the GPs suggested that a bookmark listing the 10 steps and outlining their content would be very useful to help guide the GPs through the program. Another GP commented that as they worked in two locations, they needed materials in both locations to be able to consistently use the program. Several of the GPs said that Step 5 (CBT) was the most challenging for them to work through with their patients, and one specifically noted that they did not feel confident with CBT strategies.

The three participants who were interviewed all noted that they liked the program, and had found useful information in it. One said they were pleased that the treatment was “not just medication”, but incorporated information and psychological strategies. Two out of the three reported that they found Step 5 (CBT) particularly helpful, and one requested a better quality of tape with background music on it. One participant also commented that they would have preferred a smaller, more discrete manual, as it had been too large to fit easily in the participant’s bag when they caught the bus to see their GP.

All of the GPs and participants who were interviewed said that they had no difficulty in understanding or managing the written forms involved in the study (consent form, information sheet, demographic questionnaires, and checklist).

4.4.3 Appropriateness of the psychological assessment tools

In their interviews, GPs were asked whether they thought the assessment tools were appropriate. However, while all of the interviewed GPs believed that the assessment tools were appropriate and easy to use, as noted earlier, participants did not complete a significant proportion of the tools. The assessment tools were most consistently administered by GPs at the beginning of the study, with, for example, 14 participants completing the DASS. However, at the halfway point through KBA (after
Step 5), only one 0-10 scale was collected as requested. These findings are summarised in Table 4.11.

Table 4.11. Completion of assessment tools

<table>
<thead>
<tr>
<th>Assessment tools</th>
<th>At outset (n)</th>
<th>After Step Five (n)</th>
<th>At end (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10 scale</td>
<td>11</td>
<td>1</td>
<td>9</td>
</tr>
<tr>
<td>DASS</td>
<td>14</td>
<td>N/A</td>
<td>9</td>
</tr>
<tr>
<td>QOL</td>
<td>9</td>
<td>N/A</td>
<td>10</td>
</tr>
<tr>
<td>CGI</td>
<td>N/A</td>
<td>N/A</td>
<td>7</td>
</tr>
</tbody>
</table>

4.4.4 Evaluation of the GP training program to determine its adequacy

During the interviews the GPs were asked several questions about the initial training provided. All of the GPs stated that four hours of training had not been enough to cover the content of the program. They had found the training useful, but particularly wanted more time spent explaining CBT and additional skills training. All said that they would be prepared to undertake a significantly longer training, such as a 20-hour program (as required for Level Two of BOMHC).

Adequacy of the training was also assessed by an evaluation questionnaire, completed by the eight GPs who undertook it (note that one GP dropped out of the study subsequent to the training). A copy of the questionnaire, which gathered information on whether the GPs agreed or disagreed that the different learning outcomes had been achieved, is provided in Appendix A11. At the end of the training, seven participants agreed that their knowledge of depression was improved although one was unsure. All agreed or strongly agreed that the completed training would improve their assessment of depression.

Furthermore, although the training was of limited duration, all GPs agreed that their skills in cognitive therapy had improved, although two were unsure about their awareness of the influence of underlying beliefs on cognition. All agreed that their understanding of a range of psychological issues in depression had improved, as well as recognition of the importance of social skills development in depression management. However, two GPs were unsure about having increased skills in
assertiveness training. All agreed that their skills in relapse prevention were improved. These results are summarised in 4.12.

**Table 4.12 Adequacy of GP training – evaluation findings**

<table>
<thead>
<tr>
<th>Item (related to KBA training program)</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved knowledge of depression</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Will improve assessment of depression</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Improved ability to address healthy lifestyle issues with patients</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Improved skills in assisting patients with cognitive coping strategies</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Increased proficiency in CBT</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Increased awareness of the influence of underlying beliefs on thinking</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Assisted development of skills in raising self-esteem, and dealing with grief / anger</td>
<td>0</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Helped to gain knowledge about important psychological issue in depression</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Increased ability to encourage activity planning</td>
<td>0</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Increased appreciation of the importance of developing social skills</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Increased skills in assertiveness training / helping patients deal with relationship issues</td>
<td>0</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Increased skills in preventing relapse in depression</td>
<td>5</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Helped development of skills in helping patients identify warning</td>
<td>0</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
As shown in Table 4.13, all GPs thought that the program was pitched appropriately and agreed that the content matched their learning needs. In addition, all found the method of presentation suitable and were engaged by the presenter.

**Table 4.13 General evaluation questions (on presentation and content)**

<table>
<thead>
<tr>
<th>Item (related to KBA training program)</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Unsure</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pitched appropriately</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The presenter was engaging</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>7</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

At the end of the evaluation questionnaire, GPs were asked three further questions and were provided with several lines to write their answers. The questions were:

1. What aspects of the program could have been done better?
2. What aspects of the program were done well?
3. Do you have any other comments about today’s program?

One GP responded that the program was “pretty good” and little was needed for it to be done better. Two suggested more time be spent on CBT. When asked about what aspects were done well in the training, comments included that “all of it (was) well thought out, well presented, thorough, humorous and enjoyable” and that it was “pitched at (a) realistic level”. Other comments included “(it was) great to catch up with like-minded people” and “thanks for the opportunity”.

**4.5 Discussion**

Useful insights into all of the research questions for this phase were gained from the exploratory study. The findings of this study were then used to assist in planning for
the larger pilot RCT, enabling necessary modifications to the study protocol and KBA resources.

4.5.1 Feasibility of implementing and studying the KBA program in the general practice setting

Being able to recruit a group of GPs and patients to this phase in a relatively short time frame was a positive finding. One GP withdrew from the study following the training, citing having lack of time to commit to the study. GPs often describe themselves as ‘time-poor’ due to the many demands of practice, and the GPs in this study reported one of their challenges as time-management. It was anticipated that the necessary time commitment might be a barrier to recruiting the GPs or their ability to carry out the KBA program. However, the majority of the GPs who volunteered for the study continued for the full three months. It was also expected that those GPs might have an interest in mental health and be motivated to commit the necessary time. In fact, all the GPs had previous mental health experience through completion of Level One BOMHC training, though few had completed the more extensive Level Two training or other mental health training.

The GPs reported their usual practice as being to see their patients with depression regularly for treatment and monitoring. This was encouraging as the KBA program involves seeing the patient regularly. However, they reported keeping in contact with patients over the three months as a challenge at times, and this would need to be addressed in the larger pilot study. Interestingly, despite their previous training, all of the GPs reported that they did not routinely use psychological assessment tools with their patients. The brief training provided in association with this phase of the study explained the value of assessment tools in depression, and the use of the tools incorporated into the study, and also the importance of follow-up in this study and in managing depression. However, further emphasis on these areas would be needed in the larger pilot study training, along with strategies to ensure follow-up.

The participating GPs recruited the desired number of patients within the given time frame. In this small sample, more female than male participants were recruited. It was of interest to consider what this might reflect and whether it might occur in the larger study. This finding may be related to community prevalence rates of depression, which are reported to be higher for women.(30) Also, studies have
shown that men present to GPs with different symptoms of depression to women (that is, more physical symptoms), and the diagnosis may not be made. (278)

The majority of the patient participants stated that they were currently taking antidepressant medications. This finding was consistent with the severity of depression as measured on the DASS at the start of the study. Most were found to have moderate to severe depression, and antidepressants are indicated in the treatment of these levels of depression. (84) In addition, almost half were seeing a health professional other than their GP. This was also consistent with their depression severity, but could become a confounding factor in the pilot study.

The literature reports that co-morbidities are common in depression. (59, 70) In this phase, less than half the participants reported having other medical problems, but 10 participants drank alcohol, and of these, four drank seven or more glasses per week. Anxiety symptoms were measured by the DASS, and seven patients were found to have moderate to severe anxiety. It has been noted that studies of depression in specialist settings will often have exclusion criteria around co-morbidities (199), aiming to reduce the number of variables which might influence the outcomes. (14) However, the literature and findings in this phase suggest that exclusion criteria related to co-morbidities such as anxiety might not be realistic in the general practice setting.

The number of participants completing all or a number of steps in the KBA program provided further information about the feasibility of carrying out the larger pilot study. Eight participants completed all 10 of the KBA program steps, while six completed between two and eight of the steps. Difficulties in completing the entire program were related to significant intervening life events. The findings also reinforced the importance of incorporating strategies such as stressing the need for regular follow-up of participants by GPs into the larger pilot study. The value of the study checklist (Appendix A10) to record patient progress through the study, and to remind GPs about monitoring patient progress, was also reinforced during this phase.

4.5.2 Program acceptability

In terms of using the KBA program in their clinical practice, there were relatively few comments made by GPs about barriers to implementing the KBA program in their
practice. These comments related to the GP needing to adjust their practice to doing things ‘differently’ and to ensure the required follow-up. These comments were anticipated, and suggested that there would be some challenges for the GPs in the larger study to implement the program, but that these challenges could be managed through sound training and refinement of the study protocol. The comments by several GPs that they needed more than the suggested six sessions to deliver the KBA program suggested that additional sessions (up to 12 sessions) would be required in the pilot study.

The materials and written information in the manual was well received by the GPs. One of the motivations for writing the manual was to provide a comprehensive resource. It was positive that several GPs appreciated having the information in one place. The GPs found being familiar with the materials was helpful, and one of the GPs made a helpful suggestion about having a bookmark listing the content of the program to help guide the GPs through the program. It was planned for this measure to be incorporated into the pilot study. The most challenging step for the GPs was Step 5, which covers CBT. This was not surprising as GPs are not routinely trained in this therapy, and highlighted the need to ensure this step is well covered in KBA training for the larger study.

GPs and participants all said that they had no difficulty in managing the consent form, demographic questionnaires, and checklists, and these would need only minor changes for the larger pilot study. The participants responded positively to the program. It was pleasing that patients commented on key aspects of the program, such as its holistic nature, and the incorporation of CBT. The suggestions to provide a better quality of tape with background music on it was helpful, and it was decided to do a better quality recording, namely a CD with background music on it, for the larger pilot study. The suggestion to have a smaller manual (A5-size manual rather than A4) would be considered.

4.5.3 Appropriateness of the psychological assessment tools

As outlined above, there were similar numbers of 0-10 scales, DASS and QOL questions collected at the outset of the study and at the end (post-Step 10). However, very few GPs completed CGI measures for their patients at the completion of the program, and very few tools were collected after Step 5. A greater number
were collected towards the end of the study. Given that very few of the GPs reported using assessment tools regularly prior to the study, and the loss of some participants during the study, it was disappointing but not surprising that this occurred. However, the GPs interviewed reported that they thought the assessment tools were appropriate and easy to use.

GPs might not have been familiar with using a tool such as the CGI, which requires the clinician to judge their patient’s improvement. They might have been more comfortable administering patient self-assessment tools. It was planned that the pilot study would be carried out over 12 months, and so it would be necessary to utilise assessment tools part way through the study to gauge progress. The findings in this exploratory phase indicated that measures such as extra training for GPs in the use of the CGI, reminders to administer the tools during the larger study and the provision of folders with all the required forms for individual patients, and the checklist, would be important in the pilot.

Comparison of the 0-10 scale completed by the patients at the outset of the program and at the end of the program showed some improvement in the means (4.7 to 3.4). However, the value of including this type of non-specific scale in the larger pilot was drawn into question. Also, there were a significant number of missing results. With respect to DASS scores, most of the depression scores at the outset indicated moderate or severe depression, and general improvement in depression scores could be seen by the end of the program.

Results from the questions related to the various domains of quality of life provided some useful information. For those patients who completed the questions at the beginning and end of the program, there was a reduction in means in all quality of life domains. This was not a validated tool, however, and upon reflection, it was decided that use of a validated tool in the larger pilot study would provide more reliable information.

4.5.4 Adequacy of training

The training provided to GPs was thought by the researcher and the participating GPs to be too short to address the necessary information about the study and the program. However, the GPs still reported finding the training useful. Feedback from
the GPs included that they wanted to spend more training time on CBT and additional skills training, and it was positive that they said that they would be prepared to undertake a 20-hour program, as this would allow such areas to be explored more fully. As a result of these findings, it was planned to develop a 20-hour training program incorporating more theory and skills training, including CBT, for the pilot study.

The evaluation questionnaire suggested that the pitch of the training was appropriate, and that the presentation contained content that matched the GPs’ learning needs. Despite the brevity of the training, most of the GPs indicated that their knowledge of depression and their understanding of a range of psychological issues in depression had improved, as well as their skills in the assessment of depression, cognitive therapy and relapse prevention. It was still considered important, however, to provide the longer and more comprehensive training for all of the participating GPs in the pilot study.

4.6 Summary and recommendations

The exploratory phase aimed to gather information to inform the larger pilot study. It provided a number of useful insights related to the acceptability of the program, the suitability of the KBA resources, data collection forms, psychological assessment tools and GP training for a larger pilot study. Some challenges in implementing the KBA program were identified, such as keeping contact with patients, and ensuring completion of the full 10 steps of the program. However, it was believed that these challenges could be managed through sound training and refinement of the study protocol. It was also found that additional sessions for GPs to deliver the KBA program would need to be encouraged in the pilot study training (six to twelve sessions plus follow-up sessions).

The KBA materials were generally well received, but a relaxation CD with background music would be recorded for the pilot and a bookmark for the manual created. To contain costs, the same A4 manual would be used rather than redesigning it as an A5 document. The data collection forms and checklists involved in the study were all deemed appropriate and usable, but it was decided to have a folder containing all the forms for each individual patient to assist the GP and reduce the chance of forms or tools being missed.
In terms of assessment tools, it was still considered important for the CGI to be included in the pilot study, to gather information of the GPs views of patient improvement, and for all measures to be collected part way through to monitor progress, it was decided that additional training on these aspects would be provided for the pilot study. The DASS would be administered in the larger pilot study, but not the 0-10 depression raging scale, and a validated quality of life scale would be used. It was also found that additional time should be added to the training program for the GPs participating in the larger pilot study, and the training would fit with Level Two of BOMHC, which involved 20 hours of training. Topics such as CBT would also be covered more thoroughly.

The key recommendations from this phase of the research can be summarised as follows:

1. Sound training and refinement of the study protocol in relation to assessment tools, patient follow-up and number of sessions to deliver the KBA program are required.

   **Recommendation:** The DASS, CGI, and a validated quality of life tool (WHOQOL-Bref) should be used in the pilot. GP training should address strategies for participant follow-up, and additional sessions for delivering the KBA program should be advised.

2. The KBA materials are perceived positively by GPs and participants. The provision of a recorded relaxation CD (with background music) and a bookmark for the manual are needed.

   **Recommendation:** The KBA materials should persist in the main, with several modifications, including the recording of a relaxation CD with background music.

3. More lengthy training than the three-hour exploratory phase training is required. Topics such as CBT need to be covered more thoroughly.
Recommendation: A 20-hour training package should be developed for the pilot phase incorporating more CBT.

The following four chapters present the pilot RCT phase. Chapter 5 will describe the more comprehensive KBA training program developed for the pilot RCT, and the results of an evaluation of the training carried out as part of the pilot RCT. Subsequent chapters will then address the methodology and results of the RCT.
Chapter 5. Pilot Study GP Training Program: Methods and Results

5.1 Introduction

This chapter will describe the training programs that were developed to train GPs participating in the pilot RCT of the KBA program. A 20-hour training program was provided for GPs in the intervention group (those using the KBA program), while a brief training session was provided for GPs in the control group (those undertaking usual care). The intervention GP training program was evaluated using a pre-test and post-test and feedback questionnaire. The results of the training program evaluation will be presented in this chapter, and the pilot RCT will be described in Chapter 6.

As GPs were required to guide their patients through a comprehensive treatment program incorporating a number of psychological therapies, a training program was viewed as being an inherent part of the KBA intervention. The exploratory phase of this study (Chapter 3) highlighted that participating GPs viewed the brief training provided as helpful, but not adequate. In addition, value was seen in providing Level Two (BOMHC) training for the GPs participating in the larger pilot study, to benefit their professional development. As a result, a 20-hour Level Two training program was developed by the GP researcher, and provided to GPs participating in the intervention group.

5.2 Background

The literature review in Chapter 2 highlighted the importance of GP care of patients with depression, and the need for GPs to provide longer-term depression care incorporating relapse prevention. A range of national reviews and reports have also identified the need for GPs to be educated regarding mental health. A number of studies on GP education have had positive outcomes, and other studies have had less positive results. However, the Australian Federal Government recognises the importance of GP mental health education through its various initiatives.
5.2.1 Positive outcomes from GP mental health training

In recent years, this type of GP training has been evaluated, with results indicating that GP mental health training programs can improve GP knowledge, awareness and confidence in treating depression.(281, 282) For example, in a study set on the Swedish Island of Gotland, all GPs completed an educational program on the recognition and treatment of depression. Seminars were held comprising didactic presentations, group work and sharing of personal experience. Educating GPs in this manner resulted in increased prescribing of antidepressants and a reduction in the suicide rate.(282)

In another recent study by Vicente (2007), a two-day educational training program for 37 primary care physicians measured changes in knowledge, attitudes and practice. The results suggested that the program was effective in improving knowledge about depression and in changing some unhelpful disorder-related attitudes. Following the program, the physicians also felt more confident about treating patients and demonstrated increased prescribing of antidepressant agents. The researchers concluded that the training of primary care doctors should be a central part of any initiative to improve the treatment of depression.(283)

An Australian study also assessed the acceptability and benefits of a short course (12.5 hours) on the management of depression and anxiety for GPs. The training focussed on on CBT and interpersonal skills. s, and used pre- and post- measures of knowledge, attitude and self-evaluated clinical practice, as well as measures of GP satisfaction.(284) The course was greatly appreciated by the participating GPs, and their knowledge, attitudes, and some elements of self reported clinical practice demonstrated positive changes. Clark et al. concluded that brief interventions have an important role to play in enhancing the capacity of GPs to assist people with depression and anxiety.(284)
5.2.2 Less positive outcomes from GP mental health training

However, not all studies on GP training have had such positive results. A trial by Lin and Simon (2001) assessed the effect of training 109 physicians (over three months) in depression management. The physicians attended an initial two-hour training session, and then met periodically with a psychiatrist (for 15 minutes), and were able to phone the psychiatrist if needed for advice or to refer a patient. Twelve months after the training, the intervention and usual care physicians did not differ significantly in terms of depression diagnosis or use of pharmacotherapy. (285)

Further, a RCT by Gask and Dowrick (2004) examined the health gains from 10 hours of training in depression assessment and management skills provided to 37 GPs. The GPs were assessed for recognition of psychological disorders, attitudes to depression and prescribing patterns, and were randomised to receive the training either at the beginning or end of the study. The primary outcome was patient depression severity. One hundred and eighty-nine patients were also recruited to the study, and when those with a trained GP were compared at three and 12 months to patients whose GP had not yet received training, no significant difference was found in patient depression scores. However, patients of the trained GPs reported that their GPs had demonstrated improvement in their communication skills. (286)

5.2.3 Australian GP mental health training initiatives

In Australia, there have been national initiatives encouraging mental health education for GPs. The ‘National Primary Mental Health Care Initiative’ (1999) was established to provide support for GPs through education and training, and was followed by ‘Better Outcomes in Mental Health Care’ (BOMHC) in 2001, which aimed to improve the quality of health care to people with mental health problems. A key strategy of this initiative was the education and training of GPs in mental health, with two levels of training introduced (Level One and Level Two). Level One involved six hours of training related to carrying out mental health assessments and management plans, whereas Level Two programs were of 20 hours duration and involved skills training in the use of Focused Psychological Strategies, such as problem-solving, CBT and relaxation strategies. (287) In association with this initiative a series of Medicare item numbers were introduced, relating to the assessment and plan and FPS sessions. Following the later introduction of the Better Access initiative (2007), Level One
training was no longer a requirement for GPs to carry out mental health assessments and management plans.

5.3 The pilot study training programs

Based on the exploratory study findings, the literature and Federal Government initiatives, it was decided to provide a 20-hour training program for GPs in the intervention group. A three-hour session was offered to those in the control group. These programs and their delivery will now be described.

5.3.1 The intervention (KBA) group training program

Duration, location, and presenters

The 20-hour training program involved five four-hour sessions held at a seminar room at the University of Adelaide between March and May 2004. The program was run twice in the city, and a separate 20-hour program was held over one weekend in the Riverland region of South Australia (SA) to accommodate the participating rural GPs.

The sessions were presented by the GP researcher and a Clinical Psychologist, both of whom are experienced in health professional training. This multidisciplinary approach was specifically sought and viewed as desirable, given the strong focus on psychological therapies in the KBA program. Having two facilitators enabled a range of expertise to be brought to the teaching sessions, and assisted with demonstrations during the sessions.

Accreditation

Accreditation by the General Practice Mental Health Standards Collaboration (GPMHSC), which is part of the RACGP, for Level Two mental health training was sought and achieved, and continuing professional development (CPD) points were obtained from the RACGP. This process involved completing relevant application forms, and detailing the learning objectives, content and nature of the training (see
Appendices B1-B2). Emphasis was placed on the comprehensive and interactive nature of the proposed training sessions.

Having this accreditation was helpful for the participating GPs, as it enabled them to access additional Medicare Benefits Schedule (MBS) payments to carry out an assessment, treatment plan and review with their patients, and a series of sessions utilising Focused Psychological Strategies (FPS) such as relaxation and cognitive strategies.

Content

The program included training on depression assessment, treatment planning and the range of management skills incorporated in the KBA treatment program. The training was informed by evidence in the literature and clinical guidelines, the KBA treatment manual and clinical and teaching experience, and aimed to improve the GPs’ behaviours, attitudes, skills and knowledge in assessing and managing depression and in preventing relapse.(288)

Given that this training program was part of the KBA pilot study, it was important to explain the study’s background and methodology at the outset of the training. GPs in both the intervention and control groups were required to be familiar with the information sharing and consent process and the data collection forms, assessment tools and checklists being used in the study. In addition, GPs randomised to the intervention arm were provided with training on depression assessment and management, relapse prevention and the various psycho-social strategies involved in the KBA treatment program. The topic of GP self-care was also discussed.

While in the past, medical education focussed primarily on the transfer of knowledge, the more recent approach is to address not just knowledge, but also behaviours, attitudes and skills.(288) Therefore, the KBA GP training program aimed to:

1. Improve GP knowledge about depression.
2. Develop useful and positive attitudes (such as appreciating the holistic approach to management), and increase confidence.
3. Change behaviours (such as increasing use of assessment tools).
4. Increase GP skills in managing their patients’ depression, and improve their understanding of relapse prevention strategies, such as relaxation strategies and developing a relapse prevention plan.

The content of the KBA training program was drawn from supporting literature, written material from the KBA treatment manual, and skills exercises (for example, problem-solving) used in the KBA program.

Training techniques

Because of the importance of the training techniques on the outcomes, the techniques used to educate and train GPs were considered carefully. For example, interactive seminars have been found to be more effective at improving knowledge and attitude, than simply using written material such as a treatment manual. In further studies, training in communication and the use of role-play were also found to be effective in changing GPs’ behaviours and attitudes. The RACGP has integrated findings such as these into their GP training guidelines.

All of these factors were considered in determining how the KBA training program should be delivered. The final training program structure involved the provision of information via written material and verbal presentation, and interactive discussions between the presenters and the GPs. Discussion and questions were encouraged. The GP and the Psychologist facilitators were also able to perform demonstration role-plays, with one taking on the role of the therapist and the other the role of the patient. In this way a range of skills such as problem-solving, various CBT strategies and grief counselling were able to be demonstrated. There was also opportunity for the GPs to practice skills in pairs.

Handouts and resources

GPs randomised to the intervention group were given a GP training manual (different to the KBA treatment manual) which provided an overview of the GP training, including expectations of the GPs and guidelines for the training such as GP participation being encouraged but voluntary and confidentiality within the group.
The learning outcomes for the training were listed at the start of the manual, and an outline of each session was provided. The manual is provided in Appendix B3. Practical materials from the KBA treatment manual were incorporated so that the GPs could become familiar with the materials, and have practice in using them. GPs were also given a copy of the KBA treatment manual and relaxation CD.

The following handouts were also provided:

1. A series of key articles providing information, guidelines and evidence for different aspects of the KBA treatment program (listed throughout the GP training manual, see Appendix B3).
2. Forms for GPs to register with the RACGP and Health Insurance Commission stating that they had completed the Level Two BOMHC training.

As part of the process of providing information to the GPs about the study protocol, they were also provided with a folder containing:

1. Copies of the Consent Form, the Information Sheet (Appendices B4-5) and separate ‘Contacts for information on projects and independent complaints procedure’ from the Adelaide University Human Research Ethics Committee).
2. Copies of Data Collection Forms (GP and Participant) (Appendices B6-7).
3. Copies of the assessment tools (DASS, WHOQOL and CGI) used in the study (Appendix B8).
4. The ‘Summary Checklist’ to document the progress of each participant through the study and program (Appendices B9).
5. A list of ‘Possible Reasons for Loss to Follow Up and/or Treatment’ (Appendix B10) to assist GPs in recording reasons to loss to follow-up on the Summary Checklist.
6. The post-test questionnaire (the same as the pre-test questionnaire) and evaluation forms (Appendices B11-12).

**Learning outcomes**

A series of learning outcomes were established for the 20-hour KBA training program. The following general outcomes were provided:

1. To understand the study of a primary care treatment program aiming to prevent relapse of depression.
2. To have a greater knowledge of the aetiology and epidemiology of depression.
3. To review the bio-psychosocial model of depression.
4. To have an understanding of the chronicity of depression.
5. To have a greater awareness of the co-morbidity of depression, anxiety and alcohol and drug use disorders.
6. To understand the concepts of relapse and recurrence of depression and have an overview of the literature relating to relapse and recurrence of depression.
7. To understand the 10 step KBA program and its evidence-base.
8. To gain knowledge of the management of depression including use of antidepressants and role of psychosocial treatments.

Specific learning outcomes in relation to each step of the KBA program are summarised in Table 5.1.

**Table 5.1 Learning outcomes for each step of the KBA intervention group training**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>In relation to Step 1 of the KBA program, attending GPs will:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Understand the importance of medical review in depression and use of psychosocial assessments (including risk assessment).</td>
</tr>
<tr>
<td></td>
<td>Develop their knowledge of depression assessment tools.</td>
</tr>
<tr>
<td></td>
<td>Appreciate the importance of thorough assessment of depression.</td>
</tr>
<tr>
<td></td>
<td>Gain experience in using depression assessment tools.</td>
</tr>
<tr>
<td></td>
<td>Appreciate the importance of goal-setting with patients at the outset of treatment.</td>
</tr>
<tr>
<td></td>
<td>Appreciate the importance of monitoring of progress.</td>
</tr>
<tr>
<td></td>
<td>Develop skills in goal-setting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 2</th>
<th>In relation to Step 2 of the KBA program, attending GPs will:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Appreciate the importance of psycho-education in managing depression and preventing relapse.</td>
</tr>
<tr>
<td></td>
<td>Be provided with a useful psycho-education resource (in the KBA treatment manual) and practice using it.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 3</th>
<th>In relation to Step 3 of the KBA program, attending GPs will:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Appreciate the importance of addressing healthy lifestyle issues in managing depression and preventing relapse.</td>
</tr>
<tr>
<td></td>
<td>Have a useful resource for doing so.</td>
</tr>
<tr>
<td></td>
<td>Develop skills in stress management including relaxation techniques.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step 4</th>
<th>In relation to Step 4 of the KBA program, attending GPs will:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Improve skills in helping patients develop useful coping skills such as using a mood diary, problem-solving and managing panic episodes (slow breathing and cognitive strategies).</td>
</tr>
</tbody>
</table>

| Step 5 | In relation to Step 5 of the KBA program, attending GPs will: |
• Develop sound knowledge of the theory and evidence-base of CBT.
• Have a useful resource for using CBT with patients (in treatment manual).
• See modelled and practice CBT skills such as identifying negative automatic thoughts, explaining thinking distortions to patients, helping them identify thinking errors, challenge them and develop more helpful ways of thinking.
• Have an understanding of the influence of underlying beliefs on thinking, and how to deal with being a perfectionist.

In relation to Step 6 of the KBA program, attending GPs will:
• Gain knowledge about the important psychological issues in depression, such as self-esteem and loss and grief issues.
• Learn ways of dealing with psychological issues such as raising self-esteem.
• See these skills modelled and practise these techniques.
• Develop further knowledge and skills in risk assessment.

In relation to Step 7 of the KBA program, attending GPs will:
• Appreciate the importance of encouraging activity in preventing relapse of depression.
• Develop skills in activity planning.

In relation to Step 8 of the KBA program, attending GPs will:
• Appreciate the importance of developing social skills in preventing relapse of depression.
• Develop skills in assertiveness training.
• Understand the basis and evidence-base of IPT and develop skills in helping patients deal with relationship issues.

In relation to Step 9 of the KBA program, attending GPs will:
• Appreciate the importance of identifying early warning signs of depression in preventing relapse.
• Develop skills in helping their patients identify and deal with early warning signs.

In relation to Step 10 of the KBA program, attending GPs will:
• Appreciate the importance of following-up patients methodically in preventing relapse.
• Have a resource list related to managing depression and anxiety including books and websites.

Issues addressed at the beginning of training

In the first training session, the following issues were addressed:
1. Introductions of speakers and GPs.
2. Thank you for participating in the study.
3. Aims of training - orientation to the study and study protocol.
4. GP expectations of the sessions.
5. Contacts (GP Researcher phone and email address, Project Officer details).
6. Outline of study and methodology:
   a. Aims and research questions.
   b. Ethical issues and approval.
   c. Study inclusion and exclusion criteria.
   d. GP and patient identification numbers.
   e. Information sheet for patients.
   f. Consent form (copy to patient, original to be kept).
   g. Psychosocial assessment tools – DASS, WHOQOL and CGI.
   h. Use of the patient checklist (with initial sessions, review at three months, review at 12 months).
   i. Issue of follow-up and recording reasons for loss to follow-up.
   j. Logistics of researcher or project officer visits to practice to collect data.

Background information

Background information related to depression and the KBA program was then covered:

1. Aetiology and epidemiology of depression.
2. Review of the bio-psycho-social model of depression.
3. Chronicity of depression.
5. Relapse and recurrence of depression (meaning of the terms, rates, literature).
7. The eclectic nature of KBA and the range of psychological approaches incorporated into the program, such as CBT and IPT.
8. The KBA resources.

The training then described each step of the KBA treatment program, and trained the GPs about the strategies covered in each step. The content is summarised in Table 5.2. The theoretical background to each step or strategy was also addressed, and a range of skills were demonstrated and practised in relation to each step.
Note that the topic of self-care for GPs was addressed early in the training, as work has been identified as a significant source of stress for many doctors, and managing mental health issues in practice can be particularly stressful. Self-care incorporates taking care of one’s own physical, emotional and spiritual health, and accessing assistance if needed.(293)

Table 5.2 Content of KBA intervention group training

<table>
<thead>
<tr>
<th>Training Session</th>
<th>Content / Related KBA Steps and skills training</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Session 1</strong></td>
<td>Outline of the study and the training.</td>
</tr>
<tr>
<td></td>
<td>Background and introduction to depression, depression relapse and the KBA treatment program, including evidence base and eclectic nature of KBA (discussion re range of therapies incorporated in the program).</td>
</tr>
<tr>
<td></td>
<td>GP self-care.</td>
</tr>
<tr>
<td></td>
<td><strong>KBA Step 1:</strong></td>
</tr>
<tr>
<td></td>
<td>• Assessment of depression – medical review and psychosocial assessments (including risk assessment).</td>
</tr>
<tr>
<td></td>
<td>• Assessment tools used in the study.</td>
</tr>
<tr>
<td></td>
<td>• Goal-setting.</td>
</tr>
<tr>
<td></td>
<td>• Monitoring progress.</td>
</tr>
<tr>
<td></td>
<td><strong>Skills development:</strong> use of assessment tools and goal-setting (via practice with the tools, and completing goal-setting exercise for self).</td>
</tr>
<tr>
<td><strong>Session 2</strong></td>
<td><strong>Step 2:</strong></td>
</tr>
<tr>
<td></td>
<td>• The importance of psycho-education.</td>
</tr>
<tr>
<td></td>
<td>• Review of the psycho-education Step in the KBA manual.</td>
</tr>
<tr>
<td></td>
<td><strong>Skills development:</strong> use of Step 2 as a psycho-education. resource, practicing with other GPs.</td>
</tr>
<tr>
<td></td>
<td><strong>Step 3:</strong></td>
</tr>
<tr>
<td></td>
<td>• Overview of healthy lifestyle issues and depression.</td>
</tr>
<tr>
<td></td>
<td>• Review of Step 3 of the manual, including information and exercises.</td>
</tr>
<tr>
<td></td>
<td><strong>Skills development:</strong> stress management, including relaxation techniques (listening to relaxation CD and practicing progressive muscle relaxation with another GP).</td>
</tr>
<tr>
<td></td>
<td><strong>Step 4:</strong></td>
</tr>
<tr>
<td></td>
<td>• Review of the coping skills outlined in this step including</td>
</tr>
<tr>
<td>Step 5</td>
<td>Review of KBA resource and the 5 steps in identifying and challenging unhelpful thinking.</td>
</tr>
</tbody>
</table>
|--------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------
Role-plays

As highlighted earlier, an interactive approach was taken during the sessions, and the GPs were asked to participate in role-plays to gain practical experience in a range of skills. The following skills were practised:

1. Goal-setting.
2. Problem solving (using case studies).
3. Slow breathing,
4. Progressive muscle relaxation.
6. Activity scheduling.

Relaxation CD

Over the sessions, the GPs also listened to each track on the KBA relaxation CD, in order for them to become familiar with its content, and to experience the different relaxation techniques.

5.3.2 The control group training program

The control group training program took the form of a single 3-hour information session, which was delivered by the GP researcher on a designated evening in a meeting room at the University of Adelaide.

Program outline

The following program outline was provided to the GPs:
1. Introductions of speakers and GPs.

2. Thank you for participating in the study - control group to be offered training and materials at end of the study.

3. Aims of training - orientation to the study and study protocol.

4. GP expectations of the session.

5. Contacts (GP Researcher phone and email address, Project Officer details).

6. Outline of study and methodology:
   a. Aims and research questions.
   b. Ethical issues and ethics approval.
   c. Study inclusion and exclusion criteria.
   d. GP and patient ID numbers.
   e. Information sheet for patients, separate ‘Contacts for information on projects and independent complaints procedure’ of the Adelaide University Human Research Ethics Committee.
   f. Consent form (copy to patient, original to be kept).
   g. Data Collection Forms (GP and Participant).
   h. Psychosocial assessment tools – DASS, WHOQOL and CGI.
   i. Use of the ‘Summary Checklist’ (documenting initial sessions, review at three months, review at 12 months).
   j. Follow-up and recording reasons for loss to follow-up, list of ‘Possible Reasons for Loss to Follow Up and/or Treatment’ to assist the GPs in recording reasons to loss to follow-up on the Summary Checklist.
   k. Logistics of researcher/project officer visits to practices to collect data.

7. Summary and questions.

5.4 Evaluation methods

5.4.1 Sample and attendance

Chapter 7 and 8 will provide results of the pilot study, and outline the number of GPs recruited to the study. Twenty-two GPs were randomised to the intervention arm of the study and 23 to the control arm.
Table 5.3 provides information on the number of GPs in the intervention group who attended each session of the training. Two GPs withdrew early from the study and did not attend the training, leaving 20 GPs attending the KBA training. Each of the 20 GPs attended at least four out of the five training sessions.

Table 5.3 Number of intervention group urban and rural GPs who attended each GP training session.

<table>
<thead>
<tr>
<th>Session</th>
<th>Urban GPs n = 15</th>
<th>Rural GPs n = 5</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Attended</td>
<td>Did not attend</td>
</tr>
<tr>
<td>Session 1</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Session 2</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Session 3</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Session 4</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Session 5</td>
<td>14</td>
<td>1</td>
</tr>
</tbody>
</table>

Twenty-two of the 23 control GPs attended the control training. One rural control GP was provided with the training via the resources and via email and telephone discussion.

5.5 Evaluation results

5.5.1 Pre-tests and post-tests

As required for CPD accreditation by the RACGP, GPs completed pre-test and post-test questionnaires. Copies of the pre-test and post-test are provided in Appendix B11. The questions in each were the same, to enable a comparison of results before and after the training. The pre-tests were posted out to GPs prior to the training, and the responses highlighted areas of knowledge and gaps in knowledge. This informed the presenters prior to the training sessions, to ensure that the sessions were pitched appropriately. These gaps varied between the individual GPs, but included errors or lack of response to the questions regarding goal setting, CBT (challenging unhelpful
thinking and the role of irrational beliefs in contributing to unhelpful thinking associated with depression), managing grief and anger, and activity planning.

There were 42 questions in the pre-test and post-test questionnaires. These included 37 questions testing knowledge about depression assessment and treatment, two related to GP behaviours and three assessing GP attitudes. In the knowledge questions, responses were scored as either correct or incorrect (for example, a depression prevalence figure was given and the GPs were required to mark it as true or false), or a list of responses was required (for example, a list of issues related to antidepressant medication that are important to discuss with the patient).

Pre-tests were obtained for 19 of the GPs and 14 post-tests were completed, that is, a number of GPs failed to complete the tests. The majority of GPs answered most questions correctly in the pre-test as well as the post-test, indicating a sound pre-test knowledge (on average, 84% of questions answered correctly). However, the responses for individual questions in the pre-test and post-test were compared, firstly questions with binary or true/false or correct/incorrect questions, and secondly questions requiring a number of responses, in which case totals of correct responses have been compared.

For the questions with binary responses, the frequencies of correct and incorrect responses are summarised in Table 5.4 below, and where possible, a McNemar’s test for matched data has been carried out to identify whether the pre- and post-distribution of frequencies is the same. Where the test produced a significant result, there is a significant change between the pre-and post-test measure. It can be seen in Table 5.4, that there are only a few results to which the test could be applied, because the majority of GPs answered most questions correctly both times.

In relation to the first group of questions, there were only two questions with significant changes in the post-test, namely; “What is the prevalence of depression in Australian adults?” - resulting in a McNemar’s score of 6.0 ($P = 0.0143$); and “How do you define relapse of depression?” – resulting in a score of 5.44 ($P = 0.0196$). There were no other significant results in this group.

In relation to the second group of questions which required a number of responses, the totals of correct responses have been compared. Because of the small sample
size, and the limited number of responses provided, a paired samples t-test was not appropriate and the Wilcoxon Signed Rank test was used. Each pair of responses (pre- and post-) were examined, and a significant z-score indicates a change from pre- to post-test, in all instances indicating that the post-test value is higher.

Table 5.4 Comparison pre- and post-test results (Wilcoxon Signed Rank test)

<table>
<thead>
<tr>
<th>Question</th>
<th>Z score</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>2.449</td>
<td>0.014*</td>
</tr>
<tr>
<td>13</td>
<td>1.365</td>
<td>0.172</td>
</tr>
<tr>
<td>14</td>
<td>2.489</td>
<td>0.013*</td>
</tr>
<tr>
<td>15</td>
<td>1.518</td>
<td>0.129</td>
</tr>
<tr>
<td>16</td>
<td>0.424</td>
<td>0.671</td>
</tr>
<tr>
<td>18</td>
<td>1.134</td>
<td>0.257</td>
</tr>
<tr>
<td>19</td>
<td>1.265</td>
<td>0.206</td>
</tr>
<tr>
<td>22</td>
<td>1.651</td>
<td>0.099</td>
</tr>
<tr>
<td>23</td>
<td>1.732</td>
<td>0.083</td>
</tr>
<tr>
<td>24</td>
<td>1.387</td>
<td>0.165</td>
</tr>
<tr>
<td>25</td>
<td>2.157</td>
<td>0.031*</td>
</tr>
<tr>
<td>31</td>
<td>2.113</td>
<td>0.035*</td>
</tr>
<tr>
<td>32</td>
<td>2.202</td>
<td>0.028*</td>
</tr>
<tr>
<td>35</td>
<td>1.725</td>
<td>0.084*</td>
</tr>
<tr>
<td>36</td>
<td>2.539</td>
<td>0.001*</td>
</tr>
</tbody>
</table>

* Indicates a significant result

The questions in which significant improvement occurred related to the topics of goal-setting, forms of psychotherapy commonly used in depression, CBT, strategies to manage grief and anger, and activity planning. Question 26 and 39 were not included as there were too few cases that had responses (three and two). Question 26 related to irrational beliefs (CBT) and steps in developing a plan for managing relapse of depression.

The responses to the questions about GP behaviour (question 9 and 10) related to use of psychosocial assessment tools. In the pre-test, six GPs indicated that they used assessment tools and 11 said that they did not use tools (one missing response). In the post-test, 14 GPs reported that they used assessment tools, indicating a doubling in use.
A series of rating scales at the end of the pre- and post-tests also provided some limited but interesting information about the GPs levels of confidence and self-assessed skills level. The GPs were asked to rate (as ‘poor, fair, good or excellent’) their:

1. Confidence in managing depression using both medication and psycho-social strategies.
2. Confidence incorporating treatment strategies aimed at preventing the relapse of depression.
3. Skills in preventing the relapse of depression.

In the pre-test, 12 rated their confidence using medication and psychosocial strategies as ‘fair’, and five GPs rated their confidence as ‘good’. In comparison, in the post-test two rated their confidence as fair and 11 rated their confidence as ‘good’. In response to the second question (confidence incorporating relapse prevention strategies) in the pre-test 14 rated their confidence as fair, and only three as good. In the post-test, three rated their confidence as fair, and 10 as good. In terms of skills in preventing relapse of depression, in the pre-test one GP rated their skills as poor, 13 rated their skills as fair, and three GPs rated their skills as good. In the post-test, four GPs rated their skills as fair and nine GPs rated their skills as good.

5.5.2 GP satisfaction

A series of purpose-designed, self-report questionnaires were used to evaluate the training, with the GPs completing a questionnaire at the end of each session. Each of the questionnaires was relatively brief (six to 10 questions), taking only a few minutes to complete. The questionnaire completed in the final session was longer, as it also included questions on the 36 learning outcomes. The GPs rated whether they agreed, were neutral or disagreed that each learning outcome had been met. Copies of the evaluation questionnaires are provided in Appendix B12.

The first part of each questionnaire involved the GPs rating a variety of aspects of the session on a five-point Likert scale (from strongly agree to strongly disagree), including whether the:

1. Teaching program was pitched at an appropriate level.
2. Participating GP had improved knowledge or skill in areas covered by the session.
3. Method of presentation suited the GP.
4. Presenters were engaging.
5. Content of the session matched the GPs learning needs.

The GPs were then asked to comment, using open-ended questions, on what had been done well in the session, what they thought could have been improved, and any further comment. The GPs were required to put their name on the questionnaires, to enable the allocation of CPD points. The evaluation findings for each of the five training sessions follow. Copies of the evaluation questionnaire can be found in Appendix B12.

Session 1 - Background/introduction and assessment of depression (Step 1)

Most GPs agreed or strongly agreed with the questions about the first training session, but several were not sure about whether the program increased their knowledge of depression (refer to Table 5.5).

<table>
<thead>
<tr>
<th>Table 5.5 GP training program session 1 evaluation results</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
</tr>
<tr>
<td>SA</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>The program improved my knowledge of depression</td>
</tr>
<tr>
<td>SA</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>Will improve my assessment of depression</td>
</tr>
<tr>
<td>SA</td>
</tr>
<tr>
<td>9</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
</tr>
<tr>
<td>SA</td>
</tr>
<tr>
<td>8</td>
</tr>
<tr>
<td>The presenters were engaging</td>
</tr>
<tr>
<td>SA</td>
</tr>
<tr>
<td>11</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
</tr>
<tr>
<td>SA</td>
</tr>
<tr>
<td>10</td>
</tr>
</tbody>
</table>

SA = strongly agree, A = agree, NS = not sure, D = disagree, SD = strongly disagree
In regards to aspects of the program that could have been done better, the GP responses were generally positive, including that “all aspects seemed to be covered very well” and “was an introductory session, so there were aspects which were covered only in passing”. However, the same GP also noted that “this was acceptable”.

GPs believed that a variety of aspects of the session had been “done well”, including the organisation (described as “superb”), materials (described as “very good”, “excellent”, and “very useful”), the session structure (included comments such as “time for discussion as needed”, “well-structured”, “breaking components into manageable pieces”), the assessment tools (“use of assessment scales and practising one”), and the handout provided on how the program fit with the BOMHC GP training (“very useful”).

Other comments about the session were generally positive, including “very exciting; I am feeling motivated”, “excellent”, and “looking forward to developing skills”. The only negative comment related to the time and venue (“difficult parking/timing”).

Session 2 – Psycho-education (Step 2), healthy lifestyle issues (Step 3), coping skills (Step 4)

Most GPs agreed or strongly agreed with the questions about session 2, but several were not sure about whether the program increased their ability or skills in the areas of psycho-education and cognitive coping strategies, or whether the session met their particular learning needs. See Table 5.6.
Table 5.6 GP training program session 2 evaluation results

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td>7</td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program improved my appreciation of using psycho-educational resources with patients</td>
<td>8</td>
<td>8</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program improved my ability to address healthy lifestyle issues with patients</td>
<td>4</td>
<td>10</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has increased my skills in assisting patients with cognitive coping strategies</td>
<td>5</td>
<td>9</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>7</td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td>9</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>7</td>
<td>7</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

SA = strongly agree, A = agree, NS = not sure, D = disagree, SD = strongly disagree

Most of the GPs indicated that they were very happy with the session, though suggestions made included “I would like more details about the different talking strategies”, and “a lot to cover in a short space and to also figure out how it fits in with running the program with a patient”. Several GPs felt that the relaxation techniques and CD were done well, while others felt that the general discussion, role-playing and case studies, problem-solving, and the tools covered had been useful. The only other comment from a GP was that the resource materials from the session were “great”.

Session 3 - CBT/cognitive strategies (Step 5)

The majority of the GPs agreed or strongly agreed with the questions about session 3, but there were individual GPs who were not sure about particular aspects of the training. See Table 5.7.
In response to the question, ‘What aspects of this program could have been done better?’ several GPs responded that nothing could have been improved, while others asked for more time practising analysing unhelpful thought patterns and doing the exercises. GPs felt that a variety of aspects of the session had been done well, including the mindfulness meditation, explanations of challenging negative thoughts, the provided resources/tools and the explanation of these, ideas on using CBT in general practice, and the presenter role plays and practice role-plays between GPs. Several GPs felt that the entire session had been very helpful and one commented that it had been an “excellent session”. Other comments from GPs were that the session had been “excellent, really useful”, while another GP felt that “more CBT conference would be added value, and attending/sitting in during CBT would be beneficial”.

Session 4 - Psychological issues in depression (Step 6), activity planning (Step 7)

The majority of the GPs agreed or strongly agreed with the questions about session 4, but there were individual GPs who were not sure about particular aspects of the training. See Table 5.8.
Table 5.8 GP training program session 4 evaluation results

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td>5</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has assisted me to develop skills in raising self-esteem, and dealing with grief and anger</td>
<td>11</td>
<td>5</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has helped me to gain knowledge about important psychological issues in depression</td>
<td>11</td>
<td>4</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program increased my ability to encourage activity planning to prevent depression relapse</td>
<td>9</td>
<td>6</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>8</td>
<td>8</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td>10</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>8</td>
<td>7</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

SA = strongly agree, A = agree, NS = not sure, D = disagree, SD = strongly disagree

One GP felt that nothing could have been done better in the session, while another felt that less time identifying stereotypes at the beginning of the session might have been useful, and another felt that it might have been “more useful to start this in Session 1”. The GPs reported that the “description of how narrative therapy can work with letting go”, discussion and ideas from the GPs, the role plays, case studies and the scenarios, overview of techniques to use, the tools, and the manual format had been ‘done well’. One GP felt that everything had been “done well” in this session. Other responses from GPs included that a lot of useful “stuff” had been learned from the session and that the “quotes in the book are wonderful”, but that “incorporating further exercises to help improving self-esteem” might be useful.
Session 5 - IPT/fostering support and skills (Step 8), preparing a plan for managing relapse symptoms (Step 9), patient follow-up/resources (Step 10)

Most of the GPs agreed or strongly agreed with the questions about session 5, but there were individual GPs who were not sure about particular aspects of the training. See Table 5.9.

**Table 5.9 GP training program session 5 evaluation results**

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td>5</td>
<td>10</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has increased my appreciation of the importance of developing social skills to prevent relapse in depression</td>
<td>7</td>
<td>8</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has increased my skills in assertiveness training and helping patients deal with relationship issues</td>
<td>5</td>
<td>11</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has increased my therapeutic skills in preventing relapse in depression</td>
<td>4</td>
<td>10</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program helped me develop skills in helping patients identify/deal with warning signs of relapse</td>
<td>5</td>
<td>10</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The program has helped me to understand the importance of preparing an emergency plan</td>
<td>7</td>
<td>7</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>6</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td>7</td>
<td>9</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>6</td>
<td>9</td>
<td>1</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

SA = strongly agree, A = agree, NS = not sure, D = disagree, SD = strongly disagree

There were few suggestions for how the session could have been improved, with several GPs responding that “nothing could have been done better” and “well done”, while one GP noted that although they were already aware of much of the session
content, “the structure and summary of various strategies [in the KBA program] will still be useful”. GPs found that “identifying what a person finds pleasurable”, assertiveness training, the materials and tools, exploring support systems, the discussion-based presentation style, role plays, and practising the different skills to have been done well. One GP noted that they would “need to re-read the [KBA manual] to re-enforce everything [they] have learnt”.

This final session questionnaire also asked the GPs to indicate how well they felt each of the learning outcomes had been met, by agreeing, disagreeing, or indicating that they felt neutral about each of the statements. The results of these questionnaires can be seen in Table 5.10. The majority of responses fell in the ‘agree’ column, but there were a number of ‘neutral’ responses.

**Table 5.10 GP training program learning outcomes results**

<table>
<thead>
<tr>
<th>Learning outcome</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have a greater knowledge of the aetiology and epidemiology of depression</td>
<td>11</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>I have reviewed the bio-psychosocial model of depression</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have a greater understanding of the chronicity of depression</td>
<td>12</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>I have a greater awareness of the comorbidity of depression, anxiety and alcohol and drug use disorders</td>
<td>12</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>I understand the concepts of relapse and recurrence of depression and have an overview of the literature relating to relapse and recurrence of depression</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I understand the 10 step relapse prevention program and its evidence-base</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have gained knowledge of the management of depression including use of antidepressants and role of psychological treatments</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I understand the importance of medical review in depression and use of psychological assessments (including risk assessment)</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have further developed my knowledge of depression assessment tools</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>Statement</td>
<td>Score</td>
<td>Level</td>
<td>Notes</td>
</tr>
<tr>
<td>---------------------------------------------------------------------------</td>
<td>-------</td>
<td>-------</td>
<td>-------</td>
</tr>
<tr>
<td>I have gained experience in using depression assessment tools</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of goal-setting with patients at the outset of treatment</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of monitoring progress</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have developed skills in goal-setting</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of psycho education in managing depression and preventing relapse</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have been provided with a useful psycho education resource and have practiced using it</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of addressing healthy lifestyle issues in managing depression and preventing relapse</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have a useful resource for doing so</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have developed skills in stress management including relaxation techniques</td>
<td>13</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>I have developed skills in helping patients develop useful coping skills such as using a mood diary, problem-solving and managing panic episodes (slow breathing and cognitive strategies)</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have developed sound knowledge of the theory and evidence-base of CBT</td>
<td>13</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>I have a useful resource for using CBT with patients</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have seen modelled and practice CBT skills such as identifying negative automatic thoughts, explaining thinking distortions to patients, helping them identify thinking errors, challenge them and develop more helpful ways of thinking</td>
<td>13</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>I have an understanding of the influence of underlying beliefs on thinking, and how to deal with being a perfectionist</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have gained a knowledge about the important psychological issues in depression, such as self-esteem and loss and grief issues</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have learned ways of dealing with psychological issues such as raising self-esteem, dealing with grief and managing anger</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have seen these skills modeled and practiced these techniques</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
I have developed further knowledge and skills in risk assessment
I appreciate the importance of encouraging activity in preventing relapse of depression
I have developed skills in activity planning
I appreciate the importance of developing social skills in preventing relapse of depression
I have developed skills in assertiveness training
I understand the basis and evidence-base of IPT and develop skills in helping patients deal with relationship issues
I appreciate the importance of identifying early warning signs of depression in preventing relapse
I have developed skills in helping their patients identify and deal with early warning signs
I appreciate the importance of following-up patients methodically
I have a resource list related to managing depression and anxiety including books and websites

<table>
<thead>
<tr>
<th></th>
<th>14</th>
<th>1</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have developed further knowledge and skills in risk assessment</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of encouraging activity in preventing relapse of depression</td>
<td>14</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have developed skills in activity planning</td>
<td>13</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of developing social skills in preventing relapse of depression</td>
<td>14</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have developed skills in assertiveness training</td>
<td>13</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I understand the basis and evidence-base of IPT and develop skills in helping patients deal with relationship issues</td>
<td>11</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of identifying early warning signs of depression in preventing relapse</td>
<td>13</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I have developed skills in helping their patients identify and deal with early warning signs</td>
<td>13</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>I appreciate the importance of following-up patients methodically</td>
<td>14</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>I have a resource list related to managing depression and anxiety including books and websites</td>
<td>14</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

5.6 Discussion

As outlined earlier in the chapter, studies of GP education have indicated that GP mental health training programs can improve GP knowledge, awareness and confidence in treating depression.(281, 282) The pre-test and post-test assessed GP knowledge in the main. The pre-test level of knowledge was very good, however, there were significant improvements in almost one quarter of the questions in the post-test (9 out of 42). The GPs also reported that their confidence in several areas, including strategies and skills related to preventing relapse of depression.

The findings from the evaluation of the KBA program are consistent with previous research reporting positive outcomes from GP training. Positive findings in this evaluation were that the GPs reported that they were satisfied with the pitch of the program, that the method of presentation was suitable, that the presenters were engaging and the content in the main matched their learning needs. These findings
suggested that the program was very suitable for the GP audience. The presenters are experienced in the primary care mental health area, and were also respectful in their presentations by acknowledging the GPs already existing knowledge and experience in the mental health field.

There were many positive comments about the training program and its structure and organisation. This was pleasing given the amount of time given to preparation and accreditation of the program and the actual training (60 hours in total). There were, however, some comments about difficulties covering the material in 20 hours. This was understandable, given the comprehensive and multi-modal nature of the KBA program. It was not possible to cover some topics, such as CBT or IPT, as extensively as the presenters or the GPs would have liked. The presenters did, however, think that adequate coverage of each area was provided, along with a list of resources and further reading.

The GPs indicated in the evaluation that they thought the program had improved knowledge in a range of areas, such as assessment, CBT and psychological issues in depression, and behaviours, such as “encourage(ing) activity planning”. The evaluation also gauged perceived improvement in attitudes and skills. Examples include “understanding the importance of preparing an emergency plan” and “skills in helping patients identify… warning signs of relapse”. Overall the program met the learning objectives for the GPs. However, further improvements could have been made in relation to specific topics, such as strategies for developing self-esteem.

The GPs were positive about the method of teaching. As reported earlier, interactive seminars have been found to be more effective at improving knowledge and attitude, than simply using written material.\(^{(289)}\) Also, the RACGP and GPMHSC accreditation process stipulates that an interactive teaching format should be used. The presenters were skilled in interactive teaching techniques, and probably as a result of all of these factors, the GPs found the demonstration and practice role-plays helpful, and commented in each session on the skills involved, for example, relaxation, problem solving and assertiveness.

In terms of learning outcomes, the majority of GPs agreed that they were met. A small proportion gave neutral responses, particularly about having greater knowledge of depression and co-morbidities and its chronic nature. This was understandable,
given the knowledge of the GPs in the mental health area. The neutral responses in relation to addressing the learning outcome in relation to interpersonal skills may have reflected that this area could have been better covered in the training. In retrospect, it would have also been useful to do a long-term evaluation of the impact of the training, say 12 months post-training.

**5.7 Summary**

A number of reports supported the need for education about mental health to be a priority for GPs, and the need for a more substantial training program than provided in the exploratory study was highlighted in Chapter 4. The literature provided conflicting opinion on the value of such programs, however there was adequate support to develop a significant training program for the GPs in the intervention group. This decision was also supported by Federal Government GP training initiatives, and there was benefit for the participating GPs in terms of professional development and the training was accredited with Level Two of the BOMHC initiative.

As a result, the KBA training program was delivered over 20 hours to the intervention group GPs. The control GPs were only given a three-hour information session. In the 20-hour program the GPs were provided with training on the assessment and management of depression, including relapse prevention and the practical strategies incorporated into the KBA treatment program itself. The training program was evaluated by pre- and post-test questionnaires, and an evaluation form. There were many correct responses in the pre-test, but there were improvements in a number of the questions in the post-test. The evaluation found that the KBA training was well-received by the GPs, who reported that their knowledge of depression, appreciation and awareness of the various treatments and skills improved. In terms of using the training program in the future, or carrying out further research on the training, some aspects of the training could be improved and a 12-month follow-up evaluation carried out.
Chapter 6. Pilot RCT: Background and Method

6.1 Introduction

Chapter 4 highlighted that the KBA program and resources were found to be acceptable to the GPs and the participants involved in the small exploratory study, however, useful suggestions were received from the participants, and as a result, the KBA program and resources were modified. Chapter 6 will now describe the methodology of the larger pilot RCT of the KBA program. This phase aimed to assess the feasibility and acceptability of using the KBA program in a larger group of GPs and participants, and to study its efficacy in the general practice setting. Results of the pilot RCT will be presented in subsequent chapters.

6.2 Background

The KBA program aims to improve clinical outcomes for patients by reducing relapse rate of depression. The primary care relapse rate has been found to range between 37 and 45 percent.(8, 34) As outlined in Chapter 2, it was hypothesised that the KBA program would provide a 50 percent relative reduction of depression relapse: that is, from an estimated 40 percent relapse rate (8, 34) down to 20 percent, as compared to usual care.

With time pressures often cited by GPs as a key issue in general practice, it was anticipated that GPs would need to see a significant outcome from the program for them to invest the necessary time to deliver KBA to their patients. Based on discussion with five GPs known to the researcher, a one half reduction in relapse rates was established as the necessary outcome for GPs to utilise the program in their own clinical practice in the future.

6.3 Aims

The following research questions were identified for the larger pilot study:
1. Is there a larger reduction in relapse rates of depression when patients diagnosed with major depression are managed in general practice by GPs trained in and utilising the KBA program, when compared to patients managed with usual general practice care?

2. Is there a greater reduction in the severity of depression in patients receiving the KBA program, compared to those receiving usual general practice care?

3. Comparing KBA to usual practice, is there greater clinical improvement (GP perceived) or improved quality of life.

4. Are the GPs and patients satisfied with the KBA program?

5. Is the GP training in using the KBA program adequate and effective?

The final question related to whether the GP training in using the KBA program was adequate and effective has been addressed in Chapter 5.

Secondary hypotheses of the study were related to clinical outcomes, particularly reduced severity of depression, clinical improvement, and enhanced quality of life. It was also anticipated that the process of care would improve, and that GPs and patients would be satisfied with the program.

6.4 Methodology

6.4.1 Study design

A number of trial designs were considered for the larger pilot study. As RCTs are considered to provide a reliable study design when evaluating clinical interventions, (295) this methodology was chosen, comparing usual care with the KBA intervention. In particular, the larger pilot phase utilised a cluster randomised trial. In this methodology groups of individuals (rather than single individuals) are randomised to the same treatment together. (296) It is used when individual randomisation to evaluate certain interventions is inappropriate. (297) The use of this study design in health services research has increased in recent years. (297) and is usually employed because the outcomes measure is at a patient level, but the intervention being studied targets health professionals.
The design is also used when randomising by individual is not appropriate. In this pilot study, the intervention was being implemented at the practice level, and it was important to reduce the likelihood of treatment contamination (where the control group learns of the intervention). There was also potential for contamination between treatment groups in terms of the same medical staff providing treatment to both groups, and the possibility that the individuals would interact, which would potentially reduce the ‘observed intervention’ effect. As a result, cluster randomisation methodology was considered appropriate.

There are, however, some established disadvantages of cluster randomised trials, including potential recruitment bias, which can be overcome if there are sufficient clusters. For example, individuals within a cluster may have similar demographic qualities due to the geographic location of the practice (and therefore, similarity in socio-economic status), or the patients may self-select a particular practice based on GP specialisation. Sufficient numbers of clusters, over a range of demographic locations minimises these issues.

With cluster randomised trials there is also need for larger sample sizes, because of some loss of power due to variability between practices. Sample size calculations need to take this into account. Also, analysis must take into account variation at the level of randomisation, that is at the practice level and not just at the individual level.

In recognition of the complexity of this trial and the varied aims, which included acceptability of the program to GP and participants, both quantitative and qualitative research methods were employed. Greene, Lehn, and Goodyear reported that “there has been increasingly widespread agreement that mixing methods is a useful way to collect a variety of data” (2001, p.27). The overall purpose of mixing methods is to reduce uncertainty and to attain a ‘better understanding’ of the social phenomena being studied, where the term better understanding refers to enhanced validity of inferences, greater comprehensiveness of findings and more insightful understandings.

The use of both quantitative and qualitative approaches was important in this research. A mixed approach allowed measurement of depression levels and relapse (quantitative) as well as providing rich process information (qualitative). These
approaches can be implemented separately but used in a coordinated way.\textsuperscript{(299)} The methods used in this research were implemented in an integrated way.

\section*{6.4.2 Ethics approval}

Ethics approval for this study was gained from the Human Research Committee at the University of Adelaide. The ethical considerations in this study involved consent, confidentiality and safety. A copy of the ethics application and approval letter is provided in Appendices A1-2 and renewals were sought annually.

\textbf{Consent}

Participation in this study was voluntary and informed consent was required. The question of whether patients with depression are able to give informed consent has been raised in the literature, and it is reported that there is good evidence that patients with depression are able to give informed consent.\textsuperscript{(300)}

\textbf{Confidentiality}

There was a need to ensure that any personal health information collected was protected in terms of privacy and confidentiality. Consequently:

1. Information sheets detailing the project were provided to subjects (see Appendix B5).
2. Written informed consent was obtained from patients agreeing to participate in the study (see Appendix B4).
3. Participants were also advised that the information that they provided during the study would be known only to their GP and the researcher involved in the study, and that any information recorded by the researcher would be identified by number only.
4. Appropriate security procedures were implemented in relation to data storage and access, including secure storage of documentation in a locked filing cabinet in the Discipline of General Practice at the University of Adelaide.
5. Final analysis and reporting utilised only de-identified and aggregated data.
6. Patients were informed that they could refuse to participate in the study, or that if they decided to withdraw from the study, the management of their treatment would not be compromised.

Safety

It was documented in the ethics application that entry into this study did not put the patients at risk of any foreseeable physical or psychological harm. Subjects were to be fully informed about the intervention and it was intended that they would receive a high level of care and monitoring by their GP. Patients were advised that throughout the study they would be reviewed by their GP, and any problems could be discussed and addressed. In addition, GP’s utilising the intervention received training and support.

In intervention studies, it is important that patients are not disadvantaged by participation in the study, and that the control group be offered the best available alternative treatment.(301) In this study, participants in the control group were advised that they would receive the “usual [standard of] care” from their GPs.

The assessment tools used in the study were well-recognised and widely used measures. The post-intervention interviews involved straightforward questions designed to elicit comment about GP and patient perceptions and experiences of the intervention, along with their level of satisfaction. Interview questions included, “how helpful did you find the treatment approach?”, and “Of all the help you received during your illness what did you find the most helpful?”

6.4.3 Sample size calculations

Sample size calculations were done at the outset by the researcher and a consultant statistician, and indicated that 120 participants would be required in each of the intervention and control arms to have adequate statistical power in such a study design (95% confidence, 80% power, assuming a design effect of 1.5 due to clustering).(298) The design effect refers to the ratio of the total number of subjects required using cluster randomisation to the number required using individual randomisation.(296)
6.4.4 Recruitment of practices/GPs and participants

Five South Australian Divisions of General Practice (general practice support organisations) were contacted (Adelaide Central and Eastern Division, Western GP Network, Adelaide North East Division, Adelaide Hills Division and Mid-North Division). Selected Divisions encompassed a range of socio-economic and cultural groups, as well as both urban and rural areas. Each Division sent letters inviting their GPs to participate, with an estimated total of 400 GP members invited. A total of 45 GPs from 23 urban and rural practices responded that they would be willing to participate. A copy of the letter is provided in Appendix B13. Participant recruitment began in May 2004, and the study concluded in December 2005. Financial and time constraints did not allow any further time to be spent on the recruitment phase.

6.4.5 Randomisation

Randomisation was carried out by a statistician associated with the Discipline of General Practice at the University of Adelaide. Randomisation was stratified to ensure balanced proportions of rural/urban practices in each arm of the study arm, and equal numbers of solo and group practices.

6.4.6 Participant inclusion criteria

The KBA program was designed primarily for the adult population and for individuals with a depressive disorder. An inclusion criterion related to age was therefore required, with GPs asked to identify patients aged 18 years or older. The second inclusion criterion related to diagnosis. Patients who had been diagnosed with a depressive disorder were eligible to be included in the study. To ensure the diagnosis was depression, GPs were asked to apply the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for depressive disorder to these diagnoses. (302) These criteria are described in Chapter 2.

There were two final practical inclusion criteria: that the person was available for follow up for the next 12 months (the designated follow-up period), and that they were able to give informed consent. The capacities of depressed patients to consent to research have been questioned in the past, related to the possibility that the
cognitive effects of depression may impair subjects’ abilities to consent. However, a study assessing decision-making capacities related to research in depressed patients found that there were few cognitive impairments.(300)

### 6.4.7 Participant exclusion criteria

It is equally important to exclude patients who may be potentially harmed by the intervention.(301) The exclusion criteria for the pilot study were as follows:

1. Undergoing a separate structured treatment program.
2. Experiencing symptoms of psychosis.
3. Unable to complete English language questionnaires or an interview.

The inclusion and exclusion criteria are summarised in Table 6.1.

**Table 6.1 Summary of participant inclusion and exclusion criteria**

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men and women aged 18 years or older</td>
<td>Undergoing a separate treatment program</td>
</tr>
<tr>
<td>With a diagnosis of major depression according to accepted clinical diagnostic criteria</td>
<td>Symptoms of psychosis</td>
</tr>
<tr>
<td>Available for follow up for the next 12 month</td>
<td>Unable to complete English language questionnaires or an interview</td>
</tr>
<tr>
<td>Able to give informed consent</td>
<td>Unable to provide informed consent</td>
</tr>
</tbody>
</table>

### 6.4.8 Intervention

The 10 step KBA program, which was based on literature, current thinking and clinical experience, has been outlined in Chapter 2.(303) The KBA program involves a novel, multi-modal, skills-based treatment approach, incorporating 10 steps and utilising a range of evidence-based psychosocial strategies such as problem-solving and CBT.(106, 114) The program is started once the patient’s depression has been stabilised by initial treatment. The program has been described in full in Chapter 2 (see 2.6).
The control group of GPs were to carry out their usual care of patients with depression. Based on clinical and teaching experience, it was anticipated that ‘usual care’ would involve assessment of the patient, the provision of information about depression, medication if required and a variable amount of psycho-social treatment. (Information on the nature of care provided in the control group is provided in Chapter 8).

The intervention group GPs completed 20 hours of training (conducted by a GP and a Clinical Psychologist), and outlined in Chapter 5. The training kit contained information on depression, the study protocol, assessment tools and skills training related to the KBA program. Control group GPs completed a three-hour training session on the study protocol.

GPs and participants were provided with resources including a GP training manual (see Appendix B3), KBA manual (237 pages), patient journal and purpose-designed relaxation CD.(304) The script for the relaxation CD is provided in Appendix B15. GPs were also provided with a bookmark to assist in navigating through the manual, a reminder card to recruit patients to the study (to attach to the top of their computer screen), and regular newsletters to keep them up to date with the study course and to act as reminders to recruit and follow patients up. The bookmark and a sample newsletter is provided in Appendices 16 and 17.

6.4.9 Data collection

Both quantitative (numerical) and qualitative approaches were used in the pilot study to address the study outcomes.(305) Validated assessment tools providing quantitative measures of depression severity and quality of life were utilised. The following psychological assessments were used in the larger pilot study:

1. Depression, Anxiety and Stress Scale (DASS).
2. Quality of Life Scale (WHOQOL-BREF).

These tools have been described in detail in Chapter 4 and copies are included in the appendices (Appendix B8).

The GPs were asked to administer these psychological assessment tools at baseline, three months after commencement of the study and at 12 months. The CGI Scale
(improvement component) was to be completed by GPs at the end of the KBA program and at 12 months in order to measure the GP’s impressions of the participant’s improvement. Relapse rates were determined through a retrospective audit of the clinical notes. Questionnaires were used to gather information about participant and GP experiences of the KBA program. These methods are described in more detail in the sections which follow.

**Depression severity**

Depression severity was assessed in the pilot study with the Depression Anxiety Stress self-rating Scale (DASS). The DASS is a self-report instrument that is available in a 42-item format (DASS-42) or as a shorter DASS-21, with 21 questions. The shorter 21 item version was chosen because of its high reliability, and for ease of use by the GPs. (274) This scale has been found by the GP researcher to be clinically useful to assist with diagnosis, and to measure severity of depression and monitor severity over time.

As outlined in Chapter 2, anxiety is often co-morbid with depression and its treatment is important to outcomes. (61) The KBA program addresses both anxiety and depression, and it was therefore considered beneficial that the DASS identifies anxiety in addition to depression. Also, the clinician can graph the results for the patient, which gives clear information to the patient about their levels of the depression and anxiety.

**Quality of life**

The World Health Organisation has defined quality of life as an individual’s perception of their position in life, taking into account culture and values, goals, expectations, and standards. It is a broad-ranging concept, incorporating the person’s physical and psychological health, their level of independence, social relationships, and their relationship to their environment. (306)

The World Health Organisation Quality of Life Scale (WHOQOL-BREF) was chosen to measure quality of life in the larger pilot study. The WHOQOL-BREF is an
abbreviated version of the WHOQOL-100. It was developed through the World Health Organization Quality of Life Project, an international collaboration between numerous centres worldwide, including Australia. It was intended to be both internationally applicable and cross-culturally comparable, and to be a comprehensive assessment of quality of life, including physical, psychological, social and environmental functioning. It was also intended to be a subjective assessment of quality of life, as self-perceived quality of life based on our own personal experiences and expectations, may be a more accurate measure than physician-rated quality of life.

In the WHOQOL-BREF, examples of questions related to the physical domain are; “How satisfied are you with your health?” and “To what extent do you feel that physical pain prevents you from doing what you need to do?” An example of a question related to the psychological domain is; “How much do you enjoy life?”, and an example of a question related to the social domain is; “How satisfied are you with your personal relationships?” The environmental domain questions include; “How safe do you feel in your daily life?”

The WHOQOL-BREF comprises a total of 26 items, one from each of the 24 domains of the WHOQOL-100, plus two additional items from the quality of life & general health domain. The WHOQOL-BREF was designed specifically for the Australian population, and has been modified to ensure cultural sensitivity. However, the instrument does assume knowledge of the English language and may not necessarily be culturally relevant to the entire population.

The WHOQOL-BREF comprises four domains: physical health, psychological health, social relationships and the environment, and two items regarding overall perception of QOL and health. The four domains are scored positively and range from 0-100, with higher scores denoting higher QOL. The two items are also scaled in a positive direction and range from 1-5. Domain scores are calculated by the addition of individual scores from each item, with negatively worded items requiring reverse-scoring. The raw domain scores are then transformed to a 0-100 scale format.

Initial pilot data was collected on 2056 subjects. Two field-tests have been carried out in Australia, namely the Victorian Validation Study (VVS), conducted by the Centre for Health Program Evaluation, provided data based on random sampling of the
population (n=396) and the Longitudinal Investigation of Depression Outcomes (LIDO) (n=437). Population norms established for each domain in the VVS were as follows: physical – mean score 80.0 (SD 17.1); psychological – 72.6 (SD 14.2); social 72.2 (SD 18.5); environment 74.8 (SD 13.7).(306)

Data taken from the VVS and the LIDO have shown that all four domains have excellent internal consistency and test-retest reliability.(309) The factor structure appears to be sensitive to respondents’ health status before and after treatment and the physical and psychological domains demonstrate good construct validity. The QOL and health items also showed sensitivity to change in health status and good discriminant validity, but only moderate construct validity and test-retest reliability. International data confirm good internal consistency and excellent discriminant validity across the four domains.(309)

Clinical Global Impressions

The Clinical Global Impressions (CGI) Scale (improvement component) was used to measure clinician-rated patient improvement. The CGI scale (CGI) is a brief rating instrument which has been widely used in clinical trials of psychotropic treatments,(277) with a study by Goldman, DeQuardo and Tandon (1999) indicating that single item global measures, “particularly the CGI”, may be practical tools for routine monitoring of the effectiveness of treatments for mental illness in community settings.(310) The CGI (improvement component) is a single seven-point measure that requires the clinician to assess how much the patient’s illness has improved or worsened relative to a baseline state at the beginning of the intervention.(277)

Depression relapse

A retrospective case note review, competed by a psychology graduate who was blinded to whether the patient participant was in the intervention or control arm of the study, was carried out. The graduate was trained to review the case notes using an audit record, via explanation of the audit process and demonstration of auditing a series of computerised and paper-based case notes.
Based on the literature review and clinical knowledge, the researcher established a list of potential indicators in the clinical notes of depression relapse, including:

1. Increased symptoms of depression.
2. Medication changes after previously being stable.
3. Medication dose increase.
4. Second medication added.
5. Medication recommenced (after time without the medication).
6. Referral to specialist (psychiatrist, psychologist, ACIS).
7. Hospital admissions.
8. New symptom development.

These indicators were incorporated into the audit form, which can be seen in the Appendices (Appendix B14).

Acceptability of KBA

At the end of the trial, a series of brief semi-structured interviews were undertaken to gather information about GP and participant experiences of the KBA program. A purposive sampling technique (311) was used to select a range of GPs (urban and rural GPs of both sexes from group and solo practices) to be interviewed by a Project Officer. The GPs then contacted a number of participants to be interviewed. It was anticipated that the GPs would know their patients and be able to identify patients who would be able to participate in an interview (that is, be well enough and not become too anxious about the interview).

The semi-structured format was chosen as it leads to easy to count quantitative data as well as providing opportunity for qualitative responses.(14) The interviews were conducted by a Project Officer (nursing background), and were carried out by telephone. Copies of the GP and participant interview questions are provided in the B18.

The interview questions were designed to address GP and participant:

1. KBA program content and length.
2. Satisfaction with the program.
3. Helpful and unhelpful aspects.
4. The KBA program resources.
5. Reasons for not completing the program.
6. Overall perceptions of the KBA program.

6.4.10 Data management

A database was developed at the University of Adelaide specifically for this pilot study, based on the data collection questionnaires and assessment tools. Data were entered manually by a project officer, and then rechecked or cleaned to remove any errors prior to analysis. Missing data was coded as missing and not included in the analysis.(9) Data were stored on a dedicated data server all running Windows Server O/S (2003-2008) and SQL Server 2005.

6.4.11 Data analysis

Rather than using standard techniques applied to individual units within the study (individual patients), the calculations used in data analysis addressed the clustered nature of the data (by practice).(297) This is vital to avoid errors in analysis, which may involve accepting a research hypothesis that there is difference when this is false (Type I error), or acceptance of no differences when there is actually a difference (Type II error).(14, 312) Analysis also took into account the design effect of 1.5 due to clustering.(296, 298)

Analysis looked at relapse rates and was completed on an ‘intention to treat’ basis. ‘Intention to treat’ is a strategy for the analysis of RCTs that compares patients in the groups to which they were originally randomly assigned. If this strategy is not adhered to, additional results may be included in a particular group and clinical effectiveness within this group can be overestimated.(313)

To evaluate the impact of the intervention on depression relapse rates, the analysis looked at overall relapse, rather than at individual time-points. This was due to variability in when in the 12-month period the measures were administered. Analyses took into account the range of variable potentially influencing relapse rates. Chi-square analyses were conducted to determine the relationship between relapse and
certain identified variables (study group, gender, age, length of symptoms, past history of depression), and relative risks were computed.

Logistic regression is used to analyse data when studying the influence of different factors on outcome. In this study, a logistic regression for age and group (KBA versus control) was performed. Finally, a model that included all the main effects and each variable’s interaction group was run. Interactions with a p-value less than 0.20 were then included (reported to be a standard model-building technique). In the final regression model, the variables of age, sex, group and age/group were retained.

Depression, WHOQOL and CGI measures were conducted at various points throughout the 12-month study period. As there was variability in when these measures were taken, the results were analysed according to days since baseline. A mixed models approach was used due to some missing data. The variables of group, sex, age, history of depression length of time with symptoms, antidepressant use and location were used to build a regression model to describe changes in DASS depression scores over time. The impact of KBA on quality of life was measured across the various domains (physical, psychological, social, environmental) of the WHOQOL-BREF, and results were examined using a mixed-model regression analysis.

The analysis aimed to examine the intervention group influence on the different domains of quality of life. It also examined a range of covariates: length of time with depression, past history, gender, antidepressant use, rural location. As repeated measurements were taken at variable times, the number of days since the baseline measurement was used as the time variable. A mixed model was run examining group membership and each covariate separately to assess univariate relationships over time. Also, because change over time for the quality of life variables was not constant (there seemed to be a relatively big change in the first few months and then it levelled off), a quadratic change over time was examined.

Quantitative data were analysed using SAS, version 9.1 (SAS Institute, Cary, NC, USA). Data from the semi-structured interviews were analysed using content analysis, documenting the frequencies of particular responses to questions, as well records of words and sentences used.(15)
6.5 Summary

A number of research questions were identified for the larger pilot intervention study, relating to whether there would be a reduction in relapse rates of depression when patients diagnosed with depression were managed by GPs trained in and utilising the KBA program, when compared to usual general practice care. Secondary hypotheses related to clinical outcomes (reduced severity of the depression, clinical improvement, and enhanced quality of life) and improved process of care. A RCT, utilising cluster randomised trial design, was carried out comparing usual care with the KBA intervention.

A range of urban and rural South Australian Divisions of General Practice were contacted and GPs were invited to participate in the pilot study. A total of 45 GPs responded, although two dropped out very early from the study. Twenty-three practices were recruited and randomised to intervention and control groups, with 12 in the intervention arm and 11 in the control arm. Participant recruitment began in May 2004 and the study ended in December 2005. GPs were asked to identify patients aged 18 years or older, who had been diagnosed with a depressive disorder. A total of 110 participants were recruited, with 62 randomised to the intervention group and 48 to the control group. Eleven participants withdrew during the 12 months of the study.

The intervention group GPs and participants were provided with comprehensive KBA resources, and the GPs completed 20 hours of training. Control group GPs completed brief training on the study protocol. Assessment tools providing quantitative measures of depression severity (DASS-21) and quality of life (WHOQOL) were utilised. The CGI Scale was also collected, allowing GPs to rate their patient’s improvement. At the end of the study a series of telephone interviews were undertaken to gather qualitative information about GP and participant experiences.

Data analysis looked at relapse rates. Chi-square analyses were conducted between relapse and identified variables, and relative risks were computed. A model that included all the main effects and each variable’s interaction group was run, and scores for depression, WHOQOL and CGI were carried out. A mixed models
approach to data analysis was used. Data from the semi-structured interviews were analysed using content analysis.

The main results of the pilot RCT were published in the MJA in 2008. This paper is provided as Chapter 7, and additional and some expanded results are presented in Chapter 8. Discussion of these results follows in Chapter 9.
Chapter 7. Pilot RCT: Publication of results

This chapter comprises a publication that describes key results from the pilot RCT, which aimed to assess the feasibility and acceptability of using the KBA program and study its efficacy in the general practice setting. The study methods are described, followed by the main study results related to depression relapse, depression severity, and quality of life. The GPs and participants' perceptions of the program and the associated KBA materials, as well as the limitations and strengths of the study, are also highlighted. The subsequent chapter (Chapter 8) will provide additional results to those not described in this article.

Title: Preventing relapse of depression in primary care: a pilot study of the “Keeping the blues away” program
The Medical Journal of Australia, 2008; 188(12). 138-141

Statement of Authorship

Dr C. A. Howell conceived, conceptualised, and wrote the manuscript. Professor D. A. Turnbull and Professor J. J. Beilby were supervisors for the research, reviewed the results, read the article manuscript and provided input to the final wording in the paper. C. Marshall contributed to the collation of demographic data reported in this paper and participated in discussion about the results. Dr N. Briggs, statistician, assisted in statistical analysis on the study and read the relevant parts of the paper and provided comment. W. Newbury was the project officer involved in the study, providing practical assistance throughout the study and thereby contributing to the research reported on in this paper.

NOTE: This publication is included on pages 164-167 in the print copy of the thesis held in the University of Adelaide Library.
Chapter 8. Pilot RCT – Additional Results

8.1 Introduction

This chapter describes the additional results of the pilot study, which aimed to assess the feasibility and acceptability of using the KBA program and study its efficacy in the general practice setting. Also, some of the results briefly described in the MJA article, are expanded upon in this chapter. The subsequent chapter will provide a discussion of the pilot RCT results.

8.2 The Sample

The 23 practices which were recruited (comprising 45 GPs) were randomised to intervention and control, resulting in 12 being allocated to the intervention (KBA) arm and 11 to the control arm. A total of 110 participants joined the study, with 62 randomised to the intervention group and 48 to the control group.

8.2.1 Description

The practices

The characteristics of practices involved in the trial are shown in Table 8.1 and Fig 8.1. There were more urban practices involved in the research, but similar numbers of urban and rural practices allocated to the KBA and control arms of the study.
Table 8.1 Practice location – urban and rural

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention (KBA)</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Practices</td>
<td>Urban</td>
<td>9</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Rural</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>12</td>
<td>11</td>
</tr>
</tbody>
</table>

The maps below highlight the locations of practices involved in the research. Urban practices were located at Bedford, Kingston, Parkside, Hyde Park, Sefton Park, City of Adelaide (four), Norwood (two), Unley Park, Marden, Magill, Highbury, Woodcroft and Port Adelaide. Rural locations were Port Augusta, Tumby Bay, Berri, Port Broughton and Minlaton. Hills practices (Aldgate and Piccadilly) were included in the rural group. The maps demonstrate the practice locations.

Figure 8.1 Practice locations - urban and hills practices
The GPs

There were more GPs who worked in group practices compared with solo practices. More female GPs participated in the study than male GPs, and the mean age of GPs in each arm of the study was 45 years. See Table 8.2.
Table 8.2 Characteristics of GPs randomised to intervention (KBA) group and control group.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention (KBA)</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Practitioners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Total</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>In group practice</td>
<td>17</td>
<td>21</td>
</tr>
<tr>
<td>In solo practice</td>
<td>4 (missing 1)</td>
<td>1 (missing 1)</td>
</tr>
<tr>
<td>Work full-time</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>Work part-time</td>
<td>10</td>
<td>15</td>
</tr>
<tr>
<td>Mean age (yrs)</td>
<td>45 yo</td>
<td>45 yo</td>
</tr>
<tr>
<td>Rural vs urban</td>
<td>5 rural</td>
<td>7 rural</td>
</tr>
<tr>
<td></td>
<td>15 urban</td>
<td>16 urban</td>
</tr>
<tr>
<td></td>
<td>2 – withdrew early</td>
<td></td>
</tr>
<tr>
<td>Undertaken training in mental health</td>
<td>18</td>
<td>18</td>
</tr>
</tbody>
</table>

These findings can be compared to Australian GPs (2008-9) as a whole. In Australia there are more male GPs than female (63% male and 37% female), and the majority are 45 years of age or older (70%) and work in urban areas (73%).(314)

Participants

Table 8.3 shows that balanced numbers of female and male participants were recruited into each arm of the study. Participants with a wide age range were recruited; in the intervention group the ages ranged from 18 to 62 years of age (mean age 39 years), and in the control group from 19 to 74 years (mean age 40 years). Most participants were in married or de-facto relationships and lived with other people, and many had trade, certificate or degree qualifications.

Depression scores were severe at the outset of the study in the control group and extremely severe in the intervention group. This finding will be discussed later in this chapter and in Chapter 9. There was a past history of depression in the majority of participants in both arms of the study, with most experiencing two to three episodes,
or greater than five episodes. Although there was missing data with respect to numbers of past episodes, the numbers of past episodes were relatively balanced across the KBA and control groups.

**Table 8.3 Characteristics of participants randomised to intervention (KBA) group and control group**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention</th>
<th>Control</th>
<th>total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>Female</td>
<td>46</td>
<td>40</td>
<td>86</td>
</tr>
<tr>
<td>Total</td>
<td>62</td>
<td>48</td>
<td>110</td>
</tr>
<tr>
<td>Mean age (yrs)</td>
<td>39 yo</td>
<td>40 yo</td>
<td></td>
</tr>
<tr>
<td>Married or defactc</td>
<td>24</td>
<td>26</td>
<td>50</td>
</tr>
<tr>
<td>Separated or divorced</td>
<td>9</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>Single, widowed, other or not recorded</td>
<td>25 (4 missing)</td>
<td>16</td>
<td>41</td>
</tr>
<tr>
<td>Don’t live alone</td>
<td>43</td>
<td>39</td>
<td>92</td>
</tr>
<tr>
<td>Live alone</td>
<td>14 (5 missing)</td>
<td>6 (3 missing)</td>
<td>22</td>
</tr>
<tr>
<td>Education:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Degree</td>
<td>11</td>
<td>19</td>
<td>31</td>
</tr>
<tr>
<td>Certificate</td>
<td>16</td>
<td>12</td>
<td>28</td>
</tr>
<tr>
<td>Trade</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Completed school</td>
<td>21 (11 missing)</td>
<td>14</td>
<td>35</td>
</tr>
<tr>
<td>Employed</td>
<td>23</td>
<td>33</td>
<td>55</td>
</tr>
<tr>
<td>Unemployed</td>
<td>20</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Other (home duties, student, sick leave, retired)</td>
<td>14 (5 missing)</td>
<td>10</td>
<td>24</td>
</tr>
<tr>
<td>Mean DASS (depression) scores</td>
<td>33 (extreme)</td>
<td>27.68 (severe)</td>
<td></td>
</tr>
<tr>
<td>Past history of depression</td>
<td>42</td>
<td>37</td>
<td>79</td>
</tr>
<tr>
<td>Number of previous</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
episodes:
1 3 6 9
2-3 13 14 27
4-5 3 3 6
>5 12 9 21
(2 ‘chronic’, 14 missing) 29 missing)

GP training and mental health practice

As part of the initial demographic questionnaire given to GPs, the GPs were asked a series of additional questions about previous mental health training. GPs were asked to specify if the training was accredited for Level One of BOMHC, or Level Two training in Focused Psychological Strategies, such as CBT or IPT. They were also asked if they had undertaken other training, such as counselling, CBT courses or narrative therapy. The results are outlined in Table 8.4.

Table 8.4 Mental health training undertaken by GPs in the study

<table>
<thead>
<tr>
<th>Mental Health Training</th>
<th>Intervention (KBA)</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1 BOMHC</td>
<td>14</td>
<td>13</td>
</tr>
<tr>
<td>Level 2</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Other</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

The GPs were asked about different aspects of their usual assessment and management of patients, including their use of DSM-IV criteria and use of assessment tools in diagnosing depression. They were also asked about the average number of times that they would see patients with depression, and the psychological therapies that they would utilise.

As can be seen in Table 8.5, approximately half of the GPs utilised the DSM-IV criteria for a Major Depressive Disorder(21), and the numbers using the criteria in the KBA group and the control group were balanced. Again, about half reported using a psychological assessment tool. Most of the GPs saw their patients three to four times during the first three months, averaging about every three to four weeks. This finding was balanced across the two study groups. All of the GPs responded that they used counselling with their patients, and most utilised psycho-education. Twenty-six of the
initial 45 GPs used CBT strategies, 11 used IPT and a smaller number (four) utilised other approaches such as narrative therapy.

Table 8.5 Usual GP assessment and management

<table>
<thead>
<tr>
<th>Diagnosis and Assessment</th>
<th>Intervention (KBA)</th>
<th>Control</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uses criteria for a Major Depressive Disorder (DSM-IV)</td>
<td>11 yes</td>
<td>10 yes</td>
<td>21 yes</td>
</tr>
<tr>
<td>Did not use DSM-IV criteria</td>
<td>11</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td>Uses a psychological assessment tool</td>
<td>11 yes</td>
<td>10 yes</td>
<td>21</td>
</tr>
<tr>
<td>Did not use an assessment tool</td>
<td>11</td>
<td>13</td>
<td>24</td>
</tr>
<tr>
<td>In the first month, number of times seeing the patient.</td>
<td>1-2 times: 2</td>
<td>1-2 times: 3</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>3-4 times: 18</td>
<td>3-4 times: 20</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>5-6 times: 2</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>In the three months, number of times seeing the patient.</td>
<td>3-4 times: 7</td>
<td>3-4 times: 3</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>5-6 times: 9</td>
<td>5-6 times: 17</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>7-8 times: 4</td>
<td>7-8 times: 3</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>9-10 times: 1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Psychological therapies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counselling</td>
<td>22</td>
<td>20</td>
<td>42</td>
</tr>
<tr>
<td>Psycho-education</td>
<td>16</td>
<td>20</td>
<td>36</td>
</tr>
<tr>
<td>CBT</td>
<td>12</td>
<td>14</td>
<td>26</td>
</tr>
<tr>
<td>IPT</td>
<td>6</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Other eg narrative therapy</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>
8.3 Consort Statement

A Consort Statement provides a checklist of information related to the design and conduct of the study. They were designed to improve the quality of reporting of RCTs. A Consort Statement for the pilot RCT was provided in the MJA article, but for ease of understanding subsequent discussion, it is provided in Figure 8.3 below.

Of the 45 GPs who had responded that they would be willing to participate, 43 commenced the study. Two GPs withdrew early from the study, one immediately due to distance to travel for training, and one early after the training due to work stress. One participant was excluded due to being under 18 years of age. The number of patients lost to follow-up in each arm of the study can also be seen: in the KBA group, 62 participants were recruited, but 10 withdrew during the study due to ill-health, travel or moving state. One patient withdrew from the control arm. Unfortunately data from five patients were lost when a GP moved practice.
**Figure 8.3 Consort Statement**

Randomised Primary Care Practices  
N = 23  
(43 General Practitioners [GPs])*

Practices allocated to intervention  
(n = 12)  
Number of GPs = 22

Practices allocated to control  
(n = 11)  
Number of GPs = 23

Intervention Participants recruited by GPs  
N = 62

Control Participants recruited by GPs  
N = 49

Patients lost to follow-up  
Baseline (n = 62)
- Data of 5 participants lost due to GP moving practice  
- 10 participants withdrew during the study eg due to travel or relocation

Patients lost to follow up  
Baseline (n = 48)
- One participant withdrew

* Two GPs withdrew from the study early on (prior to their recruiting any patients to the study) due to work stress and distance to travel for training.
8.4 ‘Usual care’ – treatment received by the control group

The retrospective case note review provided information about what treatment the control group received. Data were obtained for 45 control participants (four missing), indicating that they visited the GP between one and 20 times during the study, with a mean of seven visits. However, some of these visits were consultations not related to depression management. All but two of the 45 were on medication, and 39 received some sort of psychosocial treatment, such as CBT strategies, problem-solving or goal-setting.

8.5 Primary outcome – depression relapse

As outlined in the MJA article, no statistically significant differences were found between the intervention and control groups in terms of their relapse rates ($\chi^2$-square (df1) = 1.51 $P = 0.23$). However, despite not being statistically significant, a tendency was noted towards relapse rates being reduced in the intervention group (RR= 0.77; 95% CI: 0.5 - 2.05). These data on relapse rates for KBA vs. control patients is summarised in Table 8.6 (below), and in Figure 5 of the MJA article (see Chapter 7).

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>KBA</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No relapse</td>
<td>33 (40.24%)</td>
<td>49 (59.76%)</td>
<td>82</td>
</tr>
<tr>
<td>Relapse</td>
<td>15 (53.57%)</td>
<td>13 (46.43%)</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>48</td>
<td>62</td>
<td>110</td>
</tr>
</tbody>
</table>

Table 8.6 Depression relapse data by group

Given the tendency towards depression being reduced in the intervention group, sub-group (age, gender, past relapse) analyses were carried out. Interestingly, there was a significant age and group interaction. Younger people in either group tended to show similar probability of relapse, while older people in the intervention group showed a much lower probability of relapse than those in the control group. This was statistically significant ($P = 0.018$). The results indicated that age was predictive of depression relapse (with increased age being associated with decreased relapse). Older individuals (50 years+) in the KBA group showed a significantly lower
probability of relapse than those in the control group ($P = 0.018$). ‘Older’ refers to 1 SD above the mean age (where the Mean = 39.23; and SD = 11.34) Thirteen percent of the intervention group (eight participants) were aged 50 years or over (and a further 15% were aged 45 years or over). Further data, not presented in the MJA article, on relationships between depression relapse and a variety of predictors (gender, past relapse, length since previous episode), is presented.

8.5.1 Gender

Data related to depression relapse and patient gender show that female participants were less likely to relapse (22.22% relapse) than male participants (37.5% relapse rate). This result approached but was not statistically significant: Chi-square: $\chi^2$-square (df1) = 2.26 $P = 0.13$. There was a tendency for relapse to be less frequent in females (RR= 0.83; 95%CI, 0.62-1.10). The relative risk for males was 1.73 (95%CI, 0.86-1.10).

8.5.2 Past relapse

Of those who did not have a past history of depression, 76.0% did not relapse, while 24% did. This was similar to the relapse rate of those who did have a past history of depression (73.42% relapse, 26.58% no relapse). These findings were not significant: Chi-square: $\chi^2$-square (df1) = 0.07 $P = 0.79$. For those who did not relapse, 24.68% had no past history but 75.32% had a past history. For those who did relapse, 77% had past history and 22% did not.

*Table 8.8 Depression relapse data by past relapse*

<table>
<thead>
<tr>
<th></th>
<th>Past relapse NO</th>
<th>Yes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No relapse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>58</td>
<td>77</td>
</tr>
<tr>
<td></td>
<td>24.68%</td>
<td>75.32%</td>
<td>73.42%</td>
</tr>
<tr>
<td></td>
<td>76%</td>
<td>76%</td>
<td>76%</td>
</tr>
<tr>
<td>Relapse</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>21</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>22.22%</td>
<td>77.78%</td>
<td>76.58%</td>
</tr>
<tr>
<td></td>
<td>24%</td>
<td>24%</td>
<td>24%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Past relapse NO</th>
<th>Yes</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>25</td>
<td>79</td>
<td>104 (6 missing)</td>
</tr>
</tbody>
</table>
8.5.3 Length since previous episode

In relation to the length of time since participants’ last episode of depression (of those who had experienced a previous episode), relapse rates for those whose last episode had been more than six months ago were 26.79% (73.21% did not relapse), while relapse rates were similar for those who last depressive episode had been within the previous six months, at 27.5% (72.5% did not relapse). These findings were not significant: Chi-square: $\chi^2$ (df1) = 0.006 $P = 0.94$.

Looking at the data from an alternative angle, of those participants who had had a previous episode of depression and who did not relapse, 41.43% had had their last episode within the previous six months, while 58.57% had had their last episode more than six months ago. Similarly, of those who did relapse, 57.69% had experienced their last episode of depression more than 6 months ago, while 42.31% had had theirs within the last six months.

8.6 Secondary outcome – depression severity

Findings related to the severity of the participants’ depression were summarised in the MJA article, and further data will presented in this chapter. To determine whether depression severity decreased during the study, depression scores were measured over time for many of the participants. The study design involved measuring depression at baseline, three months and 12 months. However, while it was easy to identify the baseline measures, it was more difficult to ascertain whether many of follow-up measures were for the three or 12-month collections. Instead, time from baseline was calculated for each further measure taken, instead of assigning it as a three or 12-month collection.

Figure 8.4 shows the control and intervention participants’ depression severity scores over time, and indicate that while the baseline scores were consistently collected, the timing of collecting the later scores varied greatly.
The series of models in the model building process identified that length of time with depression was a significant predictor of depression score. The interaction of length, days from baseline and group was significant.
The predictors of intervention group, gender, age, history of depression, length of time with symptoms, antidepressant use and location were then used to build a regression model to describe changes in depression scores over time. The final model indicated that the interaction of the length of participants’ depressive symptoms, days in the study from baseline and group (KBA vs. control) were significant predictors of severity of depression. Participants in the KBA group who had experienced depressive symptoms for more than six months had reductions in depression scores approaching significance ($P = 0.06$).

There was a great deal of individual variation in baseline depression scores and how those scores changed over time. The depression scores are provided in Table 8.9 (below). Note that Figure 6 in the MJA article illustrates these scores as a graph. A noticeable finding in relation to depression scores was that baseline scores were higher for the intervention group than the controls. It can be seen in Table 8.9 that there was a general decrease in scores over time with the control groups and the intervention (<6 months) group showing similar values.
Table 8.10 Mean DASS scores in KBA and control groups

<table>
<thead>
<tr>
<th>Time since last episode</th>
<th>Control &lt;6 months</th>
<th>Control &gt;6 months</th>
<th>Intervention &lt;6 months</th>
<th>Intervention &gt;6 months</th>
<th>Mean Control</th>
<th>Mean Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 days from baseline</td>
<td>28.76</td>
<td>26.92</td>
<td>30.50</td>
<td>36.11</td>
<td>27.68</td>
<td>33.00</td>
</tr>
<tr>
<td>90 days from baseline</td>
<td>26.92</td>
<td>25.77</td>
<td>28.74</td>
<td>33.10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>180 days from baseline</td>
<td>25.08</td>
<td>24.95</td>
<td>26.98</td>
<td>30.09</td>
<td></td>
<td></td>
</tr>
<tr>
<td>365 days from baseline</td>
<td>21.29</td>
<td>23.26</td>
<td>23.37</td>
<td>23.90</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8.6 Quality of life

As outlined in Chapter 6, the impact of KBA on quality of life, as measured by the WHOQOL, was measured across a range of domains (physical, psychological, social and environmental), and results were examined using a mixed model regression analysis. The analysis aimed to examine the intervention group influence on the different domains of quality of life. It also examined a range of covariates: length of time with depression, past history, gender, antidepressant use, rural location. Because change over time for the quality of life variables was not constant (there seemed to be a relatively big change in the first few months and then it levelled off), a quadratic change over time was examined.

Those with depression for more than six months showed lower QOL-physical at baseline, regardless of group. By about 200 days, the scores of both groups had increased on this measure. Participants who had experienced depression for more than six months showed lower baseline QOL-psychological scores. QOL-psychological scores had also increased for both groups by day 200 from baseline, and this improvement remained present at day 400 from baseline.

At baseline KBA participants had lower QOL-social scores but as the trial progressed their scores increased more rapidly than the control group. However, by day 400, the estimated means were the same. For the QOL-environmental subscale, women showed higher values than men. Those using antidepressants showed a constant
increase in QOL-environment over time. Those not taking antidepressants showed a steeper increase within 200 days of baseline that levelled off after that.

### 8.6.1 QOL-physical

The final regression model showed effects for both group and length of time with depression. Estimated means for the groups (control group, less than six months; control group, six months or more; intervention group, less than six months; intervention group, six months or more) showed that those with depression for more than six months tended to show lower QOL physical at baseline, regardless of intervention group. By about 200 days, all groups increased and those values are steady at about 400 days. See Figures 8.4-6 below.

As shown in table 8.11, the group and length of time showed significant or nearly significant interactions with the quadratic time term. This means that the shape of the curve differed between the intervention/control groups and the length of time with depression.

**Table 8.11 Interactions between groups and length of time**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num DF</th>
<th>Den DF</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>group</td>
<td>1</td>
<td>62</td>
<td>37.28</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>length</td>
<td>1</td>
<td>62</td>
<td>0.34</td>
<td>0.5646</td>
</tr>
<tr>
<td>qdays</td>
<td>1</td>
<td>74</td>
<td>45.30</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>qdays2</td>
<td>1</td>
<td>62</td>
<td>26.85</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>qdays*group</td>
<td>1</td>
<td>62</td>
<td>8.55</td>
<td>0.0048</td>
</tr>
<tr>
<td>qdays2*group</td>
<td>1</td>
<td>62</td>
<td>3.68</td>
<td>0.0597</td>
</tr>
<tr>
<td>qdays*length</td>
<td>1</td>
<td>62</td>
<td>4.61</td>
<td>0.0357</td>
</tr>
<tr>
<td>qdays2*length</td>
<td>1</td>
<td>62</td>
<td>3.33</td>
<td>0.0728</td>
</tr>
</tbody>
</table>
8.6.2 QOL-psychological

The final model included a main effect for intervention group, and interactions with time for length of time with symptoms. The estimated means indicate that those with symptoms for longer showed lower baseline QOL. There was an increase for all groups by day 200 that remained at day 400. See Figure 8.5.

### Table 8.12 Interactions between groups and length of time

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num DF</th>
<th>Den DF</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>group</td>
<td>1</td>
<td>61</td>
<td>16.22</td>
<td>0.0002</td>
</tr>
<tr>
<td>length</td>
<td>1</td>
<td>61</td>
<td>0.10</td>
<td>0.7482</td>
</tr>
<tr>
<td>qdays</td>
<td>1</td>
<td>74</td>
<td>52.03</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>qdays*length</td>
<td>1</td>
<td>61</td>
<td>4.81</td>
<td>0.0321</td>
</tr>
<tr>
<td>qdays2</td>
<td>1</td>
<td>61</td>
<td>26.75</td>
<td>&lt;.0001</td>
</tr>
<tr>
<td>qdays2*length</td>
<td>1</td>
<td>61</td>
<td>3.35</td>
<td>0.0723</td>
</tr>
</tbody>
</table>

Figure 8.5 Quality of life score – psychological - over time
8.6.3 QOL-social relationships

The final model included an interaction between group and time. No other covariates were included. The estimated means show that those in the intervention group started out lower on QOL-social, and increased more rapidly than the control group. By day 400, the estimated means were the same. See Figure 8.6.

Table 8.13 Interactions between groups and length of time

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num</th>
<th>Den</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>group</td>
<td>1</td>
<td>63</td>
<td>11.59</td>
<td>0.0012</td>
</tr>
<tr>
<td>qdays</td>
<td>1</td>
<td>74</td>
<td>14.23</td>
<td>0.0003</td>
</tr>
<tr>
<td>qdays*group</td>
<td>1</td>
<td>63</td>
<td>6.26</td>
<td>0.0150</td>
</tr>
<tr>
<td>qdays2</td>
<td>1</td>
<td>63</td>
<td>5.22</td>
<td>0.0256</td>
</tr>
</tbody>
</table>
8.6.4 QOL-environmental

The final model included a main effect gender, and interactions between antidepressant use and time, and group and time. The coefficient for gender indicates that, in general, women showed higher values than men. As for the interaction, those using antidepressants showed a constant increase in QOL environment over time, whereas those with no antidepressants showed a steeper increase within 200 days of baseline that levelled off after that. See Figure 8.7.

Table 8.14 Interactions between groups and length of time

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num DF</th>
<th>Den DF</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>group</td>
<td>1</td>
<td>63</td>
<td>10.45</td>
<td>0.0020</td>
</tr>
<tr>
<td>qdays</td>
<td>1</td>
<td>74</td>
<td>13.16</td>
<td>0.0005</td>
</tr>
<tr>
<td>qdays*group</td>
<td>1</td>
<td>63</td>
<td>3.34</td>
<td>0.0722</td>
</tr>
<tr>
<td>antidepress</td>
<td>1</td>
<td>63</td>
<td>0.00</td>
<td>0.9494</td>
</tr>
<tr>
<td>qdays*antidep</td>
<td>1</td>
<td>63</td>
<td>4.76</td>
<td>0.0328</td>
</tr>
<tr>
<td>qdays2</td>
<td>1</td>
<td>63</td>
<td>8.77</td>
<td>0.0043</td>
</tr>
</tbody>
</table>
### Type 3 Tests of Fixed Effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Num</th>
<th>Den</th>
<th>F Value</th>
<th>Pr &gt; F</th>
</tr>
</thead>
<tbody>
<tr>
<td>qdays2*antidep</td>
<td>1</td>
<td>63</td>
<td>5.34</td>
<td>0.0241</td>
</tr>
<tr>
<td>sex</td>
<td>1</td>
<td>63</td>
<td>3.67</td>
<td>0.0601</td>
</tr>
</tbody>
</table>

**Figure 8.7 Quality of life score – environmental - over time**

![Quality of Life, Environmental Predicted Means](image)

#### 8.7 Clinical Global Improvement

There was a lot of missing data for the GP-assessed CGI, making the results on this measure difficult to interpret. GPs collected the CGI at variable intervals, and all follow-up results were combined. However, more people were improved on follow-up than were worse. The CGI results are provided in Table 8.15.
### Table 8.15 CGI results

<table>
<thead>
<tr>
<th>CGI rating</th>
<th>Control</th>
<th>Intervention</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very much worse</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Much worse</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Minimally worse</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>No change</td>
<td>3</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Minimally improved</td>
<td>7</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Much improved</td>
<td>9</td>
<td>7</td>
<td>16</td>
</tr>
<tr>
<td>Very much improved</td>
<td>9</td>
<td>11</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>32</td>
<td>32</td>
<td>64 (46 missing)</td>
</tr>
</tbody>
</table>

Multinomial logistic regression was used to look at differences between the KBA and control groups, and then looking at different predictors such as gender, past history of relapse of depression, use of antidepressants or rurality. Interactions between these predictors and the two groups were also analysed, with no significant effects were found. The only model with an effect approaching significance was the model with the length of depression (more or less than six months) and group interactions ($P = 0.08$).

### 8.8 GP and participant perceptions

To ascertain GP and patient perceptions of the KBA program a sample of GPs and participants were interviewed several months after completion of the study. A purposive sampling technique (311) was used as outlined in Chapter 6, and the GPs were selected to based on being in variable locations and practices, and based on gender. As a result, five GPs (four urban GPs and one rural GP; one male GP and four female GPs) were interviewed, and these GPs suggested the names of eight participants to be contacted and interviewed. These numbers were low due to lack of time and funds at this stage of the research. A copy of the interview questions can be found in Appendix B18 and a more detailed summary of the interview findings is provided in Appendix B19.
Questions and findings related to the following areas are now summarised:

1. KBA program content and length.
2. Satisfaction with the program.
3. Helpful and unhelpful aspects.
4. The KBA program resources.
5. Reasons for not completing the program.
6. Overall perceptions of the KBA program.

8.8.1 KBA content and length

Interview results indicated that the content of KBA was viewed by GPs and participants as highly or extremely relevant. All of the GPs indicated the KBA program provided the right amount of information. Seven out of eight patients indicated that the program had the right amount of information, one saying that it had too much information. One GP and one patient reported that program as being too long.

When asked about what could be removed from the program, no KBA program Steps were identified by GPs or patient participants. One GP commented that detail in some sections could be cut down, although another said that having more detail enabled the program to be tailored to the individual. GPs and patients were asked about topics that might be added to the program. Patients did not suggest any additions, one saying that it was a well-rounded program. Several GPs suggested more information on anxiety, even having a stand-alone step on anxiety.

8.8.2 Satisfaction with KBA

All of the GPs indicated the KBA program provided the right amount of information and that they were highly/extremely satisfied. Two participants were satisfied and six were highly or extremely satisfied.
8.8.3 Helpful and unhelpful aspects of KBA

The most helpful steps identified by GPs included Step 2 (Information on depression), Step 4 (Coping skills) and Step 5 (Cognitive-behavioural therapy). The most helpful steps identified by participants included Step 1 (Assessment and goal-setting), Step 4 and Step 5. GPs reported the least helpful sections as Steps 3, 7 and 8. Patients found Steps 3, 6, 7, 8, 9 and 10 the least helpful. These addressed lifestyle and psychological issues, the importance of activity, social connectedness and relapse prevention. Step 10 provides a summary of the KBA Steps.

8.8.4 The KBA resources

All of the GPs and the patients indicated that the KBA manual was a useful resource and that the presentation was appropriate. Two patients indicated that the drawings were not appropriate, one commenting that on first impression they appeared childish. All GPs and patients agreed that the relaxation CD was a helpful resource, although several made negative comments about it such as not liking a particular relaxation. All GPs reported the journal as being useful, but only half of the patients found it useful, several saying that they did not relate to writing things down.

8.8.5 Reasons for non-completion

One GP commented on the influence of severity of depression on ability to engage with the program, and a tendency for patients to discontinue coming when they felt better. Patients discontinued because of moving away, crises or difficulties getting to the practice.

8.8.6 Overall perceptions

One GP commented that “most people with anxiety and depression can benefit from this type of program”. One GP said that the more they used the program, the more they were able to find the relevant parts for individual patients. Others reported the manual as being very handy and simple to understand, and the program being able to be tailored for the individual patient. One commented that they liked the structure of the KBA program, with the CBT section “clearly spelled out”.
One of the participants said; “KBA helped me, it opened my eyes”. Another participant noted “It is supportive and enlightening. You can take what is needed at the time. It is a well planned program with something for everyone”. The logical structure of the program received positive comments, and a patient said that they “found it really useful at the time, and even now (they) go back to it”.

8.9 Summary

In the pilot RCT, 23 practices (45 GPs) were recruited and randomised to intervention and control arms. A total of 110 participants joined the study, with 62 randomised to the intervention group and 48 to the control group. No statistically significant differences were found between the intervention and control groups in terms of their relapse rates. However, a tendency was noted towards relapse rates being reduced in the intervention group. Younger people in either group tended to show similar probability of relapse, while older people in the intervention group showed a much lower probability of relapse than those in the control group. This was statistically significant ($P = 0.018$).

The study design involved measuring depression severity over time. Analysis indicated that the interaction of the length of participants’ depressive symptoms, days in the study from baseline and group (KBA versus control) were significant predictors of severity of depression. Participants in the KBA group who had experienced depressive symptoms for more than six months had reductions in depression scores approaching significance ($P = 0.06$). A noticeable finding in relation to depression scores was that baseline scores were higher for the intervention group than the controls. Participants in the KBA group who had experienced depression for a longer duration had higher depression scores at the beginning of the trial, but by the end of the 12 months their depression scores were indistinguishable from those of the other participants.

The impact of KBA on quality of life was measured across physical, psychological, social and environmental domains. Those with depression for $>6$ months showed lower QOL-physical at baseline. By about 200 days, the scores of both groups had increased on this measure. Participants who had experienced depression for $>6$ months showed lower baseline QOL-psychological scores. QOL-psychological
scores had also increased for both groups by day 200 from baseline, and this improvement remained present at day 400 from baseline.

A small sample of GPs and participants were interviewed after the RCT, and results indicated that the content of KBA was viewed by GPs and participants as highly or extremely relevant. The majority of participants indicated that the program had the right amount of information, and most were highly or extremely satisfied. Several GPs suggested more information on anxiety be included in the KBA program. All of the GPs and the patients indicated that the KBA manual and relaxation CD were useful resources, but only half of the patients found the journal useful. The most helpful steps in the manual included information on depression, assessment and goal-setting, coping skills and CBT. Overall comments on the program were positive, with one patient saying that they had “found it really useful at the time, and even now (they) go back to it”.
Chapter 9. Pilot RCT - discussion

9.1 Introduction

In this chapter, the findings of the pilot RCT will be discussed in relation to the study aims, and the strengths and limitations of the study. An interpretation of the pilot RCT in relation to comparable literature, and in particular recent studies, will be provided.

9.2 Overview of the aims of the pilot RCT

The overall aim of this research was to develop and implement a primary care depression RPP (the KBA program) and to evaluate its effectiveness. Several research questions were identified for the pilot RCT, related to relapse rates and severity of depression with the KBA program compared with usual general practice care, (GP perceived) clinical improvement, quality of life, and GP and participant satisfaction with the KBA program. The final research question related to the adequacy and effectiveness of the associated GP training has already been discussed in Chapter 5. To determine whether these aims were achieved, the discussion which follows will firstly address the internal validity of the pilot study, followed by consideration of the pilot RCT results in relation to each aim. Findings in relation to the GPs involved in the study and the measurement outcomes used will also be discussed.

9.2.1 Internal validity

It is important to consider the internal validity of the RCT to determine whether improvements in these clinical outcomes were achieved. Internal validity includes consideration of sampling, randomisation and conformity to intention to treat.(14) As there are many threats to the potential reliability and validity of studies such as the KBA pilot study (14), it is important to consider potential study design bias.

General practices were recruited (N=23) and randomised to intervention or control groups. It was important that the practice characteristics were relatively balanced at the outset, and this was achieved, as shown in Table 2 of Chapter 7. Many of the
GPs had undertaken some post-graduate mental health training, possibly indicating motivation in the area of mental health. This was potentially a bias, but the numbers having undertaken training in the KBA and control arms were equal.

The sample of patients (N=110) was drawn from practices across a range of urban and rural locations in SA. The patient participant sample was balanced in terms of gender and age, and patients of a wide age range were recruited. After the study had begun, it was discovered that there was an imbalance in patient depression severity with patients in the KBA group having more severe depression. However, it was not possible to avoid this with the study design. Participant numbers with a past history of depression were balanced across the study and control arms.

The main participant inclusion criterion related to having a depressive disorder. GPs were asked to utilise their clinical judgement based on the diagnostic criteria provided in DSM-IV, with results of the DASS assisting the practitioner to confirm the diagnosis. It appears that this inclusion criterion was met, as reflected by the DASS depression scores. However, participants in the intervention arm had higher depression severity scores at baseline. Other inclusion criteria were met, with the exception of one patient who had to be excluded due to being under the required age.

In relation to exclusion criteria, GPs were asked not to include patients undergoing a separate structured treatment program. This criterion also appears to have been adhered to at the outset of the study. During the study, however, a number of participants in each group (25 in total, almost equal numbers in each group) were referred to mental health professionals or psychiatrists for opinions or treatment. This could not be controlled for, as referral would have been made based on clinical judgement.

Cluster randomisation of practices was chosen as the best approach. Randomising by individual GPs or participants was not appropriate as it could potentially have resulted in contamination between GPs or patient participants. The advantages and disadvantages of cluster randomisation were discussed in Chapter 6. It was explained that larger sample sizes are needed with cluster randomised trials because of the loss of some power due to variability between practices, and the design effect of 1.5 due to clustering.
The design effect was taken into account in sample size calculations which indicated that 120 participants would be required in each of the intervention and control arms. Unfortunately a smaller number of patients were recruited to the study than required, limiting its power. This issue will be discussed further under 'limitations of the study' later in this chapter. In relation to study methodology, data analysis was completed on an intention to treat basis and also addressed the clustered nature of the data.

The pathway of participants through the study was highlighted in the consort statement provided in Chapter 8, and the number of patients lost to follow-up in each arm of the study was shown. In the KBA group, 10 withdrew during the study and one participant withdrew from the control arm. Also, data from five participants in the KBA arm were lost. Despite these losses, overall losses to follow-up were 14.5 per cent. The withdrawal rate could have been predicted, as it is established that drop-out from mental health treatment for reasons other than symptoms improvement is a common problem. (316)

9.2.2 Issues related to GPs involved in the study and measurement of outcomes

GPs involved in the study

Descriptive information about the GPs involved in the pilot RCT yielded some interesting findings worthy of discussion. As outlined in Chapters 7 and 8, there were more GPs who worked in group practices compared with solo practices. This was somewhat predictable, given a trend observed by the researcher towards group practices in Australia. The finding may also reflect that GPs in group practices are more able to participate in research, perhaps because there is more support provided to GPs in group settings (from other GPs or practice staff).

Also, although there are more male GPs practicing in Australia than females (314), more female GPs than male GPs offered to participate in the study, which may indicate that Divisions approached more female GPs or that female GPs have a greater interest in research or the mental health area than male GPs. (317) Whilst teaching across Australia, the researcher has been told by many female GPs in
practice that they have a focus on mental health and women’s health. Also, the mean age of GPs in each arm of the study was 45 years. This is consistent with national figures (314), and might be representative of an ageing general practice workforce (318). It may also indicate a tendency to be more interested in being involved in mental health with increasing years in practice.

At the outset of the study, GPs were asked about their usual practice, including how often they routinely saw their patients with depression, whether they used DSM-1V criteria or assessment tools in the diagnosis of depression, and which treatment strategies they utilised. The results of these questions were presented in Chapter 8. The KBA program required that they carry out an extensive assessment of patients, that they on average see patients more frequently and use a wide range of strategies.

Therefore, it was likely to be a challenge for the GPs to be involved in the study, and the program would require changes in their usual practice. It was pleasing that a group of GPs volunteered for the study, attended the training, and carried out the program with their patients. The implication is that GPs a proportion of GPs are able to participate and be involved in a clinical intervention study, such as the KBA pilot study, that involves a relatively intense program and practice changes.

Measurement of outcomes

As outlined in Chapter 8, the study used a range of psychological assessment tools, including the DASS, the WHOQOL and the CGI. In relation to the DASS, while it was easy to identify DASS baseline measures, it was more difficult to ascertain whether many of the follow-up measures were for the three or 12-month collections. As a result, time from baseline was used in the analysis. Also, despite instructions in the use of the CGI during the GP training and reminders to use the tool during the study, there was a lot of missing data for this measure. The long duration of the study, and lack of use of this tool generally in practice, compared to the DASS, may have impacted on poor use of the CGI by GPs. The implication of these issues is that GPs experienced difficulties in complying with the study protocol in relation to the timing and use of the measurement tools.
Depression relapse itself was assessed retrospectively through a blinded review. This method gathered useful information, but was reliant on the skills of the recorder and the clinical notes containing the appropriate information. Other methods of determining depression relapse could have potentially been used (see the section on limitations of the study). The semi-structured interviews of GP and patient participants carried out at the end of the trial were not difficult to do and provided some very useful information. Having some structured questions provided quantitative information, and open-ended questions provided useful qualitative feedback. However, only a small number were collected due to time and funding constraints.

9.3 Discussion of the findings in relation to the study aims

9.3.1 Aim 1 - reduction in depression relapse

The primary hypothesis of this research was that the KBA program would reduce relapse rates of depression in patients with major depression, by one half, when compared with usual general practice care. The pilot found that while there were no significant differences in depression relapse rates between the KBA and control groups, there was a non-significant tendency for relapse to be reduced in the KBA group. This was an encouraging finding. These findings imply that there is possible merit in the KBA program with respect to relapse prevention, and it warrants further investigation. It should also be said that the primary hypothesis may have been too ambitious, aiming for a 50% reduction in relapse rates, and this figure may need to be reconsidered in future research.

A particularly interesting finding was that age was predictive of depression relapse, with increased age associated with decreased risk of relapse. Older patients (over 50 years) in the KBA group showed a significantly lower probability of relapse than those in the control group. This is a very promising finding, especially given that older patients are potentially likely to have had a greater number of past episodes of depression, which may predispose them to further episodes of relapse.(164) It may also be an important finding, as a study by Dowrick and colleagues (319), which assessed the views of GPs and patients on depression severity questionnaires,
found that older patients were less likely to be treated for depression. Having treatment options for older patients may be particularly important.

Possible reasons for this finding are that older patients may have been more motivated in their use the KBA program, or the structured nature or contents of the program may have been particularly appropriate for them. The variable of gender was also looked at in relation to depression relapse and it was found that women in both groups were less likely to relapse. This finding approached significance and the question as to why this occurred was raised. Further information on adherence to medication or co-morbid conditions (such as substance use) may be useful and warrant exploration.

9.3.2 Aim 2- reduction in depression severity

Secondary study hypotheses related to clinical outcomes including that, in patients with major depression treated by their GPs, the KBA program will reduce severity of the depression symptoms. The results of the pilot study indicated that there was a general decrease in depression scores over time, with patients in the KBA group and those in the control group who had experienced depression for less than six months showing similar values.

However, patients in the KBA group who had experienced depression for more than six months had higher depression scores at the start of the trial, but by 12 months after baseline, their depression scores were indistinguishable from those of most other patients. This reduction approached significance. A possible reason for patients in the KBA arm having more severe depression at the outset may have been because the GPs were enabled to offer another treatment to patients whom they were finding more difficult to manage. This was an interesting finding, and it was encouraging that patients with a more significant history of depression still improved. However, this result may be related to the potential for natural regression to the mean over time.
9.3.3 Aim 3 – enhancement of quality of life and production of greater clinical improvement

Enhancement of quality of life

As reported in Chapter 7 and 8, patient participants with depression for more than six months had lower physical QOL at baseline in both the KBA and control groups. This is understandable given the debilitating effect of depression, which has said to be equivalent to that of heart disease.\(^{(40)}\) By 200 days after baseline, the scores for physical, psychological and social QOL had improved, with these improvements persisting over the 12 months of the study. Hence, the KBA program and usual GP care were both associated with persistent improvements in quality of life, and these improvements were most striking for participants with more long term depression symptoms. Interestingly, the estimated means show that those in the intervention group started out lower on QOL-social, and increased more rapidly than the control group. This is not surprising given the KBA group had more severe depression at the outset of the study, and it could be expected that more severe depression would impact more significantly on social functioning.\(^{(40)}\)

In relation to QOL-environment, it was interesting that women showed higher values than men. Also, analysis of the interaction between antidepressant use and time showed that those patients not taking antidepressants had a steeper increase within 200 days of baseline that then levelled off. It is difficult to explain this finding, though possible explanations may relate to the potential side-effects or negative perceptions of their use as un-natural or addictive.\(^{(320)}\) However, the difference was not significant.

Production of greater clinical improvement

In relation to clinical improvement, unfortunately the results of the CGI were not meaningful due to the amounts of missing data. However, the other clinical outcome measures (relapse rates, depression severity) did provide meaningful information and so it was not a major problem that the CGI did not yield useful results. This
finding suggests that the CGI measure may not be appropriate for studies of KBA in the general practice setting.

Note - the fifth aim of the pilot RCT relating to the GP training program has already been discussed in Chapter 5.

9.3.4 Aim 4 – satisfaction with the KBA program

As outlined in Chapters 6, 7 and 8, a small sample of GPs and participants were interviewed several months after completion of the pilot study to ascertain perceptions of the KBA program, including satisfaction. Interview results indicated that the content of KBA was viewed by GPs and participants as relevant and satisfactory, and it was pleasing that it was so well received.

In regards to the KBA resources, the treatment manual and relaxation CD were generally well received. The journal was not found to be as helpful, which suggests that its use should be discontinued. Certain steps, in particular information on depression, coping skills and CBT, were reported to be particularly useful. This finding implies that psycho-education and skills-based strategies are particularly relevant and useful in a program such as KBA.

Also, although there was some information on anxiety in the program, several GPs suggested that more information on anxiety be included, even having a stand-alone step on anxiety. As reported in Chapter 2, co-morbidities of depression include anxiety disorders (59), and having a co-morbid anxiety disorder was a predictor of worsened functioning after recovery from the depression.(61) The literature and this study finding imply that more attention needs to be placed on anxiety in the KBA program.

9.4 Pilot RCT strengths and limitations

9.4.1 Study strengths

The key strength of this RCT is that it has addressed the important clinical problem of depression and depression relapse, and that it involved a new clinical intervention,
the KBA program. The RCT addressed a number of varied aims, related to both clinical and process outcomes. It utilised a strong study design (RCT). Cluster randomisation was appropriate to an intervention study across a number of practices. The study was undertaken in multiple and varied general practices, both solo and group, in urban and rural locations, suggesting that the results may be generalisable across a range of practices.

9.4.2 Limitations of the study

GP participation in the KBA program required a lot of time and effort, and concerns about this may have influenced recruitment to the study. However, the major limitation of the study was recruitment of patients. Due to lack of statistical power as a result of lower than desired numbers of participants, the validity of the findings may be questionable. Future studies would need to address these issues.

Difficulties were experienced in recruiting the required number of patient participants to the RCT. Even though recruitment occurred over eight months, and reminders to recruit were incorporated into the study, fewer than required patients were recruited to the study. This was not unexpected as recruitment of patients through GPs is reported to be very difficult, particularly in treatment-based longitudinal studies.(321) Also, it was not possible to extend the recruitment phase due to time and financial constraints.

As it proceeded there was some loss of patients from the study, which were all due to significant life events intervening. Unfortunately, an additional loss of patient data occurred when a GP moved practice. It was difficult to safeguard against this sort of event as GPs needed to hold onto patient progress records during the study so they could be used during follow-up. However, an alternative may have been to gather photocopies of documents at intervals during the study.

A further limitation of the pilot study was the potential lack of standardisation of clinical data collection, in relation to depression severity and relapse, and other outcome measures. A stronger methodological approach to retrospective review of case note records and regular collection of basic clinical measures by un-blinded GPs could have been used, and use of an additional means of gathering relapse
information such as structured interviews performed by external and blinded research assessors could have been considered.

A further tool, the ‘Longitudinal Interval Follow-up Evaluation’ (LIFE), was found after the commencement of the study. LIFE is designed to assess the course of long-term psychiatric disorders, and consists of a semi-structured interview and rating system that measures several areas of functioning. This tool could potentially provide the additional means of gathering information in studies of depression relapse prevention, and it may have provided more reliable information in relation to depression relapse in the KBA study.(322)

Another limitation of the study that emerged after the data collection was that the KBA and control groups were imbalanced on severity of initial depression. Unfortunately this relatively disadvantaged the KBA intervention group, whose depressions were typically more severe, and served to raise the bar for the RPP to demonstrate efficacy. Patient participants in the KBA study were followed for 12 months. In relation to depression recurrence, which refers to a later return of symptoms after a period of remission,(26) and the determination of the long-term effectiveness of a treatment program, it would have been useful to follow patients for two years. However, a two-year time-frame was not practically possible. In addition, in relation to the KBA intervention, collecting some health economic data would have provided potentially valuable information on the cost of the intervention.

A further potential limitation may have been related to the control group GPs and their patients who were potentially at risk of demoralisation due to lack of participation (training, treatment options and support), and the study therefore at risk of bias.(323) One option would have been to attempt to equalise this source of bias, by introducing a basic structured program to lift the level of treatment expectation in the control group. On the other hand, control GPs were given three hours of training, and it was seen as important not to influence control GPs’ treatment of patients away from ‘usual care’. In addition, the GPs were offered the KBA training on completion of the study, and many took up this offer.
9.5 Interpretation of the pilot RCT in relation to comparable literature

As highlighted in the literature review, initially only one comparable study by Katon and colleagues (8) from the USA was located. This study consisted of a RCT involving 386 patients, who were randomised to intervention and control groups. As outlined in Chapter 2, the intervention in this study was of relatively low intensity, including education, two primary care visits with a specialist, and several telephone consultations over a one-year period with feedback to the GP. The KBA program was more intensive, and it utilised specially prepared resources. In the American study, the intervention was built on collaboration between the specialist, study nurses and the GPs, whereas KBA was delivered solely by the GPs involved in the study.

The intervention in the American study aimed to improve long-term adherence to medication, to increase awareness of prodromal symptoms, and the ability to identify recurrence and to increase proactive steps to manage the symptoms. As outlined earlier in this chapter, the KBA study aims were different and possibly more extensive. They were to reduce severity and relapse of depression and improve quality of life, as well as to be a satisfactory program from patient and GP perspectives.

In the US study each patient’s adherence to medication was assessed at three monthly intervals by a blinded interviewer, prescriptions were monitored and a depression assessment tool was used during the telephone interviews. The KBA study utilised different measures, namely assessment tools given to the patient by the GPs, a semi-structured telephone interview at the end of the study, and retrospective case-note audit. As previously suggested, the KBA study would have benefited from structured interviews performed by external and blinded assessors.

It was reported that patients in the USA intervention group had significantly greater adherence to medication and were more likely to refill prescriptions during the 12-month follow-up. These individuals also had fewer depressive symptoms, but their relapse rates were not reduced. Similarly, depression scores were reduced in the KBA study, and the tendency was for relapse rates to be reduced, although not significantly. However, older patients in the KBA group had lower rates of relapse.
One weakness in the USA study was the high level of missing data (20%), compared to 14.5% of missing data in the KBA study. The Katon (8) study was specific to the American health system and in particular to a Health Maintenance Organisation, and therefore the generalisability of these findings to other groups or health systems is questionable. The KBA study was carried out in the Australian setting, but it is likely that the results can be generalised across a wide range of general practices.

The study from the USA concluded that primary care requires systematic change to improve chronic illness management, and that strategies such as education and activation, monitoring of adherence and outcomes of treatment are important.(8) The KBA program incorporated principles of CDM, and addressed the strategies recommended by Katon. The study’s major recommendation, that a more intensive RPP might be needed to decrease relapse rates, was pivotal in the development of the KBA program.(8)

In recent years in the Netherlands, there has been research work carried out on primary care depression relapse. In a 2008 literature search, a doctoral thesis by Smit (19) was located. This researcher carried out a RCT involving 267 patients with depression assigned to one of four treatment arms – usual care that the GP deemed appropriate, an enhanced care program, and enhanced care program with psychiatric consultation or brief CBT. The enhanced primary care program involved a structured psycho-educational program, aiming to reduce depression relapse. It involved three individual face-to-face sessions (in which a relapse prevention plan for each individual was developed), followed by four telephone monitoring contacts per year over three years. Patients were provided with a book. This research appears to have been modelled on the work of Katon (8), but with some additional treatment and more treatment arms.

Results indicated that there were no statistically significant differences between treatment groups, and it was concluded that enhancement of GP treatment with the relapse prevention program had no additional benefits over usual care. These results were published in 2006-7.(18, 19) An economic evaluation of this study has also been carried out by Stant (20) and a meeting abstract reporting that the RPPs were not cost effective compared with treatment as usual.
This research has similarities to the work by Katon (8), and the research presented in this document. All have involved developing and studying primary care interventions aiming to prevent depression relapse. The RPPs have been studied in RCTs and compared to usual GP care. One difference is that the study by Smit (18) involved several treatment arms. The Smit (2006-7) intervention was somewhat more complex than the Katon (8) intervention.(18, 19, 324) However, the KBA intervention is more intensive and multi-faceted than either of these RPPs. Another key difference was that the KBA program is fully manualised.

There have been several recent studies of interest in the field of depression relapse prevention research. A study by Conradi and colleagues (2008) focussed on the treatment of persistent dysfunctional thinking in acute-phase primary care patients with histories of multiple depression recurrences. A randomised trial was carried out, comparing 10-12 CBT plus psycho-education sessions with a psychotherapist aiming to promote social connection and restructuring of cognitions, usual care by the GP (supportive therapy, possible medication or referral), and a third arm consisting of psycho-education (three face-to-face sessions and 3-monthly follow-up telephone calls). A reliable depression measure was used and two year follow-up carried out.

The results of this study indicated that in patients with four or more prior episodes of depression, CBT was better than usual care, but not in patients with three or fewer prior episodes. It was suggested that rumination was a significant problem in patients with recurrent depression. The results support the value of a multi-modal approach, in particular psycho-education and CBT, two approaches included in the KBA program, and also support a moderate number of treatment sessions as in the KBA program. Also, the study highlights that different approaches may be necessary depending on the number of previous episodes of depression.(325)

The other study by Gonzalez et al (2007) analysed the effectiveness of several group therapy programs in the secondary prevention of depression in primary care patients with mild-to-moderate depression. Psychologists ran the three group programs, involving CBT, promotion of coping resources or social support. All patients improved initially, but at 12 months it was found that patients in the CBT and coping resources group had improved more than those allocated to social support group. This was a small study (60 patients), but it is interesting that the therapies were delivered in the group format and there were persisting results at 12 months with several
groups.(326) The KBA program also lends itself to the group setting, and has in fact been used in this clinical context at a Division of General Practice.

9.6 Summary

The pilot RCT design addressed most of the threats to internal validity, but was limited in some design aspects. It was satisfying that a reasonable number of GPs agreed to participate in the study, however the GPs did experience some difficulties in using the assessment tools.

The first aim of the study in relation to reduction in depression relapse was not achieved. However there were some promising findings, such as a tendency for relapse to be reduced in the KBA group, and there was a significant reduction in relapse in older patient participants. The second aim related to depression severity was not achieved, but again decreases in depression scores were noted, particularly in those who had experienced depression for more than six months. These findings warrant further investigation. The final aim of the study related to satisfaction with the KBA program was achieved. The content of KBA was highly regarded, along with the resources.

The KBA study has been considered in relation to the Katon (8) study and a more recent study by Smit (18, 19) in the Netherlands. These two studies had non-significant findings in relation to depression relapse.(8, 18, 19) The KBA study had some interesting findings warranting further investigation, and also involves a more holistic, intensive and multi-faceted program than either of these RPPs. Two other studies were considered as they highlighted the importance of CBT in managing cognitive ruminations in patients with recurrent depression and the value of administering such therapies in the group setting. The KBA program has clinical advantages as it includes CBT, is manualised and applicable to the group setting. The implications of the pilot RCT and recommendations from the study will be presented in the concluding chapter which follows.
Chapter 10. Conclusion

10.1 Introduction

This research work addressed the very important clinical problem of depression relapse. It involved a multi-phase approach to the conceptualisation and development of a new primary care depression RPP, the KBA program, culminating in a pilot RCT of the program. The implications and recommendations from the earlier phases, including the exploratory phase and the GP training program, have already occurred (see Chapters 4 and 5). The implications and recommendations from the pilot RCT are presented in this chapter. In addition, recent changes to the Australian primary care mental health system and relatively new depression treatment approaches will be highlighted, as they have implications for the KBA program and future research.

10.2 Pilot RCT implications and recommendations

A number of implications of the RCT findings have been suggested during the discussion in Chapter 9. They are now summarised and recommendations arising from them are provided.

10.2.1 GPs

A proportion of GPs are able to participate and be involved in a clinical intervention study such as the KBA pilot RCT that involves a relatively intensive program and practice changes. Some groups of GPs are less well represented.

Recommendation: Research involving GPs in the study of primary care mental health intervention programs (such as the KBA RPP) should continue to be pursued. It is important to encourage and support particular GP groups to participate in research, such as solo GPs, younger GPs and male GPs.
10.2.2 Measurement Tools

GPs experienced difficulties in complying with the study protocol in relation to the timing and use of measurement tools. In particular, the CGI measure may not be appropriate for a study of KBA in the general practice setting.

Recommendation: It is important to choose measurement tools carefully in relation to studies carried out in the general practice setting, and to limit the number of times the tools are to be collected by GPs. In future studies of KBA, the use of the CGI should be discontinued.

10.2.3 Study design

The pilot RCT experienced limitations in study design, including patient participant recruitment and standardisation of data collection. Also, longer term follow-up of patients and the collection of health economic data in relation to the KBA intervention would be valuable.

Recommendation: Subsequent research in regard to the KBA program should incorporate learning from the pilot study in relation to study design. Possible solutions to patient recruitment should be explored, such as recruiting more GPs to such studies who can then recruit more patients, and allowing more time for patient recruitment. In future studies the use of structured interviews carried out by blinded assessors should be considered. These may incorporate use of the LIFE. Future studies should adopt two-year patient follow-up and incorporate the collection of health economic data.

10.2.4 KBA and depression relapse and severity

The KBA program addressed an important clinical area, and there has been little research in relation to primary care depression relapse in the past. There is possible merit in the KBA program with respect to relapse prevention (particularly in older patients), and with respect to depression severity (particularly in patients with more severe depression), warranting further investigation. Also, other primary care RPPs have not yet resulted in significant findings.(8, 18, 19)
**Recommendation:** Depression relapse prevention is an important area and primary care depression RPPs are needed. Given the nature of the findings in the pilot RCT, further studies of the KBA program should be carried out.

### 10.2.5 KBA resources

The KBA manual and relaxation CD are useful resources. In relation to content of the KBA program, psycho-education and skills-based strategies are particularly relevant and useful, and more attention could be placed on anxiety. The journal component of the KBA program is not considered useful.

**Recommendation:** The resources should continue to be improved, included in further studies and potentially be made more widely available. Consideration should be given to expanding the steps related to these topics, and consideration should be given to including more information on anxiety to the KBA program. The KBA journal should be discontinued.

### 10.3 The Australian primary mental health care system

Since writing the 2004 Primary Care Mental Health Journal paper on the KBA program (Chapter 4), there have been further changes to the Australian primary care mental health system which are important to be aware of, and which will influence the implications of this RCT. Some of these are reported in the 2008 Australian Family Physician paper (provided in Chapter 11), but there have been additional changes in the last 12 months which are relevant to the importance placed on depression relapse prevention in the Australian context and future research.

On 1st November, 2006, the Better Access to Psychiatrists, Psychologists and GPs through the MBS was introduced to address persistent barriers for patients to being able to access mental health care. The Better Access Initiative encourages all GPs to work more collaboratively with psychiatrists, clinical psychologists, psychologists, occupational therapists, and social workers to improve patient outcomes. It aims to streamline access to appropriate psychological interventions in primary care by providing MBS items to mental health professionals.(327)
Under Better Access, new processes and Medicare item numbers were introduced. To access a mental health professional, referral by the GP and Item number 2710, the mental health assessment and treatment plan, are required. The Better Access program incorporated principles of CDM. Better Access enables all GPs to undertake a patient assessment, develop a care or treatment plan and refer to a mental health professional. The GP maintains a central role in coordinating care, and can also continue to offer FPS to their patients if they have the appropriate training and it is clinically appropriate.

Even more recent changes, announced in 2009 and to take effect in 2010, require that GPs have ‘Mental Health Skills Training’ (similar to previous ‘Level One’ training discussed in Chapter 2), to be able to access the existing Medicare rebate for the mental health assessment and plan. GPs not undertaking the training will still be able to do a mental health assessment and treatment plan will receive a lesser rebate. Developments in the health care system in recent years in Australia are thus conducive to GPs carrying out thorough assessments of individuals with depression and developing comprehensive management plans.

The changes to the Australian system outlined above will influence the role of relapse prevention in depression management. Relapse prevention strategies have been incorporated into the templates for mental health assessment and treatment plans provided by the Department of Health. The related item numbers provide rebates for GPs to spend the time on management planning, including relapse prevention. The plan also involves identification of key issues, goal-setting, treatment strategies and potential referrals. The GP can deliver treatment strategies through ‘FPS’ sessions or refer on to a mental health professional.

There has been greater access to MHPs since the ATAPS programs (outlined in Chapter 2) and Better Access were introduced. ATAPS programs, based in Divisions of General Practice, provide psychological treatment via MHPs to patients with mental health problems such as anxiety and depression. In addition, the recent Federal Mental Health Nurse Initiative enables general practices to employ a mental health nurse to see patients with more severe and chronic mental health problems. The greater awareness and access to MHPs has raised the possibility of MHPs delivering KBA to patients with depression in the community and involving MHPs in future studies of the program. This approach is supported by evidence from studies.
which have demonstrated that depression treatment interventions can be delivered successfully by MHPs in the primary care setting. (328)

A number of Australian and Canadian studies have recommended that depression care be coordinated by care managers. (329-332) In particular, a systematic review by Christensen, Griffiths et al (2008) examined the effectiveness of different components of depression care in primary care. The review concluded that a case management approach by a provider other than a doctor was associated with improved depression outcomes. Limitations of this study were cited as identifying all the relevant literature and difficulty analyzing which components of complex interventions were effective. (329) A further limitation not discussed relates to the existence of differing care systems in different countries and the influence of this on study findings. In the USA, for example, there are far fewer primary care physicians per capita than in Australia, and in many locations consumers self-refer to medical specialists. In other words, the gate-keeper and care coordinator roles so firmly embedded in Australian practice is not reproduced in the USA. Hence it is more applicable in the US context to involve other coordinators. The recent changes in Australia with mental health planning have cemented the role of the GP in care management.

10.4 Potential modifications and additions to the KBA program

10.4.1 Influence of new therapies and thinking

Since the inception of the KBA program, there have been further developments in psycho-social treatments for depression. The findings in the pilot RCT and these developments raise the possibility of further modifying the program to incorporate additional approaches and strategies. There are several areas of interest, the first being mindfulness and MBCT, and the second being Acceptance and Commitment Therapy (ACT).

In recent years, at conferences and in the literature, there has been greater emphasis on the role of mindfulness and MBCT in depression management. As outlined in Chapter 2, a MBCT approach that teaches patients cognitive-behavioural skills and meditation has been found to reduce relapse in patients who have had three or more episodes of depression. (123, 192) Brief material on mindfulness was
incorporated into the KBA program and a mindfulness-based meditation was provided on the relaxation CD. This area could be expanded on in the KBA program in future.

ACT has also come to the fore, with published papers and an increasing number of clinicians undertaking ACT training. ACT is a ‘mindfulness-based behaviour therapy’, which incorporates mindfulness and ‘values-guided behavioural strategies’. ACT seeks to address psychological problems by changing the function of events rather than changing their content. In contrast to traditional therapies such as CBT, symptom reduction is not the primary goal. Rather than evaluating thoughts (as in CBT), it encourages the individual to view thoughts as a series of words or stories.

ACT is based on the notion that individuals often conceptualise their distress as a problem that can be identified and controlled. ACT, however, proposes that this approach will often fail, and in the long-term, will often cause additional psychological distress. For example, endeavouring to control anxiety often induces more anxiety. Instead, ACT proposes that psychological distress does not need to be controlled in order for a valued and meaningful life to be achieved. ACT suggests that acceptance of distressing emotions or events and willingness to experience them is an alternative, and it utilises a number of techniques, such as mindfulness, observation of thoughts and defusion of unhelpful thoughts.

The work of Professor C. Dowrick in the United Kingdom in recent years may also influence KBA in future. In his book, “Beyond Depression”, Dowrick proposes other ways of understanding depression, and explores the importance of understanding the person’s story, and their sense of purpose and meaning in enabling them to deal with depression. This is consistent in some ways with the philosophy of ACT, and the role of purpose and meaning which are already highlighted in the KBA manual. As explained in Chapter 2, existential and narrative approaches were drawn upon in writing KBA. In addition, Dowrick and Associate Professor K. Hegarty have also explored the concept of resilience, and the importance placed by individuals on developing personal strengths in managing adversity. Again, some aspects of KBA are consistent with this idea and could be further developed in future modifications of the program.
10.4.2 The development of computer-assisted therapy

Computer-based therapy is being used more widely in Australia and internationally. This has come about because of difficulties accessing clinical services in some countries.\textsuperscript{(337)} There has also been a substantial amount of work done on CBT being delivered via computer programs and online, and there is evidence that these programs are efficacious and can reduce costs.\textsuperscript{(338, 339)} As a result of these developments and a perceived need in the South Australian community, a computer-assisted version of KBA has recently been developed. The findings of the RCT also informed this development, as it was thought that a computer program might appeal to younger patients. The computer-assisted version is now being used in some primary care settings in Australia.

10.5 Conclusion

In conclusion, depression and depression relapse are significant problems in our community, and important areas to research.\textsuperscript{(8, 34)} Although many patients will be managed in primary care, with much of their care being delivered by GPs,\textsuperscript{(17)} very little research has previously been carried out on depression relapse prevention in the primary care setting. Key research by Katon (2001), concluding that a more intensive RPP might be needed, and Segal (2003) suggesting that it might be possible to take the active ingredients of proven treatments and design novel preventive treatments that are skills-based, informed the KBA program.\textsuperscript{(8, 11)} Work by Katon (8) has been pivotal in the area of primary care RPPs, and more recently, similar work has been carried out in the Netherlands. These studies have had non-significant findings in relation to depression relapse. The RPPs are less intensive or multi-faceted than KBA, and the KBA intervention also offers a manualised format.\textsuperscript{(18, 19)}

The research carried out on KBA has succeeded in continuing to address the gap in knowledge and evidence in relation to effective primary care RPPs. The overall aim of this work was to develop and implement a primary care depression RPP and to evaluate its acceptability and effectiveness. The body of this work describes a careful and extensive multi-phase approach, from conceptualisation of ideas to the
development of a new depression RPP, the KBA program. This work has succeeded in the development of a new and unique primary care depression RPP, involving a multi-modal approach and incorporating a range of evidence and skills-based approaches.

As support for incorporating CDM principles into depression treatment was found in the literature,(64, 94, 340) approaches consistent with this were incorporate into KBA. Also, reports were located that bibliotherapy was a useful treatment strategy,(50, 121, 190, 199) and hence the development phase also involved the writing of a 237-page treatment manual. A number of reports and Federal Government GP training initiatives supported the need for education about mental health to be a priority for GPs, informing the development of the KBA training program, which was well-received by the GPs. In terms of using the training program in the future, some aspects of the training could be improved, but it was concluded that the education program should continue to be offered to GPs as part of ongoing professional development.

This pilot RCT which followed addressed a number of aims, related to both clinical and process outcomes. Although several of the aims were not achieved, a tendency was noted towards relapse rates being reduced in the intervention group, and significantly in older people. Also participants in the KBA group who had experienced depressive symptoms for more than six months had reductions in depression scores approaching significance. These findings suggested that there is possible merit in the KBA program with respect to relapse prevention and depression severity, enough to warrant further investigation. Further studies are suggested, in particular exploring the use of KBA in older patients and the use of other program formats (such as computer-assisted format) in younger people.

Recent qualitative studies of patient experience of depression management suggest that effective and acceptable guided self-help interventions for depression are needed.(341, 342) There were indications in this pilot research that KBA is able to be relatively easily incorporated into clinical practice, assisted by its manualised format. The content of the KBA program was viewed as highly relevant by GPs and patients, and all participants indicated that the KBA manual and relaxation CD were useful resources. The perceived value of the KBA resources was a key finding from this research, along with the potential to continue to utilise and improve the KBA program

214
and the associated resources. In addition, information on the more recent depression treatment approaches, such as MBCT and ACT, could be expanded in the KBA program.

The study was undertaken in multiple and varied general practices, suggesting that the results may be generalisable across a range of practices. Unfortunately there were difficulties recruiting GP and patient participants, which limited the power of this RCT, and these issues will need to be addressed in future research. There were also issues in relation to the follow-up of patients and administration of assessment tools, and in future studies the use of structured interviews carried out by blinded assessors should be considered. These should adopt two-year patient follow-up and incorporate the collection of health economic data.

Over the past eight years there have been many developments in the Australian primary care mental health system. Notable changes since completion of the pilot RCT have been further emphasis on mental health care planning, including relapse prevention, and improved access to mental health professionals (MHPs) through government funding of their services in late 2006. These changes are outlined in the final publication from the Australian Family Physician(3) provided in Chapter 11.

The KBA program is now being used by a number of primary care mental health programs and MHPs in Australia, assisted by its manualised format, and there is potential to carry out research incorporating such programs and professionals in the future. Recent developments in relation to the KBA program also include the creation of a computer-assisted version of KBA, and this version is now being used in some primary care settings in Australia. It is also pleasing to report that there have been further modifications to the program and associated resources (including development of the computer-assisted version).

Given that no other primary care depression RPP has as yet proven to be effective, and the pilot RCT had some promising findings, grant applications are being made to carry out further research on the KBA program, in particular involving MHPs in delivering the program. In addition, the KBA manual and CD were launched by the SA Minister for Mental Health, the Honourable Gail Gago, in 2007. (Publicity regarding KBA and the launch is provided in Appendices 20-22). More recently the resources have been published across the English-speaking world by Radcliffe
Publishers (October, 2009). The researcher has also been contracted to write a separate resource on anxiety. These developments attest to the value of mental health research being carried out in the primary care setting, with the potential to subsequently be translated into practice.
Chapter 11. Closing Statements: Publication

It was concluded by Katon (2001) that primary care requires systematic change to improve chronic illness management, and that strategies such as education and activation, monitoring of adherence and outcomes of treatment are important. The final publication returns to the principles of CDM, including use of management plans and a team care approach, and their application to the management of depression.

It is fitting that this final paper provides a context for the place of depression RPPs such as KBA in the primary care setting and in the Australian context. It gives an overview of Australian Government initiatives for the treatment of depression in primary care and the coordination of treatment by primary care providers. The article reviews relapse and recurrence of depression and useful relapse prevention strategies, why a relapse prevention plan may be useful, and briefly describes the KBA program.

Title: Management of recurrent depression

Statement of authorship:

Dr C. A. Howell conceived, conceptualised, and wrote the manuscript.
C. Marshall and M. Opolski contributed to the paper in relation to chronic disease management principles, read the article and provided feedback.
_Australian Family Physician, v. 37 (9), pp. 704-708, September 2008._

NOTE: This publication is included on pages 218-222 in the print copy of the thesis held in the University of Adelaide Library.
Chapter 12. Appendices

Exploratory study:
A1 HREC application
A2 HREC approval
A3 Introduction to the study
A4 GP training learning outcomes and outline of the training
A5 Exploratory study information sheet
A6 Exploratory study consent forms
A7 GP data collection forms
A8 Participant data collection forms
A9 Assessment tools (DASS, QOL, 0-10, CGI)
A10 KBA checklist for GPs
A11 GP training evaluation questionnaire

Pilot RCT:
B1 GPMHSC application and accreditation approval
B2 RACGP CPD application
B3 GP training manual
B4 Pilot study consent form
B5 Pilot study information sheet
B6 GP data collection forms
B7 Participant data collection forms
B8 Assessment tools – DASS, WHOQOL, CGI
B9 Checklist
B10 ‘Possible reasons for loss to follow-up and/or treatment’ sheet
B11 Pre- and post-test questionnaires
B12 GP training evaluation forms
B13 Letter sent by Divisions of General Practice to recruit GPs
B14 Case note audit record
B15 Relaxation CD script
B16 KBA bookmark
B17 Sample newsletter
B18 Post-interview questions
B19 Interview results
B20 The KBA launch
B21 Letter to the Premier of SA about the launch
B22 Publicity about the KBA program
Appendix A: Exploratory Phase
A1 - Human Research Ethics Committee Application
PROJECT NO: H/

THE UNIVERSITY OF ADELAIDE HUMAN RESEARCH ETHICS COMMITTEE

Applications will be considered in terms of the University's guidelines on the ethics of human research, based on the requirements of the National Statement on Ethical Conduct in Research Involving Humans, 1999 - refer application information material, including the list of headings applying to all applications. Submit the completed application including Information Sheet and Consent Form with 9 duplicate copies, to the Secretary, Human Research Ethics Committee, Office of the Vice-Chancellor, University of Adelaide (Ph. (08) 830 34014, Fax (08) 830 33417, email helen.malby@adelaide.edu.au)

APPLICATION FOR ETHICAL APPROVAL OF PROJECT INVOLVING HUMAN SUBJECTS - COVER SHEET - SUMMARISING PROTOCOL & INCLUDING INVESTIGATORS' SIGNATURES
Please attach this to the front of the application

<table>
<thead>
<tr>
<th>APPLICANT Name</th>
<th>include title Professor/Dr/Ms/Mr and Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Cate Howell CSM, Churchill Fellow</td>
<td>General Practitioner, Research Fellow &amp; Associate Lecturer, Department of General Practice, Adelaide University.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DEPARTMENT</th>
<th>including campus/institution contact address</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of General Practice, Adelaide University, North Terrace, Adelaide. SA. 5005.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Phone No and email address</th>
</tr>
</thead>
<tbody>
<tr>
<td>(08)83033460</td>
</tr>
<tr>
<td><a href="mailto:cate.howell@adelaide.edu.au">cate.howell@adelaide.edu.au</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OTHERS INVOLVED</th>
</tr>
</thead>
<tbody>
<tr>
<td>The research is being carried out towards a Ph.D.(Medicine), Department of General Practice, Adelaide University</td>
</tr>
<tr>
<td>Dr Justin Beilby, Head of Department, Department of General Practice (Principal Supervisor)</td>
</tr>
<tr>
<td>Professor John Marley, Pro Vice Chancellor, University of Newcastle (Co-supervisor)</td>
</tr>
<tr>
<td>If this is a student project please indicate name/department/candidature</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROJECT TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study of a primary care treatment approach aiming to reduce relapse of depression</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LOCATION OF RESEARCH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of General Practice at Adelaide University and the University Family Practice Network</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATE PROJECT TO BEGIN</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 2001, conditional upon ethics approval</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ESTIMATED DURATION OF PROJECT</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-4 years</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SOURCE OF FUNDING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support from the Department of General Practice; funding being sought from NHMRC, Rotary and Beyondblue</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AIMS OF PROJECT please give concise description in lay terms</th>
</tr>
</thead>
<tbody>
<tr>
<td>The proposed project aims to develop a depression relapse prevention program, to pilot its use in the general practice setting and to evaluate its effectiveness. Piloting the study will provide more information about the feasibility of delivering this treatment approach, its acceptability to GPs and patients, and will facilitate design of a potentially larger future study.</td>
</tr>
</tbody>
</table>
**ETHICAL IMPLICATIONS OF PROJECT**

Since patients will be approached by their General Practitioner (GP) to participate in the study, there will be a requirement to obtain informed consent. Furthermore there is a need to ensure that any personal health information collected will be protected in terms of privacy and confidentiality. Consequently:

- no approach will be made to subjects until their own GP has obtained written informed consent to be involved
- information sheets will be provided to subjects
- subjects will be informed that they may refuse to participate in the study, or should they wish to withdraw, that their treatment will not be compromised
- security procedures will be implemented in data storage and access
- final analysis and reporting will utilise only deidentified data.

**PLAN/DESIGN OF PROJECT brief description in lay terms**

The study is composed of two parts:

Part (1) Pilot study of a primary care treatment approach or intervention aiming to reduce relapse of depression. Its effectiveness will be evaluated via a cluster randomisation trial (practices will be randomised to either carry out the intervention or “treatment as usual” (forming the control group).

Part (2) Qualitative (“process”) evaluation of the intervention, based on pre and post intervention interviews.

The primary outcome will be reduction in relapse/recurrence rates at 12 months. Secondary outcomes will include increased remission time between episodes of depression and reduced severity of relapse, improved adherence to treatment and improved quality of life.

**DRUGS**

<table>
<thead>
<tr>
<th>Will drugs be administered to subjects?</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>If so give name of drug(s)</td>
<td></td>
</tr>
<tr>
<td>Dosage:</td>
<td></td>
</tr>
<tr>
<td>Method of administration</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is the administration for therapeutic purposes?</th>
<th>YES / NO</th>
</tr>
</thead>
</table>

| Will the project be conducted under the        | YES / NO |
| Clinical Trials Notification (CTN) Scheme?     |          |
| Clinical Trials Exemption (CTX) Scheme?        |          |

<table>
<thead>
<tr>
<th>Is Commonwealth Department of Health permission required?</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>If so, has permission been obtained?</td>
<td>YES / NO</td>
</tr>
</tbody>
</table>
SUBJECTS

- Source: Four of the University Family Practice Network of practices and two to three other practices (urban and rural).

- Age range: 18 to 70 years of age

- Selection criteria: men and women with a depressive disorder, diagnosed according to usual clinical practice and of sufficient severity to warrant treatment; freely able to give informed consent and to be followed up for 12 months

- Exclusion criteria: undergoing a separate structured treatment program, psychotic, unable to complete English language questionnaires / interviews.

SIGNATURE OF ALL INVESTIGATORS NAMED IN THE PROTOCOL

Date
14 December 2001

Dr C A Howell
General Practice

Dear Dr Howell

PROJECT NO: H-63-2001  Study of a primary care treatment program aiming to reduce relapse of depression

I write to advise you that the Human Research Ethics Committee has approved the above project. A copy of the endorsed application form is enclosed for your records.

Approval is current for one year. The expiry date for this project is: 31 December 2002

Where possible, subjects taking part in the study should be given a copy of the Information Sheet and the signed Consent Form to retain.

Please note that any changes to the project which might affect its continued ethical acceptability will invalidate the project’s approval. In such cases an amended protocol must be submitted to the Committee for further approval.

A standard renewal/status report form is enclosed for future use. Please fill this in prior to the above expiry date and send to the Committee’s Secretary. Applications for renewal must include a brief report on the project’s progress and on any ethical issues which may have arisen. It is a condition of approval that you inform the Committee, giving reasons, if the project is discontinued before the expected date of completion.

Yours sincerely

[Signature]

CE MORTENSEN
Convenor
Human Research Ethics Committee
A3 - Introduction to the Study

AIMS: The ideas on which this study is based initially developed during a year 2000 Churchill Fellowship to the United Kingdom on the primary care management of depression. International experts acknowledged the high relapse rate of depression and the lack of knowledge about preventing the return of symptoms. Since the Fellowship the ideas have developed into a framework for a primary health care depression relapse prevention program. Its underlying goal is the provision of integrated high quality evidence-based care. The proposed research aims to trial this innovative program in urban and rural areas.

The proposed study aims to implement a primary care depression relapse prevention program and evaluate its effectiveness via a cluster randomisation trial. The primary hypothesis is that the program will reduce the relapse rate of depression by one half when compared with usual general practice care. Secondary hypotheses include increased remission time, reduced severity of relapses, improved adherence to treatment, earlier identification of symptoms of relapse and improved quality of life. Qualitative research will be undertaken regarding practitioners’ and patients’ perceptions of the program (including level of satisfaction).

The relapse prevention program is based on a bio-psycho-social approach and involves 10 steps. It is unique because it involves an eclectic treatment approach, incorporating a range of psychosocial strategies. The program involves:

1. initial assessment (including medical status) and goal-setting with patients;
2. education about depression, including use of antidepressants and community resources (involvement of family if appropriate); support and encouragement;
3. general health promotion and lifestyle advice (nutrition, exercise and sleep);
4. development of coping skills including problem-solving, stress management, and dealing with panic;
5. key cognitive strategies to address the depression and co-morbid anxiety;
6. psychological interventions addressing issues such as self-esteem;
7. encouragement of pleasurable / meaningful activities;
8. fostering of supportive social relationships / social skills;
9. development of an emergency plan in the event of early signs of relapse.
   regular review of progress and adherence / skills (over an 18 month period);
BACKGROUND SYNOPSIS
Depression is commonly managed in the primary care setting. Management involves the use of medication and/or psychosocial interventions. In the past few years the use of psychological treatments in primary care has begun to be studied. It has been recommended that more research is needed in the area of relapse prevention, that risk factors be addressed, and that more complex interventions might be needed to decrease relapse rates. The proposed study incorporates these recommendations. The Department of General Practice at the Adelaide University has a strong interest in mental health, and is very supportive of this research.

RESEARCH PLAN SYNOPSIS
Given that a complex intervention is proposed, the study will include preclinical and exploratory phases, to prepare and trial the intervention (including assessment tools and intervention materials). A cluster randomised trial of the program with clustering at the practice level will then be carried out. One hundred and twenty subjects will be recruited for each of the intervention and control groups. The intervention will be comprehensively evaluated using mixed quantitative analysis of the randomised clusters (comparing relapse rates), and qualitative process evaluation methods (pre- and post-intervention interviews).

OUTCOMES AND SIGNIFICANCE
- Depression and anxiety are leading causes of disease-burden in Australia. One in five Australians will experience depression at some stage. Depression is distressing and disabling, and suicide is a major risk. It is costly for the community in terms of time lost from work, family breakdown and health care costs. The cost of untreated depression in Australia is estimated to be 5 billion dollars annually. If the rate of relapse could be reduced, there would be major benefits for the individual, their family and the community.
- If this innovative program is successful, the primary outcome will be reduced rates of relapse of depression. A number of secondary outcomes relate to increasing remission time between episodes of depression, reducing severity of relapses and improving quality of life. Satisfaction with the program will be an important outcome.
- The relapse prevention program has a health education and promotion focus, and involves the provision of continuity of care.
- This program fits neatly with current national mental health initiatives, and encourages up-skilling of primary care practitioners in mental health.
A4 - GP training learning outcomes and outline of the training

KBA Training Session

Learning Outcomes

At the end of training, participants will
- understand the study of a primary care treatment program aiming to prevent relapse of depression
- have a greater knowledge of the aetiology and epidemiology of depression
- review the biopsychosocial model of depression
- have an understanding of the chronicity of depression
- have a greater awareness of the co-morbidity of depression, anxiety and alcohol and drug use disorders
- understand the concepts of relapse and recurrence of depression and have an overview of the literature relating to relapse and recurrence of depression
- understand the 10 step relapse prevention program and its evidence base
- gain knowledge of the management of depression including use of antidepressants and role of psychosocial treatments

Training Outline

Introduction to the study of a primary care treatment program aiming to prevent relapse of depression.

Background information
- aetiology and epidemiology of depression
- review of the biopsychosocial model of depression
- chronicity of depression
- co-morbidity with anxiety, alcohol and drug use disorders
- relapse and recurrence of depression (meaning of the terms, rates, literature)
- development of the 10 step program for preventing relapse and the manual
- overview of management of depression - use of antidepressants, psychosocial treatment

Step 1
- assessment of depression – medical review and psychosocial assessments (including risk assessment)
- assessment tools used in the study
- goal-setting
- monitoring progress

Skills development = use of assessment tools and goal-setting

Step 2
- the importance of psychoeducation
- review of the psychoeducation resource

*Skills development* = use of the resource with patients

**Step 3**

- overview of healthy lifestyle issues and their importance in preventing relapse
- review of the resource

*Skills development* = relaxation techniques

**Step 4**

- review of the coping skills outlined in this step, including keeping a mood diary, problem-solving and managing panic

*Skills development* = problem-solving, slow breathing

**Step 5**

- CBT - background theory and evidence base
- review of resource
- the influence of underlying beliefs on thinking and how to deal with perfectionism

**Step 6**

- psychological issues in depression
- review of ways to deal with self-esteem issues, loss and grief, dealing with negative emotions, loneliness and hopelessness
- risk assessment

**Step 7**

- outline of the importance of activity in preventing relapse
- ways to encourage activity

*Skills development* = activity planning

**Step 8**

- the importance of social skills training
- assertiveness theory
- relationship issues and the role of interpersonal therapy (IPT)
- background and evidence base to IPT

*Skills development* = assertiveness

**Step 9**

- the importance of identifying early symptoms of relapse of depression
- the development of a plan for managing relapse

*Skills development* = preparing an emergency plan

**Step 10**

- importance of patient review
- follow-up of patients during the study
- review of the program
- resources list
What is the study about?
Depression is a very common and distressing problem, and unfortunately it can be a recurrent problem. Treatment of depression may include medication and psychological therapy, and often medication is continued for a year or two. This study is looking at whether a particular general practice approach might help to prevent depression from relapsing (whilst you are still on medication) or recurring later (when off medication).

Why is the study needed, and what good will it do?
We know from previous research that both medication and psychological treatment may be helpful in depression. However, there have not been many studies looking at treatments to help prevent recurrence of depression. Hopefully this study will provide us with more information about what helps or doesn't help prevent depression from returning.

Who is organizing the study?
The study is organized by Dr Cate Howell of the Department of General Practice at Adelaide University. Dr Howell is a General Practitioner with a special interest and post-graduate training in mental health. She is undertaking a doctorate under the supervision of the Head of the Department, Dr Justin Beilby. The study will be carried out in the University Family Practice Network of general practices, and several other practices. Permission to carry out the study has been sought from the Adelaide University Human Research Ethics Committee.

If I decide to take part, what is involved?
You will be asked to complete a consent form by your GP after you have considered the information provided about the study. GP's will either guide you through the usual care of depression, or they will incorporate the approach being studied over 12 months. The general practices involved have been randomly allocated to either deliver usual care or utilize the treatment approach being studied.
You will be asked by your GP to complete some straightforward questionnaires at the beginning and end of the study. You may also be asked if you would participate in an interview at the beginning and end of the study, as we are interested in your experiences, and thoughts about your treatment. If you are agreeable, your GP will let Dr Howell know your name and contact phone number to arrange the interview.
**What if I do not agree to take part?**
Your participation is entirely voluntary. If you decide not to take part this will not affect the care given to you by your GP.

**What will happen if I have any problems during the study?**
Throughout the study you will be being reviewed by your GP, and any problems can be discussed and addressed. If you need to see your GP more frequently, then do so. If you or your GP feel that seeing another mental health professional would be of benefit, then that can be arranged.

**Are there any foreseeable adverse effects of the study?**
Enter into the study does not put you at risk of any foreseeable physical or psychological harm. You will be informed about your treatment and monitored by your GP.

**Can I stop at any time during the study?**
You will be free to withdraw from the study at any time without having to explain why. This will not affect your treatment with your GP in any way.

**Will the information be treated as confidential?**
The information that you provide during the study will be known only to your GP and the researchers involved in the study. Any information recorded by the researchers will be identified only by number. The study will form the basis of Dr Howell’s doctoral thesis and publications may arise from this.

**Who can I contact if I need more information at any stage, or if I have a complaint?**
If you need any further information please contact Dr Cate Howell on 83033460 or 0417867815. Please also find attached the separate “Contacts for information on projects and independent complaints procedure” of the Adelaide University Human Research Ethics Committee.

*Thank you very much for your assistance.*
A6 - Exploratory study consent form

THE UNIVERSITY OF ADELAIDE HUMAN RESEARCH ETHICS COMMITTEE

STANDARD CONSENT FORM
FOR PEOPLE WHO ARE SUBJECTS IN A RESEARCH PROJECT

1. I, .................................................................................................................. (please print name)

   consent to take part in the research project entitled: Study of a Primary Care Treatment Program Aiming to Reduce Relapse of Depression

2. I acknowledge that I have read the attached Information Sheet entitled: Study of a Primary Care Treatment Program Aiming to Reduce Relapse of Depression

3. I have had the project, so far as it affects me, fully explained to my satisfaction by my doctor. My consent is given freely.

4. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.

5. I understand that the study that I am involved in will run for 12 months.

6. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.

7. I understand that a researcher will review my case-notes during the study.

8. I have been informed that, while information gained during the study may be published, specific data about subjects will not be used in the overall results.

9. I understand that I am free to withdraw from the study at any time and that this will not affect medical advice in the management of my health, now or in the future.

10. I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet.

   ........................................................................................................................................

   (signature)                                (date)

WITNESS

I have described to .......................................................... (name of subject)

the nature of the procedures to be carried out. In my opinion she/he understood the explanation.

Status in Project: ........................................................................................................................

Name: ......................................................................................................................................

................................................................................................................................................

(signature)                                (date)
A7 - GP data collection forms

KEEPING THE BLUES AWAY

General Practitioner Data Collection Form

1. Age: __________
2. Gender:  Male  Female

3. Practice location Postcode ________
4. Number of FTE GPs: ______

4. Do you work:  Full time  Part time

5. Have you undertaken any training in Mental Health?  Yes  No

5a. If YES, was it:

   a. Accredited for Level 1 (3 step process) of the Better Outcomes in Mental Health Care Initiative.
   b. Accredited for Level 2 (focused psychological strategies) of the Better Outcomes in Mental Health Care Initiative.
   c. Other (Please describe other mental health training).

6. Do you have access to an allied health project (involving referral to allied health professionals via the Better Outcomes in Mental Health Care Initiative) through your Division:

   Yes  No

7. When diagnosing a patient with depression, do you use the criteria for a Major Depressive Disorder as outlined in the DSM IV (Diagnostic and Statistical Manual of Mental Disorders)?

   Yes  No

7a. If NO, please comment.

8. Would you usually use assessment tools (diagnostic or severity rating scales, such as the HADS or Hamilton) when managing a patient with depression?

   Yes  No

8a. If yes, which ones?

9. In the first month, how many times on average would you see a patient with depression?
10. In the first 3 months how many times would you usually see the patient with depression?

1-2 times ☐ 3-4 ☐ 5-6 ☐

11. What psychological treatments do you utilize in managing the patient with depression? (you can tick more than one box)

- Psycho-education ☐
- Cognitive-behaviour therapy ☐
- Counselling ☐
- Interpersonal therapy ☐
- Other (Please describe) ☐

12. Do you find that there are difficulties managing the patient with depression in general practice.

Yes ☐ No ☐

12a. If YES, can you comment on what these difficulties are.

THANK YOU FOR COMPLETING THIS FORM
A8 - Participant data collection forms

KEEPING THE BLUES AWAY

Participant Data Collection Form

Thank you very much for answering the following questions. Your answers will assist us in understanding depression relapse.
(Please tick the relevant boxes. If there are any questions that you do not wish to answer, just leave the response blank.)

What is your:

1. Age? ________

2. Gender? Male □ Female □

3. Marital status? Single □ Married □ Defacto □ Separated □ Divorced □

4. Home postcode? ________

5. Do you live alone? Yes □ No □

6. Do you have family in Adelaide? Yes □ No □

7. Do you have friends in Adelaide? Yes □ No □

8. Do you have any medical problems? Yes □ No □

8a. If yes, what are they?

| Diabetes □ | Asthma □ |
| Heart Disease □ | Other (Please describe) □ |

___________________________________________________________________

9. Do you take any medications (prescribed by your doctor or bought over the counter)?

Yes □ No □

9a. If YES, please list these medications.

___________________________________________________________________

___________________________________________________________________
10. Do you smoke?  Yes □  No □

11. Do you drink alcohol?  Yes □  No □

11a. If YES, how many glasses of alcohol would you have in a week?
   1-2 □  3-4 □  5-6 □  7-8 □  More than 8 □

12. Do you use any other drugs?  Yes □  No □

12a. If YES, please describe which drugs you use.

___________________________________________________________________

13. Have you ever had depression in the past?  Yes □  No □

14. IF YES, please answer the following questions (estimate if unsure).

   Note – an episode of depression refers to a bout of significant depressive symptoms (diagnosed by your doctor as a major depressive disorder or illness)

   14a. What was your age when you had the first episode of depression?
       __________

   14b. How many episodes of depression have you had?  _________

15. When did your last episode of depression occur (not including your current episode – estimate if unsure)?

   In the past year □  1 to 2 years ago □
   2-5 years ago □  5-10 years ago □
   More than 10 years ago □

   16. How long have you had this episode of depression?

   Less than six months □  More than 6 months □

17. On a scale of 0 to 10, how would you describe the severity of the depression at the start of this episode? (0 = no depression  10 = extremely severe depression)

   Please circle the number which best describes how you felt.

   0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10
18. Between this episode of depression and the last episode, did you feel that you completely recovered?

   Yes ☐   No ☐

18a. If NO, what symptoms of depression persisted? (you may tick more than one box)

   Depressed mood most of the day, nearly every day ☐
   Difficulty sleeping or sleeping excessively ☐
   Loss of interest or pleasure ☐
   Restlessness or agitation ☐
   Weight loss or gain ☐
   Fatigue or loss of energy ☐
   Feelings of worthlessness or guilt ☐
   Reduced ability to think or concentrate ☐
   Recurrent thoughts of death or suicidal thinking ☐
   Other (Please describe) ☐

19. In the past 2 years have you had a persistently depressed mood most of the day?

   Yes ☐   No ☐

19a. If YES, was it accompanied by:

   Poor appetite or overeating ☐
   Feelings of hopelessness ☐
   Low energy or fatigue ☐
   Feelings of hopelessness ☐
   Other (Please describe) ☐
   Difficulty sleeping or sleeping excessively ☐
   Low self-esteem ☐
   Poor concentration/difficulty making decisions ☐

20. Are you being treated by your usual doctor?       Yes ☐ No ☐

21. Are you seeing more than one doctor about the depression? Yes ☐ No ☐

22. Are you seeing any other health professionals about the depression?   Yes ☐ No ☐
23. If YES, what health professional(s) are you seeing?

- Psychiatrist
- Psychologist
- Other (Please describe)
- Mental Health Nurse
- Counsellor

24. Which of the following groups best describes the highest educational qualification you have obtained?

- Left school at 15 years or less
- Left school after 15 years
- Trade qualification/ Apprenticeship
- Certificate/Diploma, one year or less, full time
- Certificate/Diploma, more than one year full time
- Bachelor degree or higher

25. Which of the following best describes your current job situation?

- Employed Full Time
- Employed Part Time
- Paid Sick Leave
- Unemployed
- Retired
- Other (Please describe)

THANK YOU FOR COMPLETING THIS FORM
A9 - Assessment tools

PSYCHO-SOCIAL ASSESSMENT TOOLS

A. Depression Scale (patient to complete)

In the past week how much have you suffered from depression? Indicate the severity of the depression; 0 represents no depression and 10 the most severe that the depression could be. Please tick the appropriate box.

0 1 2 3 4 5 6 7 8 9 10

(no depression) (most severe depression)


B. DASS Scale (see separate sheet)

C. Quality of Life Scales (patient to complete)

The following statements relate to the quality of your life at present.

How would you rate your general quality of life overall?

0 1 2 3 4 5 6 7 8 9 10

(no impairment) (most severe impairment)

How would you rate your health-related quality of life?

0 1 2 3 4 5 6 7 8 9 10

(no impairment) (most severe impairment)

Because of the depression my work is impaired

0 1 2 3 4 5 6 7 8 9 10

(no impairment) (most severe impairment)

Because of the depression my social life/leisure is impaired

0 1 2 3 4 5 6 7 8 9 10

(no impairment) (most severe impairment)

Because of the depression, my family relations is impaired
Because of the depression, my ability to manage home duties is impaired (eg shopping, cleaning, paying bills)

D. Clinical Global Improvement (GP to complete)

Compared to the patient's condition when first assessed, how much change has occurred? Please tick the appropriate box.

0 = not assessed
1 = very much improved
2 = very improved
3 = minimally improved
4 = no change
5 = minimally worse
6 = much worse
7 = very much worse

### DASS

<table>
<thead>
<tr>
<th>Anxiety</th>
<th>Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications</strong></td>
<td><strong>Indications</strong></td>
</tr>
<tr>
<td>assess quantitative scores for anxiety in o/p population</td>
<td>assess quantitative scores for Depression in o/p population</td>
</tr>
<tr>
<td><strong>Limitations</strong></td>
<td><strong>Limitations</strong></td>
</tr>
<tr>
<td>not to replace diagnostic judgement</td>
<td>not to replace diagnostic judgement</td>
</tr>
<tr>
<td><strong>scoring tips</strong></td>
<td><strong>scoring tips</strong></td>
</tr>
<tr>
<td>use transparency sheet, add 7 ‘A’ items, double score, check z score sheet</td>
<td>use transparency sheet, add 7 ‘D’ items double score, check z score sheet</td>
</tr>
<tr>
<td><strong>Cut-off scores</strong></td>
<td><strong>Cut-off scores</strong></td>
</tr>
<tr>
<td>8-9 mild</td>
<td>10-13 mild</td>
</tr>
<tr>
<td>10-14 moderate</td>
<td>14-20 moderate</td>
</tr>
<tr>
<td>severe 15-19</td>
<td>21-27 severe</td>
</tr>
<tr>
<td>extreme 20+</td>
<td>28+ extreme</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td><strong>Comments</strong></td>
</tr>
<tr>
<td>reliably correlated with Beck scale</td>
<td>reliably correlated with Beck scale</td>
</tr>
<tr>
<td>Australian norms used, good scale</td>
<td>Australian norms used, good scale</td>
</tr>
<tr>
<td><strong>Reference</strong></td>
<td><strong>Reference</strong></td>
</tr>
</tbody>
</table>
A9 cont.

<table>
<thead>
<tr>
<th></th>
<th>Statement</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I found it hard to wind down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>I was aware of dryness of my mouth</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3</td>
<td>I couldn't seem to experience any positive feeling at all</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>I found it difficult to work up the initiative to do things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6</td>
<td>I tended to over-react to situations</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>I experienced trembling (eg, in the hands)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>I felt that I was using a lot of nervous energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9</td>
<td>I was worried about situations in which I might panic and make a fool of myself</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>10</td>
<td>I felt that I had nothing to look forward to</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>11</td>
<td>I found myself getting agitated</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>12</td>
<td>I found it difficult to relax</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>13</td>
<td>I felt down-hearted and blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>I was intolerant of anything that kept me from getting on with what I was doing</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>I felt I was close to panic</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>16</td>
<td>I was unable to become enthusiastic about anything</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>17</td>
<td>I felt I wasn't worth much as a person</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>18</td>
<td>I felt that I was rather touchy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>19</td>
<td>I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>20</td>
<td>I felt scared without any good reason</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>21</td>
<td>I felt that life was meaningless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

[TOTAL SCORE (multiply by 2): D____A____S____]
# A10 – KBA checklist for GPs

- **INDIVIDUAL CHECKLIST SHEET** -

Participant ID: ..................  GP ID: ....................

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Please tick, date and comment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Phase</strong></td>
<td></td>
</tr>
<tr>
<td>- Information sheet</td>
<td></td>
</tr>
<tr>
<td>- Consent</td>
<td></td>
</tr>
<tr>
<td>- Data sheet</td>
<td></td>
</tr>
<tr>
<td><strong>Assessment tools</strong></td>
<td></td>
</tr>
<tr>
<td>1. 0-10 scale</td>
<td></td>
</tr>
<tr>
<td>2. DASS</td>
<td></td>
</tr>
<tr>
<td>3. QOL</td>
<td></td>
</tr>
<tr>
<td><strong>Patient</strong></td>
<td></td>
</tr>
<tr>
<td>- Manual &amp; journal</td>
<td></td>
</tr>
<tr>
<td><strong>Step 1</strong> - assessment and goal-setting</td>
<td></td>
</tr>
<tr>
<td><strong>Step 2</strong> - psycho-education</td>
<td></td>
</tr>
<tr>
<td><strong>Step 3</strong> - healthy lifestyle issues</td>
<td></td>
</tr>
<tr>
<td><strong>Step 4</strong> - useful coping skills</td>
<td></td>
</tr>
<tr>
<td>- Relaxation Tape</td>
<td></td>
</tr>
<tr>
<td><strong>Step 5</strong> - helpful cognitive strategies</td>
<td></td>
</tr>
<tr>
<td><strong>Review &amp; repeat assessment tools</strong></td>
<td></td>
</tr>
<tr>
<td>1. 0-10 scale</td>
<td></td>
</tr>
<tr>
<td>2. DASS</td>
<td></td>
</tr>
<tr>
<td>3. QOL</td>
<td></td>
</tr>
<tr>
<td><strong>Step 6</strong> - dealing with psychological issues</td>
<td></td>
</tr>
<tr>
<td><strong>Step 7</strong> - the benefits of activity</td>
<td></td>
</tr>
<tr>
<td><strong>Step 8</strong> - fostering social support and skills</td>
<td></td>
</tr>
<tr>
<td><strong>Step 9</strong> - developing a plan to manage early symptoms of relapse</td>
<td></td>
</tr>
<tr>
<td><strong>Step 10 – review / repeat assessment tools</strong></td>
<td></td>
</tr>
<tr>
<td>1. 0-10 scale</td>
<td></td>
</tr>
<tr>
<td>2. DASS</td>
<td></td>
</tr>
<tr>
<td>3. QOL</td>
<td></td>
</tr>
<tr>
<td>4. CGI</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
</tbody>
</table>
**A11 - Evaluation**

**Evaluation – Preventing Relapse in Depression Program**

For the following questions circle the response that most reflects your opinion.
SA = Strongly Agree;  A = Agree;  NS = Not Sure;  D = Disagree;  SD = Strongly Disagree

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program improved my knowledge of depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program will improve my assessment of depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program improved my ability to address healthy lifestyle issues with patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my skills in assisting patients with cognitive coping strategies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my proficiency in CBT skills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my awareness of the influence of underlying beliefs on thinking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has assisted me to develop skills in raising self-esteem, and dealing with grief and anger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has helped me to gain knowledge about important psychological issues in depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my ability to encourage activity planning to prevent depression relapse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my appreciation of the importance of developing social skills to prevent relapse in depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my skills in assertiveness training and helping patients deal with relationship issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my therapeutic skills in</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------------------------------------------------</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>preventing relapse in depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has helped me to develop skills in helping patients identify and deal with warning signs of relapse</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The program has helped me to understand the importance of preparing an emergency plan</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
</tbody>
</table>

**Please comment on the following:**

**What aspects of this program could have been done better?**

...........................................................................................................................................................................................
...........................................................................................................................................................................................
...........................................................................................................................................................................................

**What aspects of the program were done well?**

...........................................................................................................................................................................................
...........................................................................................................................................................................................
...........................................................................................................................................................................................

**Do you have any other comments about today's program?**

...........................................................................................................................................................................................
...........................................................................................................................................................................................
...........................................................................................................................................................................................

Thank you for completing this evaluation
Appendix B: Pilot RCT

B1 – GPMHSC application and approval letter

**GPMHSC**

General Practice Mental Health Standards Collaboration

---

### BOiMHC Level Two (FPS) Training Application

**For endorsement by the General Practice Mental Health Standards Collaboration**

---

<table>
<thead>
<tr>
<th><strong>1. General information</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1 Provider name:</strong> Department of General Practice, University of Adelaide</td>
</tr>
<tr>
<td><strong>1.2 Contact person:</strong> Dr Cate Howell</td>
</tr>
<tr>
<td><strong>1.3 Mailing address:</strong> Department of General Practice, University of Adelaide, Adelaide, 5005</td>
</tr>
<tr>
<td><strong>1.4 Contact telephone:</strong> 08 83033460</td>
</tr>
<tr>
<td><strong>1.5 Facsimile:</strong> 08 83033511</td>
</tr>
<tr>
<td><strong>1.6 Contact email:</strong> <a href="mailto:cate.howell@adelaide.edu.au">cate.howell@adelaide.edu.au</a></td>
</tr>
</tbody>
</table>

---

| **1.7 Education activity title:** *Keeping the blues away*, a primary care treatment program aiming to prevent relapse of depression – GP training |
| **1.8 Proposed dates for activity:** October, November 2003 |
| **1.9 Has this activity been adjudicated by the Royal Australian College of General Practitioners’s QA&CPD Program?** | Currently being adjudicated, copy attached |
| **1.10 Has this activity been adjudicated by the Australian College of Rural and Remote Medicine’s PD Program?** | No |

**If you answered “No” to both of the previous two questions, you will need to develop either a RACGP or an ACRRM application and attach it to this application form. Contact the relevant College for more information:**

- **RACGP**
  - Tel: 03 8699 0510
  - [http://www.racgp.org.au](http://www.racgp.org.au)

- **ACRRM**
  - Tel: 07 3356 2187

---

<table>
<thead>
<tr>
<th><strong>1.11 Please indicate any education activity numbers this activity has been assigned by either College:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RACGP:</strong> [Click here and type]</td>
</tr>
<tr>
<td><strong>ACRRM:</strong> [Click here and type]</td>
</tr>
</tbody>
</table>

---

This application must be submitted electronically via email to gpmhsc@racgp.org.au. Supporting material not available electronically may be sent to:

**GPMHSC, 1 Palmerston Crescent, South Melbourne VIC 3205.**

If you would like to discuss your application by telephone, please contact the National Mental Health Education Development Officer, on 03 8699 0576. You will receive a response on the outcome of your application within a week of the conclusion of the next meeting of the Collaboration.
2. Overview

Please give a brief overview of the activity, including program aims.

This training program has been developed for the 25-30 general practitioners who will be involved in a clinical trial of a primary care treatment program aiming to prevent relapse of depression during 2004. The treatment program that has been developed in based on current evidence, is designed for use in general practice by GPs, and fits neatly with the Better Outcomes in Mental Health Care initiative.

Information about the study (and see full research proposal which is attached) -

"The proposed study aims to implement a primary care depression relapse prevention program and evaluate its effectiveness via a cluster randomisation trial. The primary hypothesis is that the program will reduce the relapse rate of depression by one half when compared with usual general practice care. Secondary hypotheses include increased remission time, reduced severity of relapses, improved adherence to treatment, earlier identification of symptoms of relapse and improved quality of life. Qualitative research will be undertaken regarding practitioners' and patients' perceptions of the program (including level of satisfaction).

The evidence upon which this primary care relapse prevention program has been based has been gathered from literature review and clinical practice guidelines. Many years of clinical experience in primary care mental health and a year 2000 Churchill Fellowship provided valuable insight into this research area.

A formal literature review has been carried out. Electronic and hand searches have been done to find literature on the treatment of depression and relapse prevention. Over 130 articles have been found and a number of the relevant articles have already been referred to. All aspects of this project – design of the program to methodology - are well supported by current literature.

There are very few studies of primary care interventions aiming to reduce relapse of depression. An American research team has carried out work in this area, but the interventions used are designed for the American health care system which operates differently from the Australian system.

In Australia the National Mental Health Strategy provides the impetus to improve outcomes for Australians with mental health problems. To assist general practitioners in developing greater skills in the diagnosis and treatment of mental health problems the Government has introduced the Better Outcomes in Mental Health Care initiative, involving education and training, a 3 step assessment planning and review process, focused psychological strategies (such as CBT) and improving access to allied health and specialist psychiatric support.

This treatment program fits neatly with the Better Outcomes in Mental Health Care initiative. It provides a bio-psycho-social treatment approach, and involves recommending a range of focused psychological strategies be incorporated into the management of patients with depression. The program is unique in its integrated, holistic approach and its application of a range of psychosocial strategies to the primary care setting. Review of the literature provides support for a primary care depression relapse program that:

- Is evidence-based and follow current management guidelines.
- Incorporates education about depression and relapse.
- Is multifaceted and integrative and include psychosocial treatments.
- Encourages adherence to medication, and address the risk factors for relapse as well as lifestyle and well-being.
- Incorporates a chronic disease management model.

The proposed primary care relapse prevention program involves ten steps:
1. **Getting started - initial assessment (medical and psychosocial) and goal-setting**

2. **Information about depression, including treatment, relapse prevention, and community resources (with involvement of family if appropriate)**

3. **General health promotion and lifestyle advice (nutrition, exercise, sleep, reducing stress)**

4. **The development of useful coping skills including problem-solving and stress management (includes relaxation training)**

5. **Key cognitive strategies to address the depression, co-morbid anxiety and self-esteem issues**

6. **Psychological interventions addressing current psychological issues**

7. **Encouragement of pleasurable / meaningful activities**

8. **The fostering of supportive social relationships and social skills**

9. **Regular review of progress and of skills acquired, along with the development of an emergency plan to use if early signs of relapse occur**

10. **Reassessment, review and resources**

[Note: usual general practice would be to include some but not all of these steps, with less emphasis on the psychosocial strategies.]

The relapse prevention program involves:

- Initial regular (weekly to twice weekly) treatment sessions with the practitioner (up to 12 sessions, approximately 3 month period).

- Regular follow-up sessions over a 12 month period (see methodology provided in research proposal, and GP checklist in the GP training manual).

This incorporates the Better Outcomes three-step process and focused psychological strategies (Level 1 and 2).

Patients are provided with a 200 page manual containing explanations, exercises and resources relating to each step.

The intervention has been piloted during January to July, 2003, in urban and rural areas, and has been well received. Some adaptations have been made to processes and materials for the full study as a result of the pilot. The full study will commence in late 2003 and continue into 2004.

Once the study is completed, further GPs will be able to undergo training to use this treatment program.

* See training manual for a full list of the learning outcomes for this program.
3. Planning and Development

3.1 Has there been significant involvement in the development of the program each of the following groups? Please provide explicit details.

<table>
<thead>
<tr>
<th>General Practitioners</th>
<th>Pilot study has been completed, with feedback from GPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumers of mental health services</td>
<td>Consumers (patients and their carers) were consulted during the preparation of the program, the writing of the patient manual. Feedback was obtained during the pilot study via the consumers GPs and directly via patient interviews.</td>
</tr>
<tr>
<td>Carers for consumers of mental health services</td>
<td>Carers were consulted during the preparation of the program and writing of the patient manual.</td>
</tr>
<tr>
<td>Appropriately skilled and trained mental health professionals</td>
<td>Input to the program was sought from psychologists and occupational therapists.</td>
</tr>
</tbody>
</table>

Note: Consumer and carer involvement is essential in program development. For information on how to enlist consumer and carer representation in the development of your program, please contact the Mental Health Council of Australia on 02 6285 3100.

3.2 Does the program include a pre and post test?

Yes, attached.

*If Yes, please submit as an attachment*

3.3 Does the program include a Clinical Audit?

No

*If Yes, please submit as an attachment*

4. Program Delivery

4.1 Mode(s) of program delivery (face to face/on-line/CD-ROM/other - specify)

Face to face

4.2 If available online or on CD-ROM, electronic delivery covers program in whole or part? How many hours estimated for online/CD-ROM participation?

[Click here and type your response]

5. Presentation

5.1 Please indicate the breakdown of contact hours in the program (a minimum of 20 hours face to face is required. Exclude meal breaks in all cases)

<table>
<thead>
<tr>
<th>Face to face:</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online/CD-ROM:</td>
<td>[Click here and type your response]</td>
</tr>
<tr>
<td>Pre-reading/other:</td>
<td>4</td>
</tr>
<tr>
<td>Total hours:</td>
<td>24 hours</td>
</tr>
</tbody>
</table>
5.2 How does the format & content cover item Descriptors and Medicare documentation?

The program incorporates the 3 step process and focused psychological strategies. Documentation will be discussed during the program.

5.3 Programs must cover a minimum of 4 treatment modalities. Please provide details about treatments covered by the program.

<table>
<thead>
<tr>
<th>Psycho-educational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression, its aetiology, chronic nature and management, including lifestyle issues, pharmacological and non-pharmacological (see manual)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cognitive Behaviour Therapy including behaviour interventions; behaviour modifications; exposure techniques; activity scheduling.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavioural techniques in dealing with anxiety are explored, including exposure. The importance of including pleasurable activities in life and activity scheduling are covered.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cognitive Interventions (Cognitive Therapy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cognitive therapy is explained and steps provided – keeping a thought diary, understanding thinking errors, identifying thinking errors, challenging unhelpful thinking and developing more helpful thoughts.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Relaxation Strategies including Progressive Muscle relaxation; guided imagery; controlled breathing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A range of relaxation techniques are covered during the program, including progressive muscle relaxation, breathing, visualisation and mindfulness meditation (see manual).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Skills training (problem solving skills &amp; training; anger management; social skills training; communication training; stress management; parent management training.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problem-solving skills are taught, social skills including managing anger and developing assertiveness, along with stress management are covered</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpersonal Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a section on dealing with relationship issues and using problem-solving in particular. Assertiveness skills are taught</td>
</tr>
</tbody>
</table>

6. Content

Please support all responses in this section with clear examples from the program content.

6.1 Does the program have clear, measurable learning outcomes?

Yes

6.2 How will these outcomes be measured?

An evaluation will be carried out at the end of the program.

6.3 How does the title of this program communicate its content coverage to GPs?

The title conveys the focus of the program, which is aimed at preventing relapse of depression.

6.4 Please outline several mental health conditions, the related Focuses Psychological Strategies / treatment models, as covered by your program

The program focuses on depression. However, co-morbidity is common, and strategies to identify and manage anxiety disorders including panic are incorporated in the training. Drug and alcohol issues and gambling are talked about. The program provides stress and insomnia management skills. It
Level Two FPS Skills Training - Application for endorsement

incorporates psycho-education, interpersonal and cognitive behavioural techniques, relaxation strategies and problem-solving. Anger management and social skills training are covered.

6.5 What evidence is there of treatment effectiveness for the interventions covered by this program (include references)?

The program incorporates evidence-based strategies. A copy of the research proposal outlining the program and its literature base is attached.

6.6 Are the skills taught in this program transferable, and in what areas?

Many of the skills, such as behavioural, relaxation, cognitive and interpersonal, are transferable to the management of other mental health problems.

6.7 Does the program explain aetiology and epidemiology of the conditions covered?

Yes (see manual).

6.8 Does the program include discussion of treatment and planning within methodology?

Yes (see manual).

6.9 Are modes of assessment explained?

Yes, clinical assessment and assessment tools used (see manual)

6.10 Does the program discuss progress review?

Yes, this is a key part of the treatment program and is essential in monitoring for relapse of depression.

6.11 Are issues of closure covered in the program?

Yes.

7. Active Learning

Please support all responses in this section with clear examples from the program content.

7.1 Does the program include relevant case studies?

Case studies will be discussed during the training as appropriate.

7.2 Does the program include demonstrations of techniques (and who will demonstrate)?

Yes, two GPs and a psychologist are involved in the training and demonstration of techniques.

7.3 Does the program include guidance in scripting and rehearsal opportunity?

Yes, see manual.

7.4 Does the program include trainer observation and feedback (and at what points in the program will this occur)?

Yes, see manual. Feedback will be provided after individual skills are practiced.

7.5 Does the program include discussion of integrated FPS and medication?

Yes, this is the basis of the treatment of depression and is emphasized during the training.

7.6 Does the program include an opportunity to identify ongoing learning needs?

This will be addressed during the training.
8. Attachments

8.1 Have the following items been attached with this application?

<table>
<thead>
<tr>
<th>Item</th>
<th>Attached</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detailed agenda for activity</td>
<td>Yes</td>
</tr>
<tr>
<td>Advertising brochure</td>
<td>No</td>
</tr>
<tr>
<td>Copy of evaluation tool</td>
<td>Yes</td>
</tr>
</tbody>
</table>

8.2 Please provide a list of relevant additional references and websites:

- See references provided in research proposal summary.
- See training manual provided.

9. Provider Requirements

9.1 Do you, as program provider, agree to:

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Issue certificates of attendance?</td>
<td>Yes</td>
</tr>
<tr>
<td>Submit attendance lists (to the RACGP and the ACRRM)?</td>
<td>Yes</td>
</tr>
<tr>
<td>Submit summary evaluations of programs to the GPMHSC?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

9.2 Do you, as program provider, agree to ask of program participants completing post tests the following two questions, and to report a summary of the responses to the GPMHSC:

"Which Focussed Psychological Strategies have you used with your patients since completing the course?" Yes

"On a scale of 1 to 5, rate the effectiveness of the FPS skills you have acquired through this course in assisting you to provide better mental health services to your patients?" Yes

Please attach all relevant documentation and course materials and send electronically to gpmhsc@racgp.org.au. Supporting material not available electronically may be sent to: GPMHSC, 1 Palmerston Crescent, South Melbourne VIC 3205.
Dear Dr. Howell

RE: Application for approval of Level Two Focussed Psychological Strategies Training

Activity:  "Keeping the Blues Away" GP training for a treatment aiming to prevent relapse of depression (sessions 1-5)
Activity #: 701413, 701415

On behalf of the General Practice Mental Health Standards Collaboration I would like to thank you for the Level Two training application your organisation submitted. This letter is to confirm telephone discussions about the adjudication of the application.

We have great pleasure in approving your Focussed Psychological Strategies Program "Keeping the Blues Away" for Level Two for the Better Outcomes in Mental Health Initiative.

GPs who successfully undertake all five sessions after 13 October 2003 will be considered to have completed the Skills Training requirement for registration to Level Two of the Better Outcomes in Mental Health Care Initiative. CPD points gained through completion of this program in this millennium will also count towards participants’ ongoing mental health training requirements.

Please ensure that the post test component of your course includes the two questions noted in section 9.2 of your Level Two training application form.

A Level Two GP Registration form is enclosed with this letter - we recommend that you request that participants who complete your program fill out the form and return it with their post test to you, and that you then forward the applications with a copy of your attendance list to the GPMHSC.

Your program and contact information will shortly be listed on the GPMHSC website (www.racgp.org.au/mentalhealth).

Thank you for your interest in this initiative - we look forward to continued contact with you and wish you all the best for the roll out of the training. Please do not hesitate to contact Collaboration staff if we can be of assistance - either Margo Field or Julian Thomas can be reached by phone or e-mail as above.

Tuesday, 28 October 2003

Dr Cate Howell
Department of General Practice
University of Adelaide, SA 5005

CC SA/NNT RACGP Education Development Officer
B2 – RACGP professional development application

The Royal Australian College of General Practitioners

Quality Assurance and Continuing Professional Development Program

2002-2004 Triennium

Continuing Professional Development

5 Point Per Hour Activity

Applications for adjudication must be made PROSPECTIVELY. Please forward your completed form to the Unit Coordinator in your state QA&CPD Unit. Please allow eight weeks for the adjudication process.

Providers should keep a copy of this application for their own records and for RACGP review purposes. This form is available from the RACGP web site (www.racgp.org.au) and via email (qaacpd@racgp.org.au). Computer generated forms or attachments are desirable. All applications must be typed.

Details of Education Provider

<table>
<thead>
<tr>
<th>Provider/Organization Name:</th>
<th>Department of General Practice, University of Adelaide</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>Department of General Practice, University of Adelaide.</td>
</tr>
<tr>
<td></td>
<td>Postcode: 5005</td>
</tr>
<tr>
<td>Contact person(s):</td>
<td>Dr Cate Howell</td>
</tr>
<tr>
<td></td>
<td>Phone: 03033460 Fax: 03033511 Email: <a href="mailto:cate.howell@adelaide.edu.au">cate.howell@adelaide.edu.au</a></td>
</tr>
</tbody>
</table>

Other organizations involved in this application. Please include name of contact(s) and phone number(s):

Do you want this activity advertised by the RACGP?

Yes ☐ No ☑

Contact for registration enquiries:

Name: Dr Cate Howell Phone: 83033463

Details of Educational Activity

Title of activity: ‘GP Training for a Treatment Program Aiming to Prevent the Relapse of Depression’

Is the activity to be conducted in more than one State?

Yes ☐ No ☑ (send form to national QA&CPD) Yes ☐ No ☑ (send form to state QA&CPD Unit)

This activity will be:

☐ A single event (one-off)
☐ A series (eg one event / topic held over several nights)
☑ A repeated activity (identical activity repeated at different times and/or locations)
☐ Encouraging material (video, CD, website etc)

Proposed venues and dates:

Department of General Practice, University of Adelaide

July-Aug 2003

Total hours of the educational component of activity: 20 hours

Office Use Only

<table>
<thead>
<tr>
<th>ACTIVITY NUMBER</th>
<th>DURATION</th>
<th>POINTS/HR</th>
<th>TOTAL POINTS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Audit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

© Copyright RACGP 2002 – May be reproduced for submission purposes only.
5pph Activity – March 2002.

257
IMPORTANT!
Before attempting to complete this application, please ensure that you have read the RACGP Guide to CPD.

1 DESCRIPTION
Briefly summarise your educational activity.

The activity involves training GPs to carry out a treatment program aiming to prevent the relapse of depression. High relapse rates of depression and the lack of knowledge about preventing the return of symptoms are now well documented. The co-morbidity of depression and anxiety is also well recognized. A 10-step relapse prevention program, utilising a range of evidence-based psychosocial strategies, has been designed.

The GP training will be conducted in the wider context of a research study aiming to implement and evaluate this primary care depression relapse prevention program. Dr Howell is undertaking a doctorate and has the support of the Department of General Practice at the University of Adelaide, and mentors including Professor Justin Belaby, Professor Ross Kalucky, Professor Chris Dovrick and Dr Flora Hawker.

GPs will undergo training to enable them to participate in the study. A pilot study is currently being carried out, and the full 18-month study of the intervention will begin later in the year. During the full study patients will be seen regularly by their GP over the first 3 months and then seen for periodic follow-up for a total of 18 months.

The training for GPs will involve face-to-face workshops (4 hour workshops to a total of 20 hours). The relapse prevention program will be introduced. Background information will be provided on anxiety and depression, including aetiology, epidemiology, assessment and management. The 10 step program will be explored step by step (see course outline), the evidence base for each step explained and associated skills modelled and practiced.

The training program will be facilitated by Dr Cate Howell from the University of Adelaide who has developed the training package, with assistance from Dr Ian Wilson (academic GP). Participants will receive a training kit and patient manual.

2. CONTENT
Please attach a copy of your program. This must include Program Attached:

- The title of the event
- The title of each education component within the event (where the event has multiple presentations)
- A timetable indicating duration and completion for all activities eg presentations, workshops, discussions, questions, meals & breaks
- The names of all presenters and their status (eg general practitioner, specialist, other)

3. PLANNING
Please list all the members of your planning committee for this activity, including their names, qualifications, expertise and contribution.

Note: The planning committee must include one or more GPs who have experience or expertise in education. They should also have a demonstrable understanding of community health needs and/or learning needs of their colleagues.

Dr Cate Howell CSM - BMBS, FRACGP, FACPM, Dip Clin Hyp - GP with a special interest in mental health, co-director of the Primary Care Mental Health Unit, Department of General Practice, University of Adelaide, Research Fellow examining relapse prevention in depression.

Dr Ian Wilson - MBBS FRACGP FAC PSY MED - GP with special interest in mental health; Senior Lecturer and co-director of the Primary Care Mental Health Unit, Department of General Practice, University of Adelaide.

4. NEEDS ASSESSMENT
a) What evidence is there that the GP and/or the community need this activity?
All applications require supporting evidence in accordance with the RACGP Guidelines for CPD demonstrating that this activity is valid to GP needs.

(i) Please attach a statement summarising the need for this activity, reference sources and/or survey results.
(ii) The needs assessment for this activity includes: Needs assessment attached

- Information from expert bodies – eg. reference/s to peer-reviewed medical literature, recognised health organisation documentation and or government policy.
- GP perspective - eg. formal GP participant survey.
  Note: Anecdotes, informal surveys, personal opinions and single ‘expressions of interest’ are not valid
- Community perspective - eg. information from community groups, other health professionals, GP Divisions.

b) Pre-test

Please attach a copy of the proposed pre test (may be a questionnaire or a clinical audit). Attached.

Note:
- The pre-test must include an assessment of behaviour, attitudes, skills & knowledge, not simply knowledge alone.
- If the pretest is a clinical audit then a clinical audit application should be included with the CPO application.
- The Privacy Act amendments (2001) require that participants are aware of how their own data from the pre/post-tests will be used. Also if participants are required to bring along clinical case materials, please ensure that the material has been appropriately de-identified and patient consent procedures have been followed.

5. LEARNING OBJECTIVES

What will the participants be able to do as a result of this activity?

Note: Learning objectives should be specific and measurable and reflect the specific knowledge, skills, attitudes and behaviours that the activity will address.

List the learning objectives for this activity:

By the end of this activity participants will:
- have a greater knowledge of the aetiology and epidemiology of depression
- have reviewed the bio-psycho-social model of depression
- have an understanding of the chronicity of depression
- have a greater awareness of the comorbidity of depression, anxiety and alcohol and drug use disorders
- understand the concepts of relapse and recurrence of depression and have an overview of the literature relating to relapse and recurrence of depression
- understand the 10 step relapse prevention program and its evidence-base
- have gained knowledge of the management of depression including use of antidepressants and role of psycho-social treatments
- understand the importance of medical review in depression and use of psychological assessment (including risk assessment)
- develop knowledge of depression assessment tools
- gain experience in using depression assessment tools
- appreciate the importance of goal-setting with patients at the outset of treatment
- appreciate the importance of monitoring of progress
- develop skills in goal-setting
- appreciate the importance of psychoeducation in managing depression and preventing relapse
- be provided with a useful psychoeducation resource (in the training manual) and practice using it
- appreciate the importance of addressing healthy lifestyle issues in managing depression and preventing relapse
- have a useful resource for doing so
- develop skills in stress management including relaxation techniques
- develop skills in helping patients develop useful coping skills such as using a mood diary, problem-solving and managing panic episodes (slow breathing and cognitive strategies)
- develop sound knowledge of the theory and evidence based of cognitive-behaviour therapy (CBT)
- have a useful resource for using CBT with patients (treatment manual)
- have seen modeled and practiced CBT skills such as identifying negative automatic thoughts, explaining thinking distortions to patients, helping them identify thinking errors, challenge them and develop more helpful ways of thinking
- have an understanding of the influence of underlying beliefs on thinking, and how to deal with being a perfectionist
- gain knowledge about the important psychological issues in depression, such as self-esteem and loss and grief issues
- learn ways of dealing with psychological issues such as raising self-esteem, dealing with grief and managing anger
- have seen these skills modeled and practiced these techniques
- develop further knowledge and skills in risk assessment

© Copyright RACGP 2002 – May be reproduced for submission purposes only. Third Activity – March 2002.
- appreciate the importance of encouraging activity in preventing relapse of depression
- develop skills in activity planning
- appreciate the importance of developing social skills in preventing relapse of depression
- develop skills in assertiveness training
- understand the basis and evidence-base of interpersonal-therapy (IPT) and develop skills in helping patients deal with relationship issues
- appreciate the importance of identifying early warning signs of depression in preventing relapse
- develop skills in helping their patients identify and deal with early warning signs
- appreciate the importance of follow-up patients methodically in preventing relapse
- have a resource list related to managing depression and anxiety including books and websites

6. THE LEARNING ENVIRONMENT

a) What teaching/learning strategies will be used? Please indicate all the proposed methods:

- Presentations
- Small group learning
- Practical sessions / simulation
- Demonstrations
- Role plays
- Case studies for discussion in small groups
- Question/answer sessions
- Videos
- Slides
- CD ROM, On line etc
- Computer software
- Computer interactive
- Audio media
- Journals
- Printed material / handouts

Other, please specify:

b) For enduring material please include a copy of the written material, the video, the CDROM or the website address and password.

c) How will the delivery methods you have selected assist the participants to achieve the learning objectives?

The participants will be provided with comprehensive information to give a solid base to managing depression relapse. Psychosocial skills used in the management of depression will be demonstrated and then practiced. Participants will have the opportunity to ask questions and tap into the resources of everyone in the group. They will take away a training kit and patient manual, which will provide a valuable future resource when working with patients with depression.

d) How many GPs do you anticipate will attend? 9-10

Note: Where possible, all attendance lists should be submitted electronically via email or on a disc to the RACGP.

e) In what ways will GPs be involved as resource people in conducting your activity? i.e. speakers, facilitators, case presenters etc

Drs Cate Howell and Ian Wilson will be co-presenters and facilitators. The GPs within the group will be an invaluable resource to each other.

7. EVALUATION

Please provide a brief summary of your proposed evaluation process. (Including when post-test will be sent in relation to the activity. Evaluation form and post-test questionnaire attached. Post-test questionnaire to be sent out 4 weeks after seminar.

a) Evaluation of the activity
If you are using a questionnaire or survey please attach a copy of the document.

b) Post test
Please attach a copy of the proposed post-test (may be a questionnaire or a clinical audit).

Note.
- The post test must include an assessment of behaviour, attitudes, skills & knowledge. Not simply knowledge alone.

© Copyright RACGP 2002 – May be reproduced for submission purposes only.
Spph Activity – March 2002.
8. SHARED INFORMATION CONSENT

Please indicate

☑️ I give permission:  ☐ I do not give permission:
for program information to be shared with researchers and interested GPs for the purpose of continuing education coordination at the discretion of the RACGP Quality Assurance and Continuing Professional Development Program.

Note. The RACGP may use the information in this application for its own research and evaluation.

9. DECLARATION

I declare that:

- The information provided in this document is accurate and complete.
- I will provide GPs who attend this educational activity with a written record of their participation (2pph or 5pph).
- I will provide a list of all GP participants who wish to report their participation to the RACGP QACPD Program
- I will provide a summary of evaluation results, within 2 months of completion of the evaluation to the RACGP QACPD Program (unless otherwise negotiated).
- This activity has been designed to comply with the Privacy Act amendments (2001).

I understand that:

Activities allocated points in the QACPD Program are monitored randomly to ensure they are conducted in accordance with the application and to evaluate the impact of the adjudication criteria. The QACPD Program may require that any future repeats of an activity, or the enduring material, be altered or withdrawn on the basis of additional information received about the original activity.

Future applications may not be considered from providers whose activities are not conducted in accordance with their applications or who do not fulfil their undertakings.

CONTACT PERSON: ___________________________ DATE: ___________________________

SIGNED: ___________________________

This application for activity adjudication is:

☑️ An application for adjudication only, for 5pph.
☐ A post test for Accredited Provider training. Name of person: ___________________________
☐ The organisation's 5pph activity for the Accredited Provider process.

© Copyright RACGP 2002 – May be reproduced for submission purposes only.
5pph Activity – March 2002.
Contents of training manual

Overview of training

Outline of sessions
Session 1
Session 2
Session 3
Session 4
Session 5

Appendices
References

Overview of training

GP training for ‘A Primary Care Treatment Program Aiming to Prevent Relapse of Depression’ involves 20 hours (5 x 4 hour sessions)

Expectations of participants
To be discussed at the beginning of the workshop

Guidelines for the training
Participation is encouraged but voluntary
Participants are responsible for their own learning
Shared personal information is confidential

Preparation for the training
Participants are encouraged to read the materials provided prior to the training

Learning Outcomes

By the end of training, participants will

- understand the study of a primary care treatment program aiming to prevent relapse of depression
- have a greater knowledge of the aetiology and epidemiology of depression
- have reviewed the bio-psychosocial model of depression
- have an understanding of the chronicity of depression
- have a greater awareness of the co-morbidity of depression, anxiety and alcohol and drug use disorders
- understand the concepts of relapse and recurrence of depression and have an overview of the literature relating to relapse and recurrence of depression
- understand the 10 step relapse prevention program and its evidence-base
- gain knowledge of the management of depression including use of antidepressants and role of psychosocial treatments

By the end of session 1 participant will

- understand the importance of medical review in depression and use of psychosocial assessments (including risk assessment)
- have developed knowledge of depression assessment tools
- appreciate the importance of thorough assessment of depression
- gain experience in using depression assessment tools
- appreciate the importance of goal-setting with patients at the outset of treatment
- appreciate the importance of monitoring of progress
- have developed skills in goal-setting
By the end of Session 2 participants will

- appreciate the importance of psychoeducation in managing depression and preventing relapse
- be provided with a useful psychoeducation resource (in the treatment manual) and practise using it
- appreciate the importance of addressing healthy lifestyle issues in managing depression and preventing relapse
- have a useful resource for doing so
- have developed skills in stress management including relaxation techniques
- have improved knowledge of useful coping skills such as using a mood diary, problem-solving and managing panic episodes (slow breathing and cognitive strategies)
- have improved skills in helping patients develop these useful coping strategies

By the end of Session 3 participants will

- have developed a sound knowledge of the theory and evidence-base of cognitive-behaviour therapy (CBT)
- have a useful resource for using CBT with patients (in treatment manual)
- have seen modelled and practise CBT skills such as identifying negative automatic thoughts, explaining thinking distortions to patients, helping them identify thinking errors, and learn to challenge the thinking errors to develop more helpful ways of thinking
- have an understanding of the influence of underlying beliefs on thinking, and how to deal with being a perfectionist

By the end of Session 4 participants will

- have gained knowledge about the important psychological issues in depression, such as self-esteem and loss and grief issues
- have learnt ways of dealing with psychological issues such as raising self-esteem, dealing with grief and managing anger
- have seen these skills modelled and practised these techniques
- have developed further knowledge and skills in risk assessment
- appreciate the importance of encouraging activity in preventing relapse of depression
- have developed skills in activity planning
- be able to better help patients identify pleasurable activities
- appreciate the importance of developing social skills in preventing relapse of depression
- have developed skills in assertiveness training
- understand the basis and evidence-base of interpersonal-therapy (IPT) and have developed skills in helping patients deal with relationship issues

By the end of Session 5 participants will

- appreciate the importance of identifying early warning signs of depression in preventing relapse
- have developed skills in helping their patients identify and deal with early warning signs
- have the resources to develop a written relapse prevention plan with patients
- appreciate the importance of following-up patients methodically in preventing relapse
- appreciate the importance of reassessing patients with depression to monitor progress
- have a resource to review the information provided in steps 1-9
- have been provided with a resource list related to managing depression and anxiety including books and websites
Outline of Sessions

Session 1
Background information
- epidemiology of depression
- relapse and recurrence
- the bio-psycho-social model
- management of depression, including assessment (step 1)

Introduction to the study
- the 10 step relapse prevention program
- training outline

Session 2
This session will cover a range of skills which are included in steps 1-4 of the ‘Keeping the blues away’ treatment program

1. goal-setting (step 1)
2. psycho-education (step 2)
3. healthy lifestyle issues (step 3)
4. useful coping skills (step 4)
   a. keeping a mood diary
   b. problem-solving
   c. relaxation techniques

Session 3
Cognitive-behavioural therapy (CBT) and prevention of depression relapse

Introduction to CBT

5 steps to tackle unhelpful thinking that can occur in depression (step 5)

Session 4
Dealing with psychological issues
1. self-esteem
2. loss and grief
3. dealing with negative emotions
4. loneliness
5. hopelessness and suicidal thoughts (step 6)

The benefits of activity, including activity scheduling (step 7)
Fostering social support and skills – interpersonal issues (step 8)

Session 5
Developing a plan for managing early relapse symptoms (step 9)
Reassessment
Review of steps 1 to 9 (step 10)
Resources
Conclusions and questions / evaluation
Session 1

Background information

The following topics will be discussed
- epidemiology of depression
- relapse and recurrence of depression / depression as a chronic illness
- the bio-psycho-social model of depression
- management of depression

Epidemiology of depression

Depression is a common and disabling disorder. The prevalence of depressive disorders in Australian adults is approximately 6% (Casey, 2000). It often impairs social and occupational functioning, impacting on relationships and productivity. On average, depression causes 2.7 days of impaired functioning a month (adding up to almost 3.5 million person-days a year) (Casey, 2000).

The effects of depression on quality of life and daily function are said to match those of heart disease, and exceed those of diabetes (Olfson, 2002). Suicide is a major risk (Glass, 1999). In Australia, the economic cost of depression has been estimated at 5 billion dollars per annum (Casey, 2002). According to the Global Burden of Disease Study, depression is predicted to become the second leading cause of disease-burden worldwide by 2020 (Murray, 1997).

Relapse, recurrence and chronicity

Depression is a recurrent disorder (Simon, 2000). Relapse is defined as early return of symptoms; and recurrence as later return of symptoms after a period of remission (Kupfer, 1991). Relapse is reported to occur in up to 50% of individuals who have had one episode and 80% of individuals who have had two episodes, and up to 20% are said to have a chronic depressive course (Katon, 2001). Depression is now viewed as a chronic illness (Klinkman, 1997).

There is limited data on the relapse rate of depression in primary care, but it is reported to be lower than in specialist settings (Van Weel-Baumgarten, 1998). An American study found the primary care relapse rate to be 37.1% (Lin, 1998).

The risk factors for relapse and chronicity of depression are reported to be continued (including sub-threshold) symptoms and a past history of dysthymia (depressed mood for more days than not over two years) or depression (Lin, 1998; Simon, 2000). Early onset, severe depression and long duration (Clark, 1999; Mynors Wallis, 2000) are risk factors, along with co-morbidities (Simon, 2000). Lewinsohn found that initial depressive episodes are often precipitated by stressful life experiences and subsequent episodes by negative thinking styles (Lewinsohn, 1999).

<table>
<thead>
<tr>
<th>Table 1. Risk factors for depression relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td>continued symptoms</td>
</tr>
<tr>
<td>past history of dysthymia or depression</td>
</tr>
<tr>
<td>early onset</td>
</tr>
<tr>
<td>severe depression</td>
</tr>
<tr>
<td>long duration</td>
</tr>
<tr>
<td>co-morbidities</td>
</tr>
<tr>
<td>stressful life experiences</td>
</tr>
<tr>
<td>psychosocial difficulties</td>
</tr>
<tr>
<td>negative thinking styles</td>
</tr>
</tbody>
</table>

The literature on preventing the relapse of depression suggests that it is important to identify these risk factors and to try to minimize them (Fava, 2000). The presence of residual symptoms of depression after an episode is associated with rapid relapse and this has implications for treatment (Judd, 1998). Vigorous early treatment of depression is recommended to prevent chronicity, and ongoing
Two articles on the chronicity of depression will be provided, namely


The bio-psycho-social model

The cause of depression is not fully understood, but it is seen as a biological disorder that is made worse by life stress. It is thought to be the result of a number of different factors which can be summarised as the ‘bio-psycho-social’ model of depression, referring to biological, psychological and social factors (Engel, 1980).

1. Biological

*Genetic* – depression tends to run in families; that is, there is an inherited tendency to develop the disorder (Kaplan & Sadock, 1994).

*Neurotransmitter theory* – in depression there is a change in certain nerve messenger chemicals or neurotransmitters in the brain (serotonin, noradrenalin and dopamine). We do not know what causes the altered levels of chemicals, or whether they result in the depression or are actually caused by the low mood.

*Physical* illness or *medications* – infections such as glandular fever, or anaemia, low thyroid function or diabetes can produce symptoms of depression. An individual may be more prone to low mood at times of hormonal changes, such as menopause. Some prescribed medications have depression as a side effect (such as steroids and beta-blockers), and drug abuse can be associated. [Overheads – physical disorders that can cause depression / drugs that can cause depression]

2. Psychological and social

*Stressful life events* - stressful life events may have a role in the onset or relapse of depression. Stress from personal tragedies, relationship breakdown or unemployment for example, can contribute to depression. Loss and grief may be a trigger (New Zealand Guidelines on depression, 1996).

Depression occurs more commonly at different stages of life, such as adolescence, middle age, and retirement age and in the elderly. Traumatic early life experiences can be associated with later depression.

*Personality* – an individual’s personality may be a factor in depression. Some people have a tendency to be pessimistic and view things negatively, or be prone to worry. Early life traumas may influence personality and vulnerability to depression (Evans & Burrows).

*Social* - Lack of social supports is a risk factor for depression. Social and economic factors can put a lot of stress on people and decrease opportunities to look after health and well-being (Preston, 2000).

These factors may interact to trigger depression, for example someone may have a family history of depression, and at a time of life stress may become depressed. Looking at the causes of depression highlights that there are risk factors for depression as well as protective factors.
Management of depression begins with accurate diagnosis and assessment.
There will be discussion about GPs experiences with assessment, and the importance of excluding underlying medical problems.

Several articles will be provided:

The DSM IV criteria for major depression are as follows.
Five or more of the following symptoms have been present during the same 2-week period and represent a change from previous functioning; at least one of the symptoms is either
1. depressed mood or
2. loss of interest or pleasure.

The other symptoms (nearly every day) may include
- significant weight loss
- insomnia or hypersomnia
- psychomotor agitation or retardation
- fatigue or loss of energy
- feelings of worthlessness or inappropriate guilt
- diminished ability to think or concentrate

There may be recurrent thoughts of death, recurrent suicidal ideation or a suicide attempt (DSM IV).

Patients included in this study will have a diagnosis of major depressive disorder according to DSM IV.

A range of assessment tools will be discussed:
1. screening tools (to see if the condition is likely)
2. diagnostic tools (to establish a diagnosis)
3. severity rating scales (to rate severity)

The assessment tools used in this program will be outlined and demonstrated and participants will practise using the tools

1. 0-10 scale
2. Depression Anxiety Stress Scale (DASS) (Lovibond)
3. Quality of Life Scales
4. Clinical Global Improvement

Assessments 1-3 are to be completed at the beginning of the program, mid-way through and at the end of the initial sessions (about 3 months). They will again be repeated during the follow-up period.

[See appendices for copies of assessment tools used in the study.]

Comorbidities

The important issue of comorbidities will be highlighted.

1. Depression and anxiety disorders
2. Other mental illness such as schizophrenia, eating disorders
3. Substance abuse
4. Suicide

Suicidality

Suicide is a significant risk in depression. Lifetime mortality from suicide in discharged hospital populations is 15% in persons with major depression (Mann, 2002).

Risk factors include -

- Being male
- Family history of suicide
- Mental health problems such as schizophrenia or depression
- Previous attempts
- Comorbid substance abuse
- History of physical or sexual abuse
- Head injuries
- Rural area
- Access to lethal methods (e.g. gun ownership)
- Poverty and unemployment
- Social isolation (Mann, 2002).

<table>
<thead>
<tr>
<th>To assist in assessing suicidal risk, ask the following questions of the patient with respect to the last month.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you want to harm yourself?</td>
</tr>
<tr>
<td>2. Have you thought about suicide?</td>
</tr>
<tr>
<td>3. Have your made any plans to take your own life? (if yes ask specific details)</td>
</tr>
<tr>
<td>4. Have you attempted suicide?</td>
</tr>
<tr>
<td>5. And, at any time in life have your ever attempted suicide?</td>
</tr>
</tbody>
</table>

It is generally regarded that questions 2, 3, 4 & 5 are more strongly indicative of suicidal risk. Suicidal risk accelerates with an increasing number of ‘yes’ responses. However, if the patient responds with yes to any of the questions then it is vital to carefully assess the suicidal risk and organise psychiatric involvement if necessary.
Management involves pharmacotherapy and psychosocial interventions.

1. Pharmacotherapy

Choice of medication is based on individual needs and depends on:
- severity of the depression (mild vs. moderate vs. severe) and risk of suicide
- presence of co-existing medical problems
- past psychiatric history and in particular previous response to antidepressants
- side effect and drug interaction profile of different medications
- the patient’s acceptance of the choice of medication. (Therapeutic Guidelines: Psychotropic 4th Ed. 2000)
- GP’s experiences in using different medications may also be a factor.

Current guidelines recommend the selective serotonin reuptake inhibitors (such as paroxetine, sertraline and citalopram) as first-line therapy. Tricyclic antidepressants are also indicated as first-line treatment. However the tricyclics should be avoided in the suicidal patient due to life threatening effects in overdose (Starting out with antidepressants National Prescribing Service Newsletter, Nov 2000).

The serotonin and noradrenalin reuptake inhibitor, venlafaxine, and the 5HT antagonist, nefadazone are given as first-line agents in severe depression (Ellis, 2002; Hickie, 2001). Initial drug therapy is said to assist patients to get ‘out of the hole’, but ongoing maintenance therapy is also very important (Hickie, 2001). For an initial episode, the current guidelines recommend continuing antidepressant therapy and / or a CBT booster for at least one year (Ellis, 2002).
Management of depression involves both pharmacological and psychosocial interventions, and most patients “do better with a combination of medication and psychological therapy” (Mitchell, 1998). It is thought that use of medication leads to a more rapid recovery, but that patients do better long-term with additional psychological therapy (Paykel, 1999). There is evidence that for more severe and recurrent depression, combination therapy is more effective (de Oliveira, 1998).

Several recent studies have provided evidence of the effectiveness of specific interventions for depression such as cognitive-behavioural and interpersonal therapies (Goaguen, 1998; Chilvers, 2001; Mynors-Wallis, 2000; Dowrick, 2000; Fava, 2000; Ward, 2000). In the past few years the application of these treatments in the primary care setting has begun to be examined. A Norwegian study evaluated the efficacy of emotional support, counselling and follow-up combined with antidepressant medication in the treatment of depression in primary care. The response rate was found to be comparable to results reported by mental health specialists, and the combination of psychological treatment and medication was more effective than psychological treatment alone (Ward, 2000).

Depression treatment guidelines are available. These encourage and provide evidence for using combination therapy.

The beyondblue guidelines will be provided and discussed (Ellis, 2002). An article about an integrated approach to assessing and treating depression in general practice by P. Mitchell will also be provided.

3. Stages of recovery

The management of depression can be thought of in terms of stages of recovery. There is the acute or initial treatment phase, aiming to stabilize and relieve symptoms. This is followed by a stage of continuation of treatment to prevent the return of acute symptoms. A maintenance phase of treatment aims to prevent relapse. The length of this phase depends on the history of depression and the risk of developing a new episode (New Zealand guidelines on depression, 1996).

The recommendations of the beyondblue guidelines for a recurrent episode of depression are:

- antidepressant therapy be continued and / or CBT booster and monitor the patient approximately every three months for up to three years until the risk is reduced
- if no prior psychological therapy add 6-8 sessions of CBT / IPT with one booster session every three months for 2-3 years
- consider facilitating increased social support and employment, and teaching problem-solving.16

It is very important for a GP to keep in touch with patients who have had an episode of depression. During treatment of depression patients need to be seen regularly and their adherence to treatment monitored as well as progress. It is reported that many patients stop antidepressant treatment early and increase their risk of relapse as a result. It is helpful to opportunistically ask patients with a history
of depression about depressive symptoms when they present about unrelated health problems. The GP may encourage the patient to maintain relapse prevention strategies, or relapse may be diagnosed and treated earlier than otherwise (Blackburn, 1997).

**Introduction to the study**

The proposed study aims to implement a primary care depression relapse prevention program and evaluate its effectiveness via a cluster randomisation trial. The primary hypothesis is that the program will reduce the relapse rate of depression by one half when compared with usual general practice care. Secondary hypotheses include increased remission time, reduced severity of relapses, improved adherence to treatment, earlier identification of symptoms of relapse and improved quality of life. Qualitative research will be undertaken regarding practitioners’ and patients’ perceptions of the program (including level of satisfaction).

The evidence upon which this primary care relapse prevention program has been based has been gathered from literature review and clinical practice guidelines. Many years of clinical experience in primary care mental health and a year 2000 Churchill Fellowship provided valuable insight into this research area.

A formal literature review has been carried out. Electronic and hand searches have been done to find literature on the treatment of depression and relapse prevention. Over 130 articles have been found and a number of the relevant articles have already been referred to. All aspects of this project – design of the program to methodology - are well supported by current literature.

There are very few studies of primary care interventions aiming to reduce relapse of depression. A team of researchers in Washington headed by W. Katon has carried out work in this area, but the interventions used are designed for the American health care system which operates differently from the Australian system. [Note – the article by W. Katon “A Randomised Trial of Relapse Prevention of Depression in Primary Care” will be provided.]

It is generally agreed that GPs have a key role in the management of mental health problems (Phongsauan, 1995; Holmwood, 2001). There is increasing recognition of the need for GPs to carry out appropriate psychosocial treatment, and to provide longer term care (Casey, 2000; Ellis and Smith, 2002). This has implications for managing patients with depression. The GP has a central role in the management of depression and in relapse prevention.

In Australia the National Mental Health Strategy provides the impetus to improve outcomes for Australians with mental health problems. To assist general practitioners in developing greater skills in the diagnosis and treatment of mental health problems the Government has introduced the Better Outcomes in Mental Health Care initiative, involving education and training, a 3 step assessment planning and review process, focused psychological strategies (such as CBT) and improving access to allied health and specialist psychiatric support.
This treatment program fits neatly with the Better Outcomes in Mental Health Care initiative. It provides a bio-psycho-social treatment approach, and involves recommending a range of focused psychological strategies be incorporated into the management of patients with depression. The program is unique in its integrated, holistic approach and its application of a range of psychosocial strategies to the primary care setting.

Review of the literature provides support for a primary care depression relapse program that includes thorough assessment and treatment of co-morbid problems, and early vigorous treatment (Hickie, 2002). Such a program should be evidence-based and follow current management guidelines (Ellis and Smith, 2002; Hickie, 2000). Education about depression and relapse are important, and a relapse prevention program should be multifaceted and integrative and include psychosocial treatments (Katon, 2001). The program needs to encourage adherence to medication, and address the risk factors for relapse as well as lifestyle and well-being (Fava, 2000). Long-term management of depression should incorporate a chronic disease management model (Andrew, 1998).

The proposed primary care relapse prevention program involves ten steps:

1. Getting started - initial assessment (medical and psychosocial) and goal-setting
2. Information about depression, including treatment, relapse prevention, and community resources (with involvement of family if appropriate)
3. General health promotion and lifestyle advice (nutrition, exercise, sleep, reducing stress)
4. The development of useful coping skills including problem-solving and stress management (includes relaxation training)
5. Key cognitive strategies to address the depression, co-morbid anxiety and self-esteem issues
6. Psychological interventions addressing current psychological issues
7. Encouragement of pleasurable / meaningful activities
8. The fostering of supportive social relationships and social skills
9. Regular review of progress and of skills acquired, along with the development of an emergency plan to use if early signs of relapse occur
10. Reassessment, review and resources (Katon, 2001; Katon, 1999; Simon, 2000; Melfi, 1992; Schulberg 1998)

[Note - usual general practice would be to include some but not all of these steps, with less emphasis on the psychosocial strategies.]

The relapse prevention program involves:

- Initial regular (weekly to twice weekly) treatment sessions with the practitioner (up to 12 sessions, approximately 3 month period).
- Regular follow-up sessions over a 12 month period (see methodology provided in research proposal, and GP checklist).

This incorporates the Better Outcomes three-step process and focused psychological strategies (Level 1 and 2).

Patients are provided with a 200 page manual containing explanations, exercises and resources relating to each step.

The intervention has been piloted during January to July, 2003, in urban and rural areas, and has been well received. Some adaptations have been made to processes and materials for the full study as a result of the pilot.
Ethical considerations and data collection
The University of Adelaide Human Ethics Committee has approved the project. The following ethical implications were addressed in the Ethics application:

(1) Participation in this study will be voluntary with informed consent. Note that there is evidence that patients with depression are able to give informed consent.
(2) Furthermore there is need to ensure that any personal health information collected will be protected in terms of privacy and confidentiality.
(3) Consequently
   - information sheets detailing the project will be provided to subjects;
   - written informed consent will be obtained from patients agreeing to participate in the study;
   - appropriate security procedures will be implemented in data storage and access e.g. secure storage of documentation;
   - final analysis and reporting will utilize only de-identified and de-aggregated data;
   - patients will be informed that they may refuse to participate in the study or should they wish to withdraw from the study their treatment will not be compromised.

[Patients in the control group will receive the “usual (standard of) care” from their GP’s.]

Thus, patients are to be provided with an information sheet and given the opportunity to discuss this with their family and have any questions answered. A consent form needs to be signed in the presence of the GP. Also, there are data collection sheets for the GP and patient to complete (see appendices).

[See appendices for research proposal outlining the study in detail.]
Session 2

This session will cover a range of important treatment areas / skills. These are included in steps 1-4 of the ‘Keeping the blues away’ treatment program.

The skills will be discussed, modelled and practiced in the small group setting.

1. goal-setting
2. psycho-education
3. healthy lifestyle issues
4. useful coping skills
   (d) keeping a mood diary
   (e) problem-solving
   (f) relaxation techniques

Goal-setting

It is very important to involve the patient in treatment planning. Goal-setting provides a means of doing this, and tailoring treatment to the individual.

The following information on goal-setting is taken from the ‘Keeping the blues away’ patient guide.

It is helpful to have a sense of direction in managing the depression. The patient and GP can work together to establish a number of goals directed towards coping and recovery. A goal is an aim or want – it is about where you want to be. There are three steps of goal setting. (Adapted from Kidman A., Feeling Better: A Guide to Mood Management, & the World Health Organisation’s Management of Mental Disorders)

1. Make a list of what you see as your short-term goals right now.

Goals need to be realistic, as it is best to set a goal that can be achieved. Any goals you have, no matter how small, are important.

Be specific about what you want.

How you define “short-term” will vary for different people at the different stages of recovery. You may make a goal for an hour, a day, a week or a month.

It is best that goals be written in the positive sense, about what you will do rather than what you don’t want to do.

Choose goals that are not dependent on other people; that is, choose independent goals.

Here are some examples of goals:

- To turn negative thoughts into more positive thoughts
- To keep issues in perspective
- To find time to do some exercise.
Write down your goals.

<table>
<thead>
<tr>
<th>Short-term goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
</tr>
<tr>
<td>B.</td>
</tr>
<tr>
<td>C.</td>
</tr>
<tr>
<td>D.</td>
</tr>
</tbody>
</table>

2. Prioritise or rank the goals according to their importance to you right now.

<table>
<thead>
<tr>
<th>Prioritise your goals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
</tbody>
</table>

3. Now break down an important goal into steps that you will need to take to achieve the goal. The steps need to be as small and specific and achievable as possible. It is useful to identify help that you might need to achieve your goals. An example of breaking a goal down into steps: The goal, “to turn negative thoughts into positive thoughts”, could be broken down into the following steps:

- Be more aware of my negative thinking.
- Work out how to turn it into more positive thinking.
- Practise

<table>
<thead>
<tr>
<th>Steps to achieve my “number 1” priority goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
</tbody>
</table>

I plan to achieve this goal by: ____________(date)
I will know that I have achieved it because:

Repeat step 3 with your other goals:
Steps to achieve my goal

1. 
2. 
3. 
4. 

I plan to achieve this goal by: ____________ (date)
I will know that I have achieved it because:

It is important to:

Review and rewrite your goal lists regularly. They may change as different aspects of your recovery assume more importance. For example, improving health may be a priority at one time, resuming an interest or returning to work at another. As recovery occurs you will feel more able to focus on longer-term goals.

Focus on your achievements (no matter how small), and what you have learnt from setting goals, even if particular goals are not reached.

Psycho-education

Psycho-education is a vital part of treatment for patients with depression and their families / carers. Available treatments (medication and psychosocial) need to be explained.

The following areas will be discussed in detail.

Medication

- choice of antidepressant
- starting an antidepressant
- allowing time for medication to take effect
- possible side effects and drug interactions
- length of treatment (treatment guidelines)
- maintenance therapy
- changing medication
- finishing antidepressants
- useful sources of information re medication

The following will be provided

There is a range of psychological therapies for depression, namely
- Counselling.
- Cognitive-behavioural psychotherapy.
- Interpersonal psychotherapy.
- Insight-oriented psychotherapy.
- Other therapies (Evans & Burrows).

This relapse prevention program draws on a range of therapies, and is multi-modal or eclectic in its approach.

- The term counselling covers a wide range of techniques. The main focus is on providing non-judgmental support so that people can talk over their problems. Having support during a very difficult time is really important (WHO Guide to Mental Health).

- Cognitive-behavioural therapy (CBT) is one way of helping people to cope with depression, stress or anxiety. It is based on the idea that our thinking influences how we feel. CBT teaches patients to be aware of and challenge negative thinking or thoughts that produce fear (anxiety). It includes techniques that help change behaviours. In doing so it helps tackle the symptoms of anxiety and depression.

In treating depression, there is a lot more involved than just positive thinking. CBT involves relearning more helpful thinking patterns, and has been shown to be effective in treating depression and preventing relapse (Gloaguen & Cottraus, 1998).

- Interpersonal psychotherapy focuses on the impact of relationship difficulties on the depression. Mood and interpersonal events are seen as dependent on each other. Feelings of grief or conflict may be involved, or difficulties relating to people socially (for example, being assertive) (Davies, 2000).

- Insight-oriented psychotherapy aims to assist the person in understanding possible psychological causes of their depression (Evans & Burrows).

- There are other types of psychotherapy and different therapists may have a preference for using one over another, depending on their training. One that you may hear about is narrative therapy. This form of therapy involves the therapist and the individual patient working together to identify what the individual wants in their own life, and how to utilise their own knowledge and skills (White & Denborough, 1998).

Well-being therapy focuses on wellbeing rather than relieving symptoms of illness and aims to increase personal effectiveness (Fava, 1998).

GPs or therapists may choose to use a combination of talking therapies (UK Royal College of Psychiatrists website). GPs tend to be what is called eclectic or multi-modal in their approach, that is, they draw on a range of treatment approaches (Dryden & Mytton, 1999). This is because they are used to dealing with such a wide range of problems and issues in their practice.
A comprehensive psycho-education resource has been developed and incorporated into the patient manual. Refer to the patient manual. Step 2 in the manual will be outlined and discussed.

Healthy lifestyle issues

Step 3 of the program addresses lifestyle issues. The materials are based on common sense and evidence.

[see New Zealand guidelines on depression, the Australian guide to healthy eating and article on meditation by C. Hassed].

Participants will practise using the materials provided in step 3 of the patient manual.

Useful coping skills

The treatment program teaches a number of useful coping skills including

- keeping a mood diary
- problem-solving
- relaxation techniques.

The evidence base for these skills will be outlined. These articles will be provided:


Each of these skills will be explained and modelled, and participants will be able to practise these skills.

The following information is taken from the patient guide.

Keeping a Mood Diary

It can be useful to keep a diary of your mood (Greenberger, 1995). You can record what is happening with your mood each day by completing a mood scale. Rate your mood on a scale of 0 to 10, where 0 refers to no depression, and 10 to the most severe depression. Use the same diary to comment on:

- Length and quality of sleep, and what your eating is like.
- Significant events or activities of the day.

The diary will help you be more aware of what is happening and be a good basis for discussion with your GP.
The diary for one week will look like this:

<table>
<thead>
<tr>
<th>Day</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood</td>
<td>0-10</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sleep</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eating</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other e.g. events, changes to medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

As time passes you will see progress. As things improve, try and focus on positive feelings and events. What helped you pick up in mood, no matter how simple a thing? What positive events have happened in your life, no matter how small? What positive shifts are happening in your life – are you sleeping better, or becoming more active?

**Problem-Solving**

When feeling stressed or depressed, negative thoughts can seem overwhelming. It can be harder to think through a problem clearly, to even know where to start in dealing with it. One practical strategy that can help is called “structured problem solving” (WHO, 1997; Andrews, 1998). This sounds complicated, but it isn’t. Problem solving is a good way to become more self-reliant.

Problem solving involves sorting out what the problems are and looking at logical, practical ways of dealing with each of them. The steps involved are common sense. The aim is to decide on the best possible solution for the problem. This may not be a total or perfect solution, but it will be a start and it will usually be helpful and make a difference.

Here are the general rules for problem solving:

- When learning the technique, start with more straightforward problems rather than complex ones.
- Set aside time without distraction to help you think clearly.
- Consider one problem at a time.
- Go through all the steps.
- When making a list of possible solutions, write down all your ideas even if some seem wild – in the end you will need to choose an achievable solution, but the process of writing down all the possibilities often generates good ideas.
- When planning how to carry out the solution, be realistic – are the resources (time, money ...) available?
Include plans on how to deal with difficulties or negative responses that might arise (such as looking at what went right and what went wrong, and what alternative strategies could be used; acknowledge disappointment but plan to try again).

Think about how you might manage positive outcomes, as these might involve adjusting to change.

As with goal-setting it is useful to set a time by which to carry out the solution.

Remember that even partial success is a win, and the process of problem solving is a learning process (WHO, 1997).

The steps involved in problem solving are:

1. define the problem in everyday terms
2. make a list of all possible solutions
3. evaluate the solutions; that is, think about the advantages and disadvantages of each solution
4. choose the best possible solution
5. plan how to carry it out – this involves breaking the solution down into steps
6. review how you progress.

Below is a sheet that you can photocopy and use for problem solving.

PROBLEM SOLVING

STEP 1.
Define the problem – that is, write down in your own words what you think the problem is________________________________________________________________________

________________________________________________________________________

STEP 2.
Make a list of all the possible solutions to the problem.

________________________________________________________________________

________________________________________________________________________

STEP 3.
What are the advantages and disadvantages for each solution?

Solution (1)
Advantages

Disadvantages

Solution (2)
Advantages

Disadvantages

Solution (3)
<table>
<thead>
<tr>
<th>Advantages</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Disadvantages</th>
</tr>
</thead>
</table>

**STEP 4.**
Based on the solution that seems to have the most advantages rather than disadvantages, choose the best possible solution for now.

________________________________________________________________________

_____________________________________________________________________

**STEP 5.**
Do some planning – what steps will you need to do to carry out this solution?
Step
1. ___________________________________________________________________
2. ___________________________________________________________________
3. ___________________________________________________________________
4. ___________________________________________________________________
5. ___________________________________________________________________
(Plan as many steps as you need)

**STEP 6.**
Review how the problem solving is going. What has worked and been achieved? What still needs to be worked on?

______________________________________________________________

______________________________________________________________

______________________________________________________________

[Repeat the steps for other problems]

(Adapted from the GlaxoSmithKline Signals II program; Andrews G. & Hunt C. Treatments that work in anxiety disorders. *MJA Essentials.*)

**Relaxation Techniques (based on the program manual)**

A range of relaxation techniques will be demonstrated and practiced.
The ‘Keeping the blues away’ CD will be utilised.

The following articles will be provided.

There are physical and mental benefits from relaxing (Magarey, 1989; Ward, 1996). These include positive effects on blood pressure and the immune system, improved sleep and reduced anxiety.

Everyone can learn to relax more and gain the benefits. Relaxation is a positive experience in different ways. It tends to be confidence boosting and gives a sense of control. Relaxation techniques are part of a holistic approach to health and especially important to learn in depression and anxiety. A range of basic techniques will be covered here. Don’t expect to be an expert initially. Be patient and try them. You may find one technique suits you better than another.

How long should you allow to relax? You might want to set aside 20 or 30 minutes initially. As you become more familiar with the techniques you tend to relax more readily and less time is needed. Don’t let time be an excuse - even 5 minutes of relaxation is useful.

[Note - People with a psychotic illness, such as schizophrenia, should not use these techniques as the psychological condition could worsen. If you have strong emotional issues right now, talk with your GP about them. They can advise you as to whether or not the techniques are appropriate to use right now.]
1. Physical relaxation.

One of the first forms of relaxation to learn is physical relaxation. You may or may not be aware of areas of tension in the body already. Some people hold tension in muscles of their foreheads, jaws, or neck and shoulders. Some hold it in their abdomen.

When muscles are tense they tighten and become shorter in length. The body can get used to holding that area in a tense state. When muscles relax they lengthen and become looser and more comfortable.

Simple stretches can help loosen tight areas [Only do stretches that you feel that you can manage physically]. Sometimes it is good to do a few stretches before you settle down to do the other forms of relaxation.

In step 3 the “windmill stretch” was explained. An alternative is to simply reach upwards with your arms and push up onto your toes and stretch to the sky.

To loosen the head and neck and shoulder areas in particular —
- move your forehead muscles up and down, smile, loosen the jaw
- gently and slowly move your chin down towards your chest, and hold for a few seconds, and then move the head gently back [never push further than is comfortable]
- move the head gently and slowly to one side (with the ear moving towards the shoulder) and then the other, and
- gently roll the shoulders forward a few times and then roll them back

Progressive muscle relaxation is another way to relax physically (Davies, 2000; Hickie, 2000). This technique is included on the CD provided. Sit or lie in a comfortable position, go to the toilet beforehand, make sure that you are warm enough, loosen any tight clothing, make sure the legs and arms are uncrossed and remove glasses. Let your eyes close. Allow 15 to 20 minutes initially for this form of relaxation alone.

Relax each of these areas by being aware of any tension in these areas and letting go of it. Feel the muscles loosen and lengthen
- the muscles of the face (forehead, around the eyes, in the cheeks, around the mouth, in the jaw area)
- the scalp and the neck, especially the muscles at the back of the neck
- across the shoulders and down into the shoulder blades
- the muscles of the upper arms, the forearms, into the hands and fingers
- let the chest muscles relax
- and the muscles of the back, all the way up and down the spine
- relax the tummy muscles and the buttock muscles
- let relaxation flow down into the legs, through the thigh muscles, calf muscles and into the feet.

Enjoy the feelings of physical relaxation for as long as you want to, open your eyes when you are ready and return to your day.
2. Breathing techniques

Another key in learning to relax is to breathe effectively (Singh, 1996). When stressed the breathing rate can increase and breathing can become shallow, for example. The usual resting breathing rate in an adult is about 12 breaths per minute. When anxious it may go up to 25 breaths per minute.

Try this range of breathing techniques and find out what suits you:

- Breathe in and out through your nose if comfortable with this, or in through the nose and out through the mouth. Simply be aware of the breath in and then the breath out. Breathe at a gentle slow pace, and feel the cooler air moving in. Breathe out and feel the warmer air. Say “relax” as you breathe out and let go of tension and stress as you do so. (This technique is included on the tape provided).

- Abdominal breathing or diaphragmatic type breathing. Effective breathing means expanding your chest by lowering your diaphragm – in doing so the abdomen moves outwards. The larger volumes of the lungs are at the bases of the lungs. Often we think a deep breath in means raising the shoulders, but this is where the smaller volumes of the lungs are.

Try abdominal breathing in sitting or standing or lying (depending on what suits you). Place your hands over your abdomen – let them relax. Breathe in and feel the hands rise, breathe out and feel them fall. Repeat. Make an effort to pause and breathe in this way several times during the day.

[Practice this technique with your GP.]

Once you feel more confident with each of the progressive muscle relaxation technique and a breathing technique, you can combine the two. Breathe and relax as you relax each of the areas of the body, or start with one and then do the other.

3. Visualization

Are you able to picture things in your imagination? Some people can and some people find this more difficult. If you are able to visualize, then following on from physical relaxation, you may want to try a visualization technique.

Choose a special and safe place that is peaceful and relaxing to imagine. It may be curled up in a chair with a book, or it might be walking along a beach. Imagine being in that special place and doing what you enjoy. You can have someone or a pet with you if you want, always peaceful and safe. Get in touch with the different sensations such as the feel of the breeze, the smells, or the colour of the sky.

Don’t worry about thoughts that may come into the mind - let go of concern about them and let them drift past.

In this special place it is good to give yourself some encouragement. People often find affirmations helpful – these are statements about what you can do or feel or achieve, said in the present tense – such as “I am feeling more relaxed each day”, “my self-confidence is growing day by day”.

284
If you are not able to visualize that is alright, simply be in the moment and deepen the feeling of peace. Some people listen to music when they relax and focus on the music. Take the opportunity to still encourage yourself with affirmations.

In step 3 the role of colour in relaxation was mentioned. There are some very pleasant relaxation techniques based on colour (Hunter, 1988). A relaxation technique involving colour is included on the CD.

Whenever you are ready to finish the relaxation, whatever form you use, gradually head back to the present moment, by reorienting yourself to where you are and the day. On the CD counting one up to five is used to allow a few moments to reorientate yourself.

**Session 3**

CBT is based on the premise that the person’s negative thoughts lead to a negative appraisal of themself, the future and the world, and other unhelpful beliefs. It is postulated that if thinking and behaviours are targeted in therapy, that this will lead to an overall improvement in the depression. (New Zealand Guidelines on depression, 1996).

[A guide to Cognitive behaviour therapy in medical practice by J. Tiller will be provided.]

**CBT and prevention of depression relapse**

There is evidence for the effectiveness of Cognitive-Behavioural Therapy (CBT) in preventing relapse (Blackburn, 1997; Jarrett, 2001; Fava, 1998; Gortner, 1998; Paykel, 1999). A study looking at the prevention of recurrent depression with CBT after pharmacotherapy found lower relapse rates resulted (persisting for four years) (Fava, 2001).

A mindfulness-based approach has been developed by Z. Segal and this has been evaluated in a randomised controlled trial involving 145 patients (group mindfulness-based cognitive therapy versus normal treatment). For patients with three or more episodes of depression, this form of cognitive therapy significantly reduced relapse, but there was no difference in patients with two previous episodes (Teasdale, 2000).

Articles will be provided, and the following CBT skills will be discussed, modelled and practiced.

**Introduction to Cognitive-behavioural Therapy** (based on the program manual).

CBT is an effective means of tackling symptoms of anxiety and depression. It involves changes in our behaviour and thinking. It is a very practical therapy, is useful in everyday life, and deals with current problems and ways of coping.
In depression the thinking is negative, and is often self-blaming and self-critical. There can be a negative view of the world and the future (Blackburn, 1990). CBT involves learning strategies to change this negative thinking.

Learning how thinking and feeling interact, and how to develop different ways of thinking is the basis of the cognitive part of CBT. What you think affects how you feel and how you feel affects what you think. What you do impacts on how you feel and think. Going out for a walk in the sunshine, for example, may lift mood.

Our minds are busy most of the time. We have a lot of thoughts that occur automatically. How we respond to everyday situations is often based on habit. Automatic thoughts occur and may be positive such as “I'll give it a go”, or negative such as “I'll never be able to do it” (Tanner, 1991). Automatic thoughts may not be a problem, but they may be unhelpful and interfere with handling everyday activities.

5 steps to tackle unhelpful thinking that can occur in depression

a. Keeping a thought diary

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Situation</th>
<th>What you were feeling (0-10)</th>
<th>What you were thinking</th>
<th>What did you do?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worst mood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Best mood</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

b. Understanding thinking errors - examples will be given

<table>
<thead>
<tr>
<th>Thinking Errors</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-or-nothing (or black and white) thinking</td>
<td>There is no middle ground. Things are seen in black and white; e.g., if you make a small error at work, you see yourself as a failure.</td>
</tr>
<tr>
<td>Overgeneralisation</td>
<td>Because something has gone wrong in the past, you see a continuing pattern of defeats – “I always mess things up”.</td>
</tr>
<tr>
<td>Disqualifying the positives</td>
<td>This refers to discounting any positive experiences and maintaining a negative outlook.</td>
</tr>
<tr>
<td>Jumping to conclusions</td>
<td>You make a negative interpretation of things; for example, you may interpret that someone is thinking negatively about you (mind reading) when there is no evidence of this – “they think I’m a loser”; or you may presume that things will turn out badly (fortune-telling)</td>
</tr>
</tbody>
</table>
| Catastrophising | This is exaggerating the importance of things; for example, a small
mistake may be perceived as a disaster.

<table>
<thead>
<tr>
<th>Should Statements</th>
<th>This is about motivating yourself with “shoulds” and “musts”. It is about setting high expectations for yourself, and the emotional results may be guilt, frustration or anger.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labelling</td>
<td>This is giving yourself a label and follows on from overgeneralisation; for example, making a mistake results in thinking “I’m a loser”.</td>
</tr>
<tr>
<td>Personalisation</td>
<td>You assume responsibility for a negative event, which you did not cause – “it’s all my fault”.</td>
</tr>
</tbody>
</table>

(Adapted from Burns D., *Feeling Good the New Mood Therapy*, and Tanner S. & Ball J., *Beating the Blues A Self-Help Approach to Overcoming Depression.*)

c. Identifying thinking errors

Another column can be added to the thought diary.

<table>
<thead>
<tr>
<th>Day / situation</th>
<th>What you were feeling (0-10)</th>
<th>What you were thinking (automatic thoughts)</th>
<th>Thinking errors</th>
</tr>
</thead>
</table>

d. Challenging unhelpful thinking

- Recognize that thoughts are not facts, they are actually assumptions.

- Look for evidence to prove or disprove your thinking, for example get feedback from other people or consider past experience.

- Put the situation into perspective by looking for other explanations or imagine talking with a friend with the same issue – how would you advise them?

- Test out the thinking by gathering information and asking others.

- Consider the advantages or disadvantages of having the thought.

- Change the words used in the thought; for example, “I should have done better”, can be reworded or reframed as “I did the best I could on the day - I’ll keep working on things and next time do better”

- Avoid using labels, for example “I’m a failure”.

- Use flexible words such as “I would like to” rather than should or must.

e. Developing more helpful thoughts - examples will be given

<table>
<thead>
<tr>
<th>Common thinking errors in depression:</th>
<th>More helpful ways of thinking</th>
</tr>
</thead>
</table>
| All or nothing, or black and white thinking – for example, “I’ll never be able to manage”, or “I have to get top marks”. | Change your perspective by considering other possibilities, such as “I may have some trouble managing, but I can cope”, or “I don’t have to be perfect”.
| Overgeneralisation – for example, “I always mess things up”, “I never get it right”.                        | Look for evidence to disprove your thinking – think about the times you did “get it right”? |
Labelling - “I’m hopeless”. Avoid naming yourself. Use different words such as “there are things I did well today, and I will work on the things that I want to do better”.

Catastrophising – “It’s a disaster”, “What if I never meet anyone else?” Work on a more balanced outlook – there is no reason to think the worst is likely to happen. Ask yourself what the most likely outcome is going to be. Questions like “is it the end of the world” or “am I exaggerating?” can be helpful. Avoid “what ifs” - consider that something may be possible, but not actually probable.

(Adapted from Tanner S. & Ball J., *Beating the Blues*; Burns D., *Feeling Good The New Mood Therapy*.)

Use the table below to work on developing more helpful thinking:

<table>
<thead>
<tr>
<th>Day / situation</th>
<th>What you were feeling? (0-10)</th>
<th>What you were thinking (automatic thoughts)</th>
<th>Thinking errors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>More helpful thoughts</th>
<th>What did you do?</th>
<th>Outcome (feeling 0-10)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

An important question in CBT - “Where do thinking errors come from?”

We develop assumptions and beliefs about the world, others and ourselves as we go through life. Beliefs operate at an unconscious level, but come into play when we need to respond to situations. Just as you have learnt to identify automatic thoughts, you can learn to identify underlying beliefs.

The psychological theory is that we can develop a number of unhelpful or irrational beliefs (Blackburn, 1990).

- In depression the beliefs tend to be negative. They may relate to needing to be loved by everyone or needing to be 100% successful – otherwise “I’m a failure”.
- In anxiety the beliefs relate to a sense of being threatened and lacking the ability to deal with threats; for example, “I should always watch out if I am to avoid something awful happening”, or “if I feel anxious, this means I am losing control”.

Here are some examples of irrational vs. rational beliefs:

<table>
<thead>
<tr>
<th>I must be loved or approved of by every significant person.</th>
<th>I would prefer to be liked by people but there is no way I can guarantee it.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I must be competent, adequate and achieving in all respects.</td>
<td>No-one can be like that all the time – I accept my strengths and weaknesses.</td>
</tr>
</tbody>
</table>
My life experiences determine how I feel. How can I feel good when things don’t go as they should?

I must always be in control of situations.

People should be sensitive to my needs and do what I believe is right.

Depending on how you view the world, individuals can be sad or disappointed.

The world is full of chance, but life can be enjoyed despite this. Wanting perfect control leads to a sense of loss of control.

People’s sensitivity varies greatly, and they are generally looking after their own interests. I can be assertive about my needs.

(Adapted from a patient handout from the London Institute of Psychiatry, based on Ellis A. (1962) Reason and Emotion in Psychotherapy.)

Dennis Greenberger and Christine Padesky in their CBT program Mind over Mood, suggest identifying themes from your thought diaries. Can you identify themes that may suggest underlying beliefs about yourself, others or the world? An example might be being a failure or not lovable. Are you a perfectionist, expecting a lot from yourself?

Greenberger and Padesky also suggest a “downward arrow technique” – taking a situation and a thought and then asking yourself “what does this say or mean about me?” Repeat this question until you get to the heart of the issue. For example:

```
I don’t seem to have any friends
(What does this say about me?)
```

```
I try hard but people just don’t seem to like me
(What does this say about me?)
```

```
I’ll never have any friends
(What does this say about me?)
```

```
I must be unlikable
```

Depending on the thought it may be more appropriate to ask “what does this say or mean about others … or the world?”

Once you have identified an unhelpful belief, make a list of its advantages and disadvantages. You may well find the disadvantages outweigh the advantages. Challenge unhelpful thinking relating to these beliefs.
As suggested by Bev Aisbett in her book “Living with It”, be a friend to yourself. This might mean giving encouragement to yourself. One way of doing this is through affirmations. These are positive statements about how one can think or feel or behave. Examples are; “I am feeling calmer and more confident each day”, or “I don’t have to be perfect – we are all human”.

See sections in program manual on
- being a perfectionist
- mindfulness-based CBT.

**Session 4**

**This session will cover steps 6, 7 and 8 of the program.**

**Step 6** addresses a number of key psychological issues that may be experienced by individuals with depression. These are
1. Self-esteem
2. Loss and grief
3. The negative emotions (anger and jealousy, guilt and shame)
4. Letting go of negative emotions
5. Loneliness and depression
6. Hopelessness, suicidal thoughts and depression
7. Finding hope and meaning

**Step 7** looks at the benefits of
- enjoyable activities
- activity scheduling
- keeping life simple
- laughter and humour

**Step 8** looks at ways to foster social support and skills. It looks at
1. Connectedness
2. Assertiveness
3. Dealing with relationship issues (including conflict)
4. Dealing with unemployment
5. Identifying supports

**Psychological issues (see step 6)**

The following issues will be discussed
1. Self-esteem
2. Loss and grief
3. Dealing with negative emotions
4. Letting go
5. Loneliness
6. Hopelessness and suicidal thoughts

The program manual will provide the basis for discussion and small group exercises. Examples from the manual on
- loss and grief
- the benefits of activity
- fostering social support and skills
Loss and grief and depression

The information presented in this section on loss and grief is largely based on the work of Adelaide grief expert, Dr. Sheila Clark, and the Graduate Program in Grief and Palliative Care Counselling at the University of Adelaide.

As mentioned in step 2, depression may be triggered by loss in life. Loss is defined by Dr. Sheila Clark as “a perceived negative change by an individual due to the withdrawal of any valued person, object, commodity, state or opportunity from the life of the individual that results in grief”. Grief is defined as the response to perceived loss by an individual.

Loss may be death-related or non-death related (Bowlby, 1980). We may grieve the death of a person or pet. An example of a non-death related loss would be divorce, loss of one’s job or health. Bowlby also wrote of ‘attachment’ between individuals which develops to maintain a state of balance in life. Loss and grief disturbs this balance – people often describe a sense of their “whole world being thrown upside down”.

Grief affects many aspects of the individual – physical, emotional, behavioural, cognitive (such as memory and concentration), social and spiritual. The process of grief involves adaptation to loss by the individual (Corr, 1999). Parkes described grief as a ‘psycho-social transition’. He said that loss threatens our inner assumptions about the world and it takes time to readjust (Parkes, 1988).

Loss may be hidden by individuals, particularly if there is stigma or shame involved. Loss may be gradual, such as adapting to dementia in a parent. There may be differences between men and women in grieving, or cultural differences. Individuals may not seek help with their grief because of these factors.

Sometimes individuals can become stuck in their grief and an intense grief reaction continues (Rando, 1984). This can be related to unresolved feelings such as guilt. An ongoing or long-term grief is called chronic grief (Parkes, 1998 & Middleton, 1996).

Grief is accompanied by sad and low feelings. Many of the symptoms experienced in normal grief overlap with the symptoms of depression, such as sadness, crying, loss of appetite, disturbed sleep and poor concentration. These symptoms gradually lessen over time, however. On some occasions a depressive illness may develop. This is when depressive symptoms are prolonged (more than two months) and more severe than expected (Davies, 2000 & DSM IV).

Depression itself may cause losses, such as loss of health, social contacts or ability to work. These losses in turn, may add feelings of grief to the depression. Depression can be a hidden illness, due to the stigma associated with mental health problems. It affects every aspect of one’s life, and can be prolonged. What losses have resulted from your depression?
Grief work

Adjusting to loss takes time and effort. It can be very useful to talk with your GP, therapist or friend. It is important to find someone who is a good listener and someone whom you trust.

There has been a lot written about grief work, and there are a number of different approaches to grief therapy. Several approaches will be highlighted. They provide a holistic approach to dealing with loss and grief.

Grief therapy [based on the work of Worden (1982, 1991), as outlined by Payne et al, 1999] involves:

- Understanding the process of grief, and that it is normal to have positive as well as negative feelings about the lost person or object.
- Sharing thoughts and feelings about the loss and reviewing what it means to the individual. It can be helpful to look at photographs or mementos of the lost person or pet together, for example.
- Identifying and expressing negative emotions associated with the loss – such as self-blame or anger. One way to do this is to talk about things that we miss or don’t miss about the person.
- Problem-solving ways of coping with either troublesome feelings resulting from the loss, practical problems, or new ways of coping in life (see step 4).
- Eventually letting go of attachment – this does not mean giving up on the lost person or object, but rather “finding an appropriate place” for them in our emotional lives.

Dr Sheila Clark advises:

1. Allocating grief time each day – say 15 to 20 minutes in which to have a cry or write about the loss (such as in your journal).
2. Naming the problems – emotional or practical.
3. A range of strategies for living with grief
   - looking after general health – endeavouring to still eat, and avoiding overindulging in alcohol or smoking
   - taking time out to walk in the park or play with the kids
   - sometimes spoiling yourself, for example have a coffee with a friend or a nice bath
   - not making any major decisions before one year at least,
   - continuing existing relationships, seek support
   - get some advice on dealing with practical issues, or dealing with special occasions such as Christmas or the anniversary of the loss
   - understand that your ability to think and remember is reduced– don’t be too hard on yourself, and use lists
   - consider whether you need some time off work, take breaks at work or negotiate reduced working hours, and
   - if possible find some meaning out of the loss, such as growing in strength as a result (Clark, 1995).
There are also a number of strategies for dealing with negative thinking that can occur in grief. Fear, guilt, anger, sadness, self-blame or blame of others can all occur in grief. The principles of CBT outlined in step 5 can be applied in the context of loss and grief, namely:

- Be aware of your thinking (keep a thought diary).
- Identify thinking errors, for example all or nothing thinking (“I’m losing it, I’m hopeless – I can’t manage everything”) or catastrophising (“what if I lose something or someone else?”).
- Challenge unhelpful thinking.
- Work on developing more helpful thoughts.

Sometimes thoughts can be intrusive in grief. You may not want to deal with them at the time (it may not be an appropriate time to have a cry, for example), or just need a break from them. Try imagining putting the thought aside, perhaps into a box on a shelf. You can then come back to it later, such as in your grief time, and deal with it.

Note too that self-esteem can be adversely affected with loss and grief. Be aware of this and work on raising self-esteem (see earlier discussion).

Reviewing progress can be a powerful tool in recovering from a loss – could you have coped as well 3 or 6 months ago, for example? What resources have you found within yourself that have helped you cope?

A number of factors which help individuals adjust to loss have been identified (Gamino, 2000). At some stage achieving a sense of closure is important. This refers to closure to the physical body after a death, but it does not include closure to the love and influences of the person who died. Letting go of the lost person or object can be difficult, and tends to happen gradually – part of this may be gradually giving away the deceased person’s belongings. Sometime there are still things that need to be said to the deceased, and it can help to say these at the graveside or in written form, perhaps a letter.

Narrative therapy speaks of ‘saying hullo again’ to the deceased rather than saying goodbye (White & Denborough, 1998). This relates to incorporating what has been lost into the present, for example, holding onto the influence or some other aspect of that person that is meaningful. An example would be thinking of what that person would have done in a situation, or remembering that the person’s children have inherited some aspects of that person.

Although someone may no longer be alive does not mean they no longer exert influence. What would they have said or done in certain situations? Can you see their characteristics in your sibling or child for example? I remember a young woman whose father had died. Her grief was very distressing, but the thing that comforted her most was realizing that special aspects of him lived on in her, and possibly later in her children.
The other factors include creating positive memories of the lost person or object. (Note – if the person was abusive this may not always be appropriate). You may choose to look at photos and talk about the loss. Creating a special scrapbook or memory box with photos and mementos can also help. Focusing on what was special about the person and the things they brought into your life is part of discovering meaning.

Consider what you have learnt through the loss – have you grown in any way, developed strengths or discovered true friends? What about spiritual beliefs? There are studies that indicate that spiritual beliefs assist in resolving grief (Walsh & King, 2002). Spirituality may be based on a range of beliefs, but “it places one’s relationship with a higher power at centre stage and using a religious creed to organise life events and experiences” (Allport & Ross, 1967). Have your beliefs been challenged, changed or strengthened?

Consider looking at the website Grieflink [www.grieflink.asn.au], contacting Relationships Australia regarding courses on relationship loss, or well known Funeral Directors regarding grief work in groups. There are many good books available on grief (try Cope Bookshop in Hutt Street or your local library).

**The benefits of activity (see step 7)**

Activity or occupation is central to life. Our daily routine, our work and leisure time involves activities. Activity provides us with routine, rhythm and balance in life, and can give us a great sense of satisfaction and achievement (Barris & Kielhofner, 1988). Activities provide us with a lot of fun and enjoyment.

Loss of motivation and lethargy are common in depression (see page 17). This means the individual with depression is less likely to do the activities that usually provide them with pleasure. A vicious circle can result – the less active the individual becomes, the more depressed they feel and the less they do (Kidman, 1999; Hickie, 2000).

Activity is a very broad term and includes a wide range of pursuits – from very physical sports through to gentle activities such as reading and meditation. It is important not only to recognise the importance and benefits of activity, but to give yourself permission to enjoy relaxing and pampering activities.
Different people enjoy different sorts of activities. Some people like to move and they might enjoy sport, walking the dog, scuba-diving or yoga. Some people enjoy auditory activities such as music, and others enjoy visual things such as art. Activities stimulate a range of senses – think about gardening or cooking.

Don’t forget creative activities, such as art and crafts, as they can be very satisfying. Everyone has creative potential – it is a matter of finding the sort of activity that brings out your creativity. This may be in drawing, music, crafts or writing. Creative activities also allow you to express yourself, and build self-esteem.

Some activities are very social – joining a walking group or book club, or taking dancing lessons. You can get to know people in your community by joining a local group or club.

Some activities have great physical health benefits, or incorporate wonderful relaxation such as yoga or tai chi. Caring for a pet can be a great source of enjoyment and occupation. Is there something you would like to learn more about? There are many places to do courses, such as your local community health centre or adult education. Learning can be fun and very satisfying.

During my career I have seen people’s lives changed greatly and their mood lifted through activity. The key is finding activities that are meaningful to the person – perhaps something creative, or doing something to help another person, or teaching a skill.

Andrew Solomon in his book *The Noonday Demon, An Anatomy of Depression*, tells a story, which demonstrates the power of activity. He writes about a Cambodian woman called Phaly Nuon, who helped many women during the time of the Khmer Rouge. Phaly found many women were depressed and traumatised as a result of the war, and she developed her own way of helping these women. She found that helping the women “forget” the traumas by hearing the women’s stories and using craft and music as a distraction was helpful. She would then involve them in activity or work – teaching them skills that they could use in later employment. Finally Phaly taught the women how to love – beginning with taking care of themselves and each other and in doing so how to make friends.

A list of pleasurable activities is provided, and ways to include these in life is discussed. The following activity scheduling technique (taken from the patient guide) will be utilised. Participants will see the technique modelled and practice in pairs.

Activity scheduling aims to help restore routine and normality in life. It is also about gaining a greater sense of control and satisfaction in life. It can help you manage your day and make better use of your time. Now that you have thought about pleasant activities, think about ways to incorporate these into your life.

Let’s review the guidelines for planning daily activities (WHO, 1997; Tanner, 1991)

- plan one day at a time
- plan the activities a day ahead
- plan them in one hour time slots
- try and include some activities which give you pleasure
- start with easy to achieve activities, and gradually include more difficult tasks
- if an activity is missed, go on with the next one
- note any extra activities that occurred during the day
- work towards getting back to more normal routine, and
- try the “activity scheduling” for at least a week.

To get started you can try just working on one activity per day – it may be getting out of bed or having a shower, or it may be having a walk. Build up your level of activity gradually. Encourage yourself with thoughts, such as “I’ll give it a go”, or “it will get easier once I start”. Once you are doing more, try and include more activities that give you pleasure and a sense of achievement.

An activity scheduling chart is given below. It can be copied for use.

- The **pleasure rating** refers to giving some indication of the degree of pleasure you associated with the activity. Use a scale of 0 to 5 with 0 for no pleasure and 5 for maximum pleasure.
- The **achievement rating** refers to the sense of achievement you gained from the activity. Again rate it from 0-5, with 0 for no achievement and 5 for maximum achievement.

**Activity Schedule:**

<table>
<thead>
<tr>
<th>Date________</th>
<th>Planned Activities</th>
<th>Tick when done, or note other activities</th>
<th>Rate pleasure and achievement (0-5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7-8am</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8-9am</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9-10am</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10-11am</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-1pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-3pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-4pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-6pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-7pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7-8pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8-9pm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9-12pm</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Adapted from Tanner S. *Beating the Blues*, & Burns D., *Feeling Good New Mood Therapy*.)

**Fostering social support and skills** (see step 8)

This step is very much based on **interpersonal therapy** or IPT. IPT is a specific type of short-term psychotherapy. Mood and the person’s interpersonal world are viewed as interdependent. IPT emphasizes the role of psychosocial difficulties in the depression – interpersonal events can lead to depressive symptoms and the depression can impair a person’s ability to function interpersonally (Kaplan, 1994; Davies, 2000).

With IPT patients are seen over a period of months. They are taught to evaluate their interactions with others and identify what contributes to the depression. Therapy focuses on current issues and improving interpersonal communication and skills (Davies, 2000; Mynors-Wallis, 1999). Grief issues are identified and addressed (Davies, 2000).

This treatment program is based on an eclectic approach, incorporating aspects of different therapies which are likely to help prevent depression relapse. Interpersonal problem often arise as key issues in depression. A good starting point is to help the patient identify what the issues are and establish
treatment goals (see step 1). Working on the development of particular interpersonal skills such as conflict resolution and assertiveness can be very helpful.

In step 8 the following issues will be covered

1. Connectedness
2. assertiveness
3. dealing with relationship issues (including conflict)
4. dealing with unemployment
5. identifying supports

The section on assertiveness from the patient manual is provided as an example. Assertiveness theory will be outlined during the training, and techniques below role-played.

We all need to be able to express ourselves assertively or directly at times. Do you have difficulty expressing your opinion, or find it hard to be clear in what you want to say? Do you find your needs are not being met, or you unintentionally upset people by what you say? If the answer is yes to any of these questions, then working on becoming more assertive is important for you (WHO, 1997; Page, 1996). In the long run being more assertive also helps develop a greater sense of self-esteem.

Assertiveness means being able to express your needs and feelings more directly. It involves changing the ways in which you relate to people and the behaviours that you use (Corey, 1991).

What can you gain from being more assertive? It can be helpful in starting conversations, confronting others, dealing with annoyance, responding to criticism, turning down requests or asking for favours (WHO, 1997).

Assertiveness is based on a number of rules and rights (Williams, 2000). These are worth remembering.

“I have the right to”:
- Respect myself
- Recognise my own needs as an individual
- Make clear ‘I’ statements
- Allow myself to make mistakes
- Change my mind
- Ask for ‘thinking over time’
- Allow myself to enjoy my successes
- Ask for what I want
- Recognise that I am not responsible for the behaviour of other adults, and
- Respect other people

The table below summarises different behaviours. There is passive behaviour, which is the opposite of assertive behaviour, and there is aggressive behaviour, which is different from assertiveness (Page, 1996).

<table>
<thead>
<tr>
<th>Passive</th>
<th>Aggressive</th>
<th>Assertive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involves not expressing your thoughts, feelings and wishes when you would like to. It means that you put other needs first.</td>
<td>Standing up for your rights in a way that is pushy and inappropriate. This often offends others. It may be related to poor self-esteem.</td>
<td>Honestly communicating your thoughts, feelings and needs to others in appropriate ways. Not saying, “it doesn’t matter”</td>
</tr>
<tr>
<td>people’s needs before own.</td>
<td>communication skills.</td>
<td>when it does, but still being tactful.</td>
</tr>
<tr>
<td>---------------------------</td>
<td>----------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td>Being passive may stem from a belief around being inferior.</td>
<td>Aggressive behaviour can stem from being passive and letting things build up until you ‘explode’.</td>
<td>You know that you have rights, but you also remember that other people have rights too.</td>
</tr>
</tbody>
</table>

(Adapted from Page, A. & C. *Assert yourself!* How to resolve conflict and say what you mean; WHO Collaboration, Management of Mental Disorders)

There are different types of assertion (Page, 1996). There is positive assertion or giving compliments. There is negative assertion, such as refusing a request or saying “no”. Here is an example of negative assertion: A friend rings and asks if you can babysit her child - you had planned to go out.

- The passive response would be to say “yes”.
- The aggressive response would be to say “you can’t ask me to put myself out like that”.
- An assertive response would be “unfortunately I can’t help today as I already have a commitment”.

Why does non-assertiveness develop?

Assertive or non-assertive behaviour is learned. As a child we are taught how to behave. For example, how did your family handle conflict? What did they do when they disagreed with someone? What did you learn from them? In what ways did I learn to get what I wanted without asking for it directly, for example yelling or crying? Do you still use those ways (WHO, 1997)?

There can be obstacles to being assertive. These may be fear of offending the other person, or worry that they won’t approve. It is good to be sensitive to others, but your rights are important too and you are not responsible for how the other person reacts (Page, 1996). Look back at the role of beliefs in our thinking (step 5). A belief in needing approval from everyone can be a barrier to being assertive. Shyness or a problem with social anxiety (see page 42) can also be a barrier to speaking out.

How to be more assertive -

Firstly, what do you say? It is helpful to use “I” statements. These can explain

1. your feelings about the person’s behaviour or the effect of the behaviour (“I feel”)
2. what the unacceptable behaviour is in a non-blameful way (“when you”)
3. the effects of the behaviour on you (“because”), and
4. what you want to happen (Burns, R., 1992; O’Connor, 2001).

It is important to also acknowledge the other person at the start of what you say. This means saying something like “I appreciate (or) I can see that you feel ...”

Here is an example:

“I can see that you are annoyed. However, I feel upset when you say ‘I’m hopeless’ because it affects my confidence. I want you to stop saying that and recognize that I do a lot of things well”.

298
Secondly, how does being assertive look and sound? Here are some tips. Stand or sit firmly and be upright and not fidgeting. Have an open body posture (no folded arms or crossed legs). Speak in a clear steady tone of voice, in a calm way. Use eye contact, and have relaxed facial gestures.

The key is to practise. Practice with your GP, with a friend, or in front of the mirror. Even write scripts to help practice what you want to say (How to be stop worrying and be happy, 1996).

Identify situations where you might need to be assertive and prepare. If you have to speak with someone over the phone, for example, you could make some notes and have them in front of you.

Here are a few more tips on how, when and where to put assertiveness into practice.

Sometimes there are very difficult situations in which to be assertive. The other person may be fairly aggressive. It may help to

- repeat your answer,
- not respond to inappropriate conversation or requests, or
- refuse to carry on a conversation with that person until the anger dies down.

Here is another example - you are in a conversation where the other person is mixing issues up and raising unrelated emotional issues. You can say that “it’s not that I don’t care about that issue, but I don’t want to discuss it – I want to focus on...”

Feelings of guilt can get in the way of assertiveness. You may like to do a really good or perfect job, and others try to get what they want by making you feel guilty. Be aware of this when prone to guilt. Remember that sorry is a word that we can overuse - only say “sorry” if it is genuine.

Practice saying “no”. Remind yourself of why you are saying no – that you don’t have the time, it’s inconvenient, or you are not interested – and be direct about it. Use tact in making requests as this allows the other person to say yes or no. Be specific and give the reasons as to why you are asking, for example “I’m tired”. Don’t wait until the last minute (WHO, 1997).

**Cases for discussion**

**Grief**

A 50 year old male patient develops depression after the death of his disabled daughter. He had been devoted to her care and an advocate for the disabled. He feels disinterested in work and life in general.

A young woman is depressed 12 months after the death of her father. She was very close to him and they did a lot of activities together such as sailing. She cannot make sense of the loss.
Anger
A 30 year old woman is depressed and angry 6 months after her marriage broke down. Her ex-husband now lives with a work colleague, with whom he had been having an affair.

Assertiveness
A young woman with depression finds it very difficult to assert herself, particularly at work and in her family. She sets high standards for herself and likes to please. Saying no is very hard for her and then she finds herself overwhelmed at work and resentful of doing so much for her family.

Session 5
Developing a plan for managing early relapse symptoms
In this session, step 9 of the program will be outlined. This is based on earlier discussion about depression being a relapsing and sometimes chronic condition. This has implications on management, in terms of the viewing the condition as long-term. This means that it is important to incorporate relapse prevention strategies into treatment.

The Keeping the Blues Away program recognises the importance of
- monitoring progress by regular follow-up
- involving family or carers wherever possible
- using maintenance medication if clinically indicated
- managing co-existing medical problems
- developing a range of coping skills, such as relaxation training
- incorporating psychosocial treatment such as teaching problem-solving, CBT and IPT.
  (WHO, 1997)

It is important to develop a written relapse prevention plan with the patient. This involves helping the patient identify and record early warning symptoms, which might suggest a recurrence, and specific risk factors. It is important that the plan addresses the maintenance of physical health and strategies to reduce stress and anxiety. Participants will be shown how to develop an emergency plan for relapse, targeting early warning symptoms and possible high-risk situations (WHO, 1997; Hickie, 2000; Williams, 2000).

The following discussion about developing a plan for managing relapse is taken from the patient manual.

Three vital steps in developing a plan for managing relapse
1. The first is to learn to identify the early warning symptoms. These are the early symptoms that you experience when becoming depressed. They might include difficulty sleeping, tiredness, tearfulness, loss of interest in usual activities, or increased irritability or anxiety (WHO, 1997; Hickie, 2000).
List your early warning symptoms of depression in the table below. Here are a few tips for identifying early warning symptoms.

- Think broadly, because depression can affect how you think as well as feel and behave. This includes how you relate to people. For example, you might withdraw from people (Williams, 2000; Yapko, 1997).
- Try and be specific in how you describe the symptom (WHO, 1997).
- It may be helpful to ask a friend or relative what they noticed early in the depression.

<table>
<thead>
<tr>
<th>My early warning symptoms of depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
<tr>
<td>4.</td>
</tr>
<tr>
<td>5.</td>
</tr>
</tbody>
</table>

[Note – you may want to advise someone close to you about these early warning symptoms. Sometimes it is easier for them to notice changes than for you (WHO, 1997).]

2. The second is to identify possible high-risk situations for relapse. Everyone will be different. There may be times when you become stressed, or overtired. Perhaps relationship difficulties increase the likelihood of relapse, or becoming less involved with certain activities (Preston, 2000). It may be that a certain time of the year, such as Christmas time or the anniversary of losing someone close, is difficult.

Think about situations that might be high-risk for you, and write them down.

<table>
<thead>
<tr>
<th>List of possible high-risk situations</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
</tr>
<tr>
<td>2.</td>
</tr>
<tr>
<td>3.</td>
</tr>
</tbody>
</table>

Now consider what you need to do to protect yourself, or do differently if a situation like this occurs. You will be able to use some of the skills that you have learnt during this program – for example, problem-solving or relaxation techniques.

<table>
<thead>
<tr>
<th>How to cope with high-risk situations</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.</td>
</tr>
</tbody>
</table>

3. The last step is to prepare an emergency plan to put into action when you recognize that the depression is relapsing. This might include:
- Monitoring and challenging your thinking.
- Focusing on the here and now.
- Taking some time out.
- Getting support from friends or family.
- Making an earlier, or urgent, appointment with your GP.
- Using medication (restoring or increasing the dose under the guidance of your GP).
- Talking with your GP or mental health professional.
- Expressing how you feel.
- Using problem-solving (Murtagh, 2001).
- Reviewing the earlier steps in this program.

Now work on an emergency plan. Try and target your early warning symptoms, and make your plan as specific as possible (Williams, 2000). You may want to include contact numbers of people who can help you.

<table>
<thead>
<tr>
<th>My emergency plan for relapse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

Keep your plan in a place where you can get hold of it easily. Refer to it if needed.

**Step 10 – reassessment, review and helpful resources** (see step 10 in patient guide)

At step 10 of the program, the patient progress will be reassessed. Steps 1 to 9 are reviewed, as repetition and reinforcement are important aspects of any psychosocial treatment program for depression.

A list of useful resources has been provided in the guide and is shown in the *appendices*.

**Conclusions and questions**

- Depression and anxiety are leading causes of disease-burden in Australia. One in five Australians will experience depression at some stage. Suicide is a major risk.
- Depression is costly for the community in terms of time lost from work, family breakdown and health care costs. The cost of untreated depression in Australia is estimated to be 5 billion dollars annually.
- If this innovative program is successful, the primary outcome will be reduced rates of relapse of depression. A number of secondary outcomes relate to increasing remission time between episodes of depression, reducing severity of relapses and improving quality of life. Satisfaction with the program will be an important outcome.
- The relapse prevention program has a health education and promotion focus, involves the family, and encourages the provision of continuity of care. This program fits well with the Better Outcomes in Mental Health Care initiative.
- If the rate of relapse of depression could be reduced, there would be major benefits for the individual, their family and the community as a whole.
Thank you for very much for participating in the training program

Appendices

Research proposal

[WHOQOL and DASS

Patient information sheet

Consent form

General practitioner data collection form

Participant data collection form

General practitioner checklist]

Relaxation CD script

Resource list

Resources – where to go for help

BOOKS

Books on Depression

- An easy to read and useful overview

- This wise book has appealed to a number of patients, and has many useful charts and tips.

- Wonderful book explaining the cognitive approach to treating depression. There is a chapter about depression written for family.

- This is quite a lengthy and very comprehensive book. It is focused on stress, but addresses depression. It contains many useful ideas and techniques. Focus on the chapters that relate to you.

- A very readable book, with especially good sections on the causation of depression and relapse prevention.

- A helpful and very readable book, incorporating a cognitive approach. It has amusing cartoons and is particularly liked by young people.
- L. Wolpert is a Professor of Biology. He writes about his own experiences with depression. It is written like a novel. Some patients have found they can really relate to his account of depression.

- A useful book for friends and relatives to read. It explains depression, its impact on relationships, and how to support the person with depression as well as look after oneself.

**Books on Anxiety**

- Another good little book by this author. A seemingly light-hearted approach to panic attacks, but full of gems of wisdom. Most patients find this a really useful book. It is based on a cognitive therapy.

- A very readable book on anxiety and panic, using case histories to illustrate important points.

- A gold standard book on anxiety. More lengthy, but a good read if you want more detailed information.

**Books on Cognitive Therapy**


- Explains cognitive therapy for depression, quite detailed, but sections that apply to the individual can be focussed on.

- The self-help guide that accompanies “Feeling Good The New Mood Therapy”. Lengthy.

- Clearly set out, practical book with exercises to be completed.

- A guide for clinicians to use in helping patients work through “Mind Over Mood”.

**Books on Complementary Therapies**


- Professor Ernst, head of the Department of Complementary Medicine at the University of Exeter in the United Kingdom, reviews complementary therapies for depression.

**Books on lifestyle**


WEBSITES

AUSTRALIAN

Beyondblue:
www.beyondblue.org.au

Blue pages
www.bluepages.anu.edu.au

DepressioNet:
www.depressioNet.com.au

Mental health and well-being (Department of Health and Ageing):

Healthy SA – South Australian Department of Human Services - provides information on a range of health issues, including mental health: www.healthysa.sa.gov.au/

CRUFAD (Clinical Research Unit for Anxiety Disorders University of NSW) - Information on diagnosis and treatments, for those with anxiety and professionals working in the area:
www.unsw.edu.au

Mood Disorders Unit, University of New South Wales – general information about depression:
www.mdu.unsw.edu.au

The Panic and Anxiety Hub - aiming to help people learn about anxiety disorders:
www.paems.com.au

Panic online – project of the University of Ballarat – CBT based
www.ballarat.edu.au/mentalhealth/panic_resource/

Site established by SANE
www.sane.org/
Professor John Murtagh patient information sheets on depression and anxiety (Go to John Murtagh GP series):
www.nevdgp.org.au

Headroom (a website designed for young people):
www.headroom.net.com

For young adults;
www.reachout.com.au
MoodGym
http://moodgym.anu.edu.au

About grief;
Grieflink
About lifestyle issues;

‘Sleep Better Without Drugs’ program information;
www.sleepbetter.com.au

For information on hypnosis;
www.ozhypnosis.com.au

For information on laughter therapy;
www.worldlaughtertours.com

For information on work stress:
Stress release health enterprises
www.stressrelease.com
International Stress Management Association
www.isma.org.uk

BRITISH

Site of the Royal College of Psychiatrists in the United Kingdom - has sections on depression and anxiety:
www.rcpsych.ac.uk/public/help/welcome.htm

World Health Organisation site - useful information sheets on depression and anxiety:
www.whoguidemhpcuk.org/

The Happiness Project
www.happiness.co.uk

AMERICAN

For GP information and depression guidelines:
www.mentalhealth.com
www.surgeongeneral.gov/library/mentalhealth

COMMUNITY RESOURCES

Mental Health Resource Centre – 82215166
Provides information on community resources.

Mood Disorders Association – 82215170

SANE Helpline (Information and referral re mental health problems) - 1800688382
SA Panic and Anxiety Disorders Association – 83732161

Obsessive-Compulsive Disorders Support Service – 82311588
Connect – Social anxiety support Network of Australia - 82215166

Association for Friends and Relatives of the Mentally Ill – 82215166

GROW Community Centre - 82316566

Community Health Centres (listed in phonebook)
Cope – bookshop, library and courses – 82233433
(Cope has an excellent range of books on depression and some very useful short courses)

Local libraries (listed in phonebook)

TREATMENT SERVICES

Centre for Anxiety and Related Disorders (Flinders Medical Centre) – 82044779.
Treatment programs for patients diagnosed with anxiety disorders

Local community health centres
May have group educational and support programs on anxiety and depression

Community mental health teams of the State Mental Health Services
Individual treatment and possibly group treatment programs for anxiety and depression.

To find out more about private psychologists, psychiatrists, or qualified hypnotherapists the following
organisations can be contacted;
Royal Australian and New Zealand College of Psychiatrists – 82392911
The Australian Psychological Society – 1800333497
The Australian Society of Hypnosis (SA Branch) – 82336422

EMERGENCY NUMBERS

Lifeline – 131114
Mental Health 24 hour State-wide Emergency – 131465
Alcohol and Drug Information Service - 1300131340

References (GP Training Manual)

American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (4th ed.).
American Psychiatric Press.


Fava, G., Ruini, C., Mangelli, L. Patients with depression can be taught how to improve recovery. *BMJ*, 2001; 332: 1428.

Glass R. Treating depression as a recurrent or chronic disease. *JAMA*, 1999; 281 (1).


GlaxoSmith Kline Signals Program.


Holmwood, C. Major issues facing primary care mental health in Australia 2001.


# B4 - Pilot RCT consent form

**THE UNIVERSITY OF ADELAIDE HUMAN RESEARCH ETHICS COMMITTEE**

**STANDARD CONSENT FORM**

**FOR PEOPLE WHO ARE SUBJECTS IN A RESEARCH PROJECT**

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I, ……………………………………………………………… (please print name) consent to take part in the research project entitled: <strong>Study of a Primary Care Treatment Program Aiming to Reduce Relapse of Depression</strong></td>
</tr>
<tr>
<td>2.</td>
<td>I acknowledge that I have read the attached Information Sheet entitled: <strong>Study of a Primary Care Treatment Program Aiming to Reduce Relapse of Depression</strong></td>
</tr>
<tr>
<td>3.</td>
<td>I have had the project, so far as it affects me, fully explained to my satisfaction by my doctor. My consent is given freely.</td>
</tr>
<tr>
<td>4.</td>
<td>Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any benefit to me.</td>
</tr>
<tr>
<td>5.</td>
<td>I understand that the study that I am involved in will run for 12 months.</td>
</tr>
<tr>
<td>6.</td>
<td>I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.</td>
</tr>
<tr>
<td>7.</td>
<td>I understand that a researcher will review my case-notes during the study.</td>
</tr>
<tr>
<td>8.</td>
<td>I have been informed that, while information gained during the study may be published, specific data about subjects will not be used in the overall results.</td>
</tr>
<tr>
<td>9.</td>
<td>I understand that I am free to withdraw from the study at any time and that this will not affect medical advice in the management of my health, now or in the future.</td>
</tr>
<tr>
<td>10.</td>
<td>I am aware that I should retain a copy of this Consent Form, when completed, and the attached Information Sheet.</td>
</tr>
</tbody>
</table>

..................................................................................................................................................................................  
  
**WITNESS**

I have described to ……………………………………………………………… (name of subject) the nature of the procedures to be carried out. In my opinion she/he understood the explanation.

Status in Project: …………………………………………………………………………….

Name: ………………………………………………………………………………

..................................................................................................................................................................................  
  
(signature) (date)
What is the study about?
Depression is a very common and distressing problem, and it can be a recurrent problem. Treatment of depression may include medication and psychological therapy. This new study is looking at whether a particular general practice approach might help to prevent depression from relapsing (in the early stages of treatment) or recurring later on.

Why is the study needed, and what good will it do?
This study will aim to provide us with more information about what helps or doesn't help prevent depression from returning.

Who is organizing the study?
The study is organized by Dr Cate Howell of the Department of General Practice at Adelaide University. I am a General Practitioner (GP) with a special interest and post-graduate training in mental health. I am undertaking a doctorate under the supervision of the Head of the Department, Dr Justin Beilby. The study will be carried out in a number of general practices in Adelaide and in rural South Australia. Permission to carry out the study has been sought from the Adelaide University Human Research Ethics Committee.

If I decide to take part what is involved?
You will be asked to complete a consent form by your GP after you have considered the information provided about the study. GPs will either provide the normal care of depression, or they will use the program being studied. The general practices involved have been randomly allocated to either deliver normal care or utilize the treatment program being studied.

GPs providing normal care during the study will be offered training in the treatment program at the end of the study. This is to enable the GPs to offer participants in the normal care group the treatment program at the end of the study.

You will be asked by your GP to complete some questionnaires during the study, and a researcher may need to review your case-notes related to the depression. You may also be asked if you would participate in an interview at the end of the study, as we are interested in your experiences, and thoughts about your treatment. If you are agreeable, your GP will let Dr Howell know your name and contact phone number to arrange the interview.
What if I do not agree to take part?
Your participation is entirely voluntary. If you decide not to take part this will not affect the care given to you by your GP.

What will happen if I have any problems during the study?
Throughout the study you will be reviewed by your GP, and any problems can be discussed and addressed. If you need to see your GP more frequently, then you can. If you or your GP feel that seeing another mental health professional would be of benefit, then that can be arranged.

Are there any foreseeable adverse effects of the study?
Enter into the study does not put you at risk of any foreseeable physical or psychological harm. You will be informed about your treatment and monitored by your GP.

Can I stop at any time during the study?
You will be free to withdraw from the study at any time without having to explain why. This will not affect your treatment with your GP in any way.

Will the information be treated as confidential?
The information that you provide during the study will be known only to your GP and the researcher involved in the study. Any information recorded by the researcher will be identified by number only. The initial data collected in the pilot study will not be included in the larger study research, but completion of the data collection forms will still be very helpful. The study will form the basis of my doctoral thesis and publications may arise from this.

Who can I contact if I need more information at any stage, or if I have a complaint?
If you need any further information please contact Dr Cate Howell on 83033460 or 0417867815.
Please also find attached the separate “Contacts for information on projects and independent complaints procedure” of the Adelaide University Human Research Ethics Committee.
Thank you very much for your assistance.
Dr Cate Howell CSM
B6 - GP Data collection form

KEEPING THE BLUES AWAY

General Practitioner Data Collection Form

1. Age: ________
2. Gender: Male □ Female □

3. Practice location Postcode ________
4. Number of FTE GPs: ________

4. Do you work: Full time □ Part time □

5. Have you undertaken any training in Mental Health? Yes □ No □

5a. If YES, was it:

   d. Accredited for Level 1 (3 step process) of the Better Outcomes in Mental Health Care Initiative.
   e. Accredited for Level 2 (focused psychological strategies) of the Better Outcomes in Mental Health Care Initiative.
   f. Other (Please describe other mental health training).

   □

6. Do you have access to an allied health project (involving referral to allied health professionals via the Better Outcomes in Mental Health Care Initiative) through your Division:

   Yes □ No □

   7. When diagnosing a patient with depression, do you use the criteria for a Major Depressive Disorder as outlined in the DSM IV (Diagnostic and Statistical Manual of Mental Disorders)?

      Yes □ No □

   7a. If NO, please comment.

      ____________________________________________________________
      ____________________________________________________________

   8. Would you usually use assessment tools (diagnostic or severity rating scales, such as the HADS or Hamilton) when managing a patient with depression?

      Yes □ No □

   8a. If yes, which ones?

      ____________________________________________________________
      ____________________________________________________________
9. In the first month, how many times on average would you see the patient with depression?

1-2 times □  3-4 □  5-6 □

10. In the first 3 months how many times would you usually see the patient with depression?

1-2 times □  3-4 □  5-6 □  7-8 □  9-10 □

11. What psychological treatments do you utilize in managing the patient with depression?

Psycho-education □  Counselling □
Cognitive-behaviour therapy □  Interpersonal therapy □
Other (Please describe) □

____________________________________________________________________

12. Do you find that there are difficulties managing the patient with depression in general practice.

Yes □  No □

12a. If YES, can you comment on what these difficulties are.

____________________________________________________________________

____________________________________________________________________

THANK YOU FOR COMPLETING THIS FORM
B7 - Participant data collection form

KEEPING THE BLUES AWAY

Participant Data Collection Form

Thank you very much for answering the following questions. Your answers will assist us in understanding depression relapse.
(Please tick the relevant boxes. If there are any questions that you do not wish to answer, just leave the response blank.)

What is your:

1. Age? _________
2. Gender? Male ☐ Female ☐
3. Marital status? Single ☐ married ☐ defacto ☐ separated ☐ divorced ☐
4. Home postcode? _________
5. Do you live alone? Yes ☐ No ☐
6. Do you have family in Adelaide? Yes ☐ No ☐
7. Do you have friends in Adelaide? Yes ☐ No ☐
8. Do you have any medical problems? Yes ☐ No ☐
8a. If yes, what are they?
   Diabetes ☐ Asthma ☐
   Heart Disease ☐ Other (Please describe) ☐

_________________________________________________________________

9. Do you take any medications (prescribed by your doctor or bought over the counter)?
   Yes ☐ No ☐
9a. If YES, please list these medications.

_________________________________________________________________

10. Do you smoke? Yes ☐ No ☐
11. Do you drink alcohol? Yes ☐ No ☐
11a. If YES, how many glasses of alcohol would you have in a week?

1-2 □ 3-4 □ 5-6 □ 7-8 □ More than 8 □

12. Do you use any other drugs? Yes □ No □

12a. If YES, please describe which drugs you use.

___________________________________________________________________

13. Have you ever had depression in the past? Yes □ No □

14. IF YES, please answer the following questions (estimate if unsure).

Note – an episode of depression refers to a bout of significant depressive symptoms (diagnosed by your doctor as a major depressive disorder or illness)

14a. What was your age when you had the first episode of depression? _______

14b. How many episodes of depression have you had? ______________________

15. When did your last episode of depression occur (not including your current episode – estimate if unsure)?

   In the past year □ 1 to 2 years ago □
   2-5 years ago □ 5-10 years ago □
   More than 10 years ago? □

16. How long have you had this episode of depression?

   Less than six months □ More than 6 months □
17. On a scale of 0 to 10, how would you describe the severity of the depression at the start of this episode? (0 = no depression 10 = extremely severe depression) Please circle the number which best describes how you felt.

0-----1-----2-----3-----4-----5-----6-----7-----8-----9-----10

18. Between this episode of depression and the last episode, did you feel that you completely recovered?

Yes ☐ No ☐

18a. If NO, what symptoms of depression persisted?

- Depressed mood most of the day, nearly every day ☐
- Difficulty sleeping or sleeping excessively ☐
- Loss of interest or pleasure ☐
- Restlessness or agitation ☐
- Weight loss or gain ☐
- Fatigue or loss of energy ☐
- Feelings of worthlessness or guilt ☐
- Reduced ability to think or concentrate ☐
- Recurrent thoughts of death or suicidal thinking ☐
- Other (Please describe) ☐

19. In the past 2 years have you had a persistently depressed mood most of the day?

Yes ☐ No ☐

19a. If YES, was it accompanied by:

- Poor appetite or overeating ☐
- Feelings of hopelessness ☐
- Low energy or fatigue ☐
- Feelings of hopelessness ☐
- Difficulty sleeping or sleeping excessively ☐
- Low self-esteem ☐
- Poor concentration or difficulty making decisions ☐
- Other (Please describe) ☐

20. Are you being treated by your usual doctor?

Yes ☐ No ☐

21. Are you seeing more than one doctor about the depression?

Yes ☐ No ☐

22. Are you seeing any other health professionals about the depression?

Yes ☐ No ☐
23. If YES, what health professional(s) are you seeing?

- Psychiatrist
- Psychologist
- Mental Health Nurse
- Counsellor
- Other (Please describe)

___________________________________________________________________

24. Which of the following groups best describes the highest educational qualification you have obtained?

- Left school at 15 years or less
- Left school after 15 years
- Trade qualification/ Apprenticeship
- Certificate/Diploma, one year or less, full time
- Certificate/Diploma, more than one year full time
- Bachelor degree or higher

25. Which of the following groups best describes your current job situation?

- Employed Full Time
- Employed Part Time
- Paid Sick Leave
- Unemployed
- Retired
- Other (Please describe)

___________________________________________________________________

THANK YOU FOR COMPLETING THIS FORM
PSYCHO-SOCIAL ASSESSMENT TOOLS

A. **DASS Scale** (participant to complete, see separate sheet)
B. **WHO Quality of Life Scale** (participant to complete, see separate sheet)
C. **Clinical Global Improvement** (GP to complete at end of the program)

Compared to the patient’s condition when first assessed, how much change has occurred? *Please circle the appropriate number.*

0 = not assessed  
1 = very much improved  
2 = very improved  
3 = minimally improved  
4 = no change  
5 = minimally worse  
6 = much worse  
7 = very much worse

**DEPRESSION, ANXIETY, STRESS SCALE (DASS)**

<table>
<thead>
<tr>
<th>Indications</th>
<th>Assess quantitative scores for depression, anxiety and stress in out-patient population.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limitations</td>
<td>Not to replace diagnostic judgement.</td>
</tr>
<tr>
<td>Scoring Tips</td>
<td>Use transparency sheet. Add 7 ‘A’, ‘D’ &amp; ‘S’ items separately, then double the score obtained. Refer to z scores if you wish, pg 24.</td>
</tr>
<tr>
<td>Cut-off Scores</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mild</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Severe</td>
</tr>
<tr>
<td></td>
<td>Extreme</td>
</tr>
<tr>
<td>Comments</td>
<td>Scores depression, anxiety and stress in one test. See pg 25 for anxiety only or pg 35 for depression only. Reliably correlated with Beck scale. Australian norms used, good scale. 3 scores in one test. Based on the last 7 days. Patient to fill out.</td>
</tr>
</tbody>
</table>
**DASS21**

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

*The rating scale is as follows:*

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I found it hard to wind down</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>2</td>
<td>I was aware of dryness of my mouth</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>I couldn’t seem to experience any positive feeling at all</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>4</td>
<td>I experienced breathing difficulty (e.g., excessively rapid breathing, breathlessness in the absence of physical exertion)</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>5</td>
<td>I found it difficult to work up the initiative to do things</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>I tended to over-react to situations</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>I experienced trembling (e.g., in the hands)</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>8</td>
<td>I felt that I was using a lot of nervous energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>9</td>
<td>I was worried about situations in which I might panic and make a fool of myself</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>10</td>
<td>I felt that I had nothing to look forward to</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>11</td>
<td>I found myself getting agitated</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>12</td>
<td>I found it difficult to relax</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>13</td>
<td>I felt down-hearted and blue</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>14</td>
<td>I was intolerant of anything that kept me from getting on with what I was doing</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>15</td>
<td>I felt I was close to panic</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>16</td>
<td>I was unable to become enthusiastic about anything</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>17</td>
<td>I felt I wasn't worth much as a person</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>18</td>
<td>I felt that I was rather touchy</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>19</td>
<td>I was aware of the action of my heart in the absence of physical exertion (e.g., sense of heart rate increase, heart missing a beat)</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>20</td>
<td>I felt scared without any good reason</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>21</td>
<td>I felt that life was meaningless</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
DASS Profile Sheet

<table>
<thead>
<tr>
<th>Z Score</th>
<th>35-42</th>
<th>25-42</th>
<th>41-42</th>
<th>Percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0</td>
<td>34</td>
<td>24</td>
<td>42</td>
<td>99.5</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>23</td>
<td>40</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>31</td>
<td>21</td>
<td>39</td>
<td>Extremely</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>20</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td></td>
<td>29</td>
<td>19</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>3.0</td>
<td>28</td>
<td>18</td>
<td>33</td>
<td></td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.0</td>
<td>25</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>24</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>23</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.0</td>
<td>22</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>21</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.0</td>
<td>19</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>17</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-1.0</td>
<td>16</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For each scale, draw a horizontal line through the score obtained for that scale, and fill in the dotted lines below to form a bar graph. The heights of the bars are in Z score units and may be compared with each other and with the severity labels. Note that conversion to percentiles on the right hand axis is approximate only.
World Health Organisation
Quality of Life
WHOQOL – BREF
Australian Version (May 2000)

Instructions

This assessment asks how you feel about your quality of life, health, and other areas of your life. Please answer all the questions. If you are unsure about which response to give to a question, please choose the one that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the **last two weeks**

**Example:**

<table>
<thead>
<tr>
<th>Do you get the kind of support from others that you need?</th>
<th>Not at all</th>
<th>slightly</th>
<th>moderately</th>
<th>very</th>
<th>completely</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

You would circle the number 4 if in the last two weeks you got a great deal of support from others…

- but if you did not get any of the support from others that you needed in the last two weeks you would circle 1.

Thank you for your help.
Please read each question and assess your feelings, for the last two weeks, and circle the number on the scale for each question that gives the best answer for you.

<table>
<thead>
<tr>
<th>Question</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How would you rate your quality of life?</td>
<td>Very poor</td>
</tr>
<tr>
<td>2. How satisfied are you with your health?</td>
<td>Very Dissatisfied</td>
</tr>
<tr>
<td>The following questions ask about how much you have experienced certain things in the <strong>last two weeks</strong>.</td>
<td></td>
</tr>
<tr>
<td>3. To what extent do you feel that physical pain prevents you from doing what you need to do?</td>
<td>Not at all</td>
</tr>
<tr>
<td>4. How much do you need any medical treatment to function in your daily life?</td>
<td>Not at all</td>
</tr>
<tr>
<td>5. How much do you enjoy life?</td>
<td>Not at all</td>
</tr>
<tr>
<td>6. To what extent do you feel your life to be meaningful?</td>
<td>Not at all</td>
</tr>
<tr>
<td>7. How well are you able to concentrate?</td>
<td>Not at all</td>
</tr>
<tr>
<td>8. How safe do you feel in your daily life?</td>
<td>Not at all</td>
</tr>
<tr>
<td>9. How healthy is your physical environment?</td>
<td>Not at all</td>
</tr>
<tr>
<td>10. Do you have enough energy for everyday life?</td>
<td>Not at all</td>
</tr>
<tr>
<td>11. Are you able to accept your bodily appearance?</td>
<td>Not at all</td>
</tr>
<tr>
<td>12. Have you enough money to meet your needs?</td>
<td>Not at all</td>
</tr>
<tr>
<td>13. How available to you is the information you need in your daily life?</td>
<td>Not at all</td>
</tr>
</tbody>
</table>
14. To what extent do you have the opportunity for leisure activities?  

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Very</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

15. How well are you able to get around physically?  

<table>
<thead>
<tr>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Very</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

The following questions ask you to say how good or satisfied you have felt about various aspects of your life over the last two weeks.

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>Slightly</th>
<th>Moderately</th>
<th>Very</th>
<th>Extremely</th>
</tr>
</thead>
<tbody>
<tr>
<td>16. How satisfied are you with your sleep?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17. How satisfied are you with your ability to perform your daily living activities?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18. How satisfied are you with your capacity for work?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19. How satisfied are you with yourself?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20. How satisfied are you with your personal relationships?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>21. How satisfied are you with your sex life?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>22. How satisfied are you with the support you get from your friends?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>23. How satisfied are you with the conditions of your living place?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>24. How satisfied are you with your access to health services?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>25. How satisfied are you with your transport?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>26. How often do you have negative feelings such as blue mood, despair, anxiety, depression?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
B9 – Checklists (intervention and control)

Pilot RCT- INDIVIDUAL CHECKLIST SHEET

Participant ID: ……………..   GP ID: ………………..

<table>
<thead>
<tr>
<th>Checklist</th>
<th>Please tick, date &amp; comments (e.g. why unable to complete)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Phase</td>
<td></td>
</tr>
<tr>
<td>Information sheet</td>
<td></td>
</tr>
<tr>
<td>Consent</td>
<td></td>
</tr>
<tr>
<td>Data sheet</td>
<td></td>
</tr>
<tr>
<td>Assessment tools</td>
<td></td>
</tr>
<tr>
<td>4. 0-10 scale</td>
<td></td>
</tr>
<tr>
<td>5. DASS</td>
<td></td>
</tr>
<tr>
<td>6. QOL</td>
<td></td>
</tr>
<tr>
<td>• Patient Manual &amp; journal</td>
<td></td>
</tr>
<tr>
<td>Step 1 - assessment and goal-setting</td>
<td></td>
</tr>
<tr>
<td>Step 2 - psycho-education</td>
<td></td>
</tr>
<tr>
<td>Step 3 - healthy lifestyle issues</td>
<td></td>
</tr>
<tr>
<td>Step 4 - useful coping skills</td>
<td></td>
</tr>
<tr>
<td>Relaxation CD</td>
<td></td>
</tr>
<tr>
<td>Step 5 - helpful cognitive strategies</td>
<td></td>
</tr>
<tr>
<td>Review &amp; repeat assessment tools</td>
<td></td>
</tr>
<tr>
<td>0-10 scale</td>
<td></td>
</tr>
<tr>
<td>DASS</td>
<td></td>
</tr>
<tr>
<td>QOL</td>
<td></td>
</tr>
<tr>
<td>Step 6 - dealing with psychological issues</td>
<td></td>
</tr>
<tr>
<td>Step 7 - the benefits of activity</td>
<td></td>
</tr>
<tr>
<td>Step 8 - fostering social support and skills</td>
<td></td>
</tr>
<tr>
<td>Step 9 - managing early relapse symptoms</td>
<td></td>
</tr>
<tr>
<td>Step 10 – review &amp; repeat assessment tools</td>
<td></td>
</tr>
<tr>
<td>1. 0-10 scale</td>
<td></td>
</tr>
<tr>
<td>2. DASS</td>
<td></td>
</tr>
<tr>
<td>3. QOL</td>
<td></td>
</tr>
<tr>
<td>4. CGI</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Follow-up</td>
<td></td>
</tr>
<tr>
<td>Review &amp; repeat assessment tools</td>
<td></td>
</tr>
<tr>
<td>1. 0-10 scale</td>
<td></td>
</tr>
<tr>
<td>2. DASS</td>
<td></td>
</tr>
<tr>
<td>3. QOL</td>
<td></td>
</tr>
<tr>
<td>4. CGI</td>
<td></td>
</tr>
</tbody>
</table>
**CONTROL GROUP**

**SUMMARY CHECKLIST**

<table>
<thead>
<tr>
<th>Please</th>
<th>Pat ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>- date sessions</td>
<td></td>
</tr>
<tr>
<td>- tick when task done</td>
<td></td>
</tr>
<tr>
<td>- record events (e.g. relapse or loss to follow-up – specify reason)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial Phase</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Information sheet</td>
<td></td>
</tr>
<tr>
<td>Consent</td>
<td></td>
</tr>
<tr>
<td>Data sheet</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Initial assessment tools</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10 scale</td>
<td></td>
</tr>
<tr>
<td>DASS</td>
<td></td>
</tr>
<tr>
<td>QOL</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review / repeat assessments at 3 months</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10 scale</td>
<td></td>
</tr>
<tr>
<td>DASS</td>
<td></td>
</tr>
<tr>
<td>QOL</td>
<td></td>
</tr>
<tr>
<td>CGI</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Review &amp; repeat assessments at 12 months</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10 scale</td>
<td></td>
</tr>
<tr>
<td>DASS</td>
<td></td>
</tr>
<tr>
<td>QOL</td>
<td></td>
</tr>
<tr>
<td>CGI</td>
<td></td>
</tr>
</tbody>
</table>
B10 - Possible reasons for loss to follow-up and/or treatment

Keeping the Blues Away
REASONS FOR LOSS TO FOLLOW UP AND/OR TREATMENT

The following are possible reasons for loss to follow up & / or treatment.
It is important that you record the reason on the ‘individual checklist’.

The participant has:

- decided not to continue treatment
- insufficient time to continue the program
- not presented for follow up despite reminders
- found the treatment program too difficult (please provide any explanatory information)
- decided to see another doctor
- been advised not to continue treatment (please provide any explanatory information)
- decided to pursue a different treatment
- had difficulties getting to the practice
- been unable to afford to attend the practice for further appointments
- had a relapse of depression
- developed another medical condition (please clarify)
- moved away from the area
- experienced a major life upheaval (please provide any explanatory information, e.g. has lost job, someone in family died)
- participant has died (please give cause if related to depression)
- other commitments which preclude them continuing with the program (e.g. study, increased work etc)
- gone away temporarily for work/holiday and will not be able to complete the program during the study period
- had changes in personal circumstances
- no known reason
- other (please specify on the checklist)
B11 – Pre-Test and Post-Test Questionnaire

QU. 1. Depression is a common and disabling illness.
ANS. True ☐ False ☐

QU. 2. What is the prevalence of depression in Australian adults?
ANS: 3% ☐ 6% ☐ 10% ☐ 20% ☐

QU. 3. The bio-psycho-social model refers to the biological, psychological and social factors involved in the causation of depression.
ANS. True ☐ False ☐

QU. 4. List the DSM IV criteria for the diagnosis of depression.
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 5. In managing depression it is important to consider depression as a chronic illness.
ANS. True ☐ False ☐

QU. 6. How do you define relapse and recurrence of depression?
ANS:
___________________________________________________________________

QU. 7. What is the rate of relapse of depression in the primary care setting? (Please tick)
ANS: 10% ☐ 25% ☐ 40% ☐ 60% ☐

QU. 8. A medical and psychosocial assessment needs to be carried out in the early stages of treatment of depression.
ANS. True ☐ False ☐

QU. 9. Do you use psychosocial assessment tools in managing depression?
ANS: Yes ☐ No ☐

QU. 10. Which psychosocial assessment tools do you use in depression?
___________________________________________________________________
___________________________________________________________________

QU. 11. Describe the steps in goal setting that can be used with a patient at the outset of treatment planning.
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 12. Psycho-education is vital in managing depression and preventing relapse.
ANS. True ☐ False ☐

QU. 13. What issues related to antidepressant medication are important to discuss with the patient?
ANS.
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 14. What forms of psychotherapy are commonly used in depression?
ANS.
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 15. List a number of lifestyle issues that are important to address in managing depression and preventing relapse.
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
QU. 16. What sleep tips do you find helpful for patients who are having difficulty sleeping as a result of their depression?

ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 17. Relaxation techniques can be useful in stress management.

ANS. True ☐ False ☐

QU. 18. What advice do you give patients with depression about alcohol intake?

ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 19. List the steps involved in problem-solving.
(1)_______________________________
(2)_______________________________
(3)_______________________________
(4)_______________________________
(5)_______________________________
(6)_______________________________

QU. 20. Relaxation techniques include progressive muscle relaxation, breathing techniques and visualisation.

ANS. True ☐ False ☐

QU. 21. How do you define a panic attack?

ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 22. What techniques can be useful in dealing with panic?

(1)_________________________________________________________________
(2)_________________________________________________________________
(3)_________________________________________________________________

QU. 23. How do you define cognitive-behaviour therapy?

ANS:_________________________________________________________________
QU. 24. List some of the common thinking errors or distortions that are important to identify in CBT
(1) 
(2) 
(3) 
(4) 

QU. 25. How can patients challenge unhelpful thinking?
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 26. List a number of irrational beliefs that can lead to negative thinking in depression.
(1) 
(2) 
(3) 
(4) 

QU. 27. Many patients with depression experience low self-esteem.
ANS. True ☐ False ☐

ANS. True ☐ False ☐

QU. 29. Depression can be triggered by loss in life.
ANS. True ☐ False ☐

QU. 30. How do you define grief?
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 31. What are some of the helpful strategies for working through grief?
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

334
QU. 32. How can you advise a patient to manage feelings of anger?
ANS:

___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 33. Depression can be associated with feeling hopeless and suicidal thoughts.
ANS. True ☐ False ☐

QU. 34. It is vital to assess suicidal risk in depression.
ANS. True ☐ False ☐

QU. 35. What are the benefits of activity for a patient with depression?
ANS:
___________________________________________________________________
___________________________________________________________________

QU. 36. What are the guidelines on planning activities?
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 37. What is the definition of assertiveness?
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 38. How would you advise a patient to be more assertive?
ANS:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

QU. 39. When you are assisting a patient to develop a plan for managing relapse of depression, what are the three important steps to work through?
(1)_____________________________________________________
(2)_____________________________________________________

QU. 40. Using the following rating scale self-assess your confidence in managing depression using both medication and psychosocial strategies.

1 poor                      2 fair                 3 good                    4 excellent

QU. 41. Using the following rating scale self-assess your confidence incorporating treatment strategies aimed at preventing the relapse of depression

1 poor                      2 fair                 3 good                    4 excellent

QU. 42. Using the following rating scale self-assess your skills in preventing the relapse of depression

1 poor                      2 fair                 3 good                    4 excellent

Thank you for completing the questionnaire.
B12 – GP Training Evaluation –
For the following questions circle the response that most reflects your opinion.
SA = Strongly Agree;   A = Agree;   NS = Not Sure;   D = Disagree;   SD = Strongly Disagree

Session 1  Background/Introduction and Assessment of Depression (Step1)

<table>
<thead>
<tr>
<th>The program was pitched at an appropriate level</th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program improved my knowledge of depression</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The program will improve my assessment of depression</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
</tbody>
</table>

Please comment on the following:

What aspects of this program could have been done better?
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

What aspects of the program were done well?
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................

Do you have any other comments about today’s program?
........................................................................................................................................
........................................................................................................................................
........................................................................................................................................
### Session 2  Psychoeducation (Step2), Healthy Lifestyle Issues (Step3), Coping Skills (Step 4)

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program improved my appreciation of using psychoeducational resources with patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program improved my ability to address healthy lifestyle issues with patients</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my skills in assisting patients with cognitive coping strategies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please comment on the following:

What aspects of this program could have been done better?

What aspects of the program were done well?

Do you have any other comments about today's program?
### Session 3  Cognitive Behavioural Therapy/Cognitive Strategies (Step 5)

<table>
<thead>
<tr>
<th>Statement</th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program increased my understanding of the theory and evidence-base of cognitive-behaviour therapy (CBT)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my proficiency in CBT skills</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my awareness of the influence of underlying beliefs on thinking</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please comment on the following:

What aspects of this program could have been done better?

What aspects of the program were done well?

Do you have any other comments about today's program?
Session 4 Psychological issues in Depression (Step 6), Activity Planning (Step 7)

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The program has assisted me to develop skills in raising self-esteem, and dealing with grief and anger</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The program has helped me to gain knowledge about important psychological issues in depression</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The program has increased my ability to encourage activity planning to prevent depression relapse</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td>SA</td>
<td>A</td>
<td>NS</td>
<td>D</td>
<td>SD</td>
</tr>
</tbody>
</table>

Please comment on the following:

What aspects of this program could have been done better?

........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................

What aspects of the program were done well?

........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................

Do you have any other comments about today’s program?

........................................................................................................................................................................................................................................................................................................................................................................................................................................
........................................................................................................................................................................................................................................................................................................................................................................................................................................
Session 5 Interpersonal Therapy/Fostering Support and Skills (Step 8), Preparing a Plan for Managing Relapse Symptoms (Step 9), Patient Follow-up and Resources (Step 10)

<table>
<thead>
<tr>
<th></th>
<th>SA</th>
<th>A</th>
<th>NS</th>
<th>D</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>The program was pitched at an appropriate level</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my appreciation of the importance of developing social skills to prevent relapse in depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my skills in assertiveness training and helping patients deal with relationship issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has increased my therapeutic skills in preventing relapse in depression</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has helped me to develop skills in helping patients identify and deal with warning signs of relapse</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The program has helped me to understand the importance of preparing an emergency plan</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The method of presentation suited me</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The presenters were engaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The content matched my learning needs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please comment on the following:

What aspects of this program could have been done better?

What aspects of the program were done well?

Do you have any other comments about today’s program?
Evaluation of Learning Outcomes

Below are the learning outcomes of the GP Training in a Treatment Program Aiming to Prevent Relapse of Depression. Please consider each goal and indicate your opinion of how well the goals were met.

1. I have a greater knowledge of the aetiology and epidemiology of depression
   Agree □ Neutral □ Disagree □

2. I have reviewed the bio-psychosocial model of depression
   Agree □ Neutral □ Disagree □

3. I have a greater understanding of the chronicity of depression
   Agree □ Neutral □ Disagree □

4. I have a greater awareness of the comorbidity of depression, anxiety and alcohol and drug use disorders
   Agree □ Neutral □ Disagree □

5. I understand the concepts of relapse and recurrence of depression and have an overview of the literature relating to relapse and recurrence of depression
   Agree □ Neutral □ Disagree □

6. I understand the 10 step relapse prevention program and its evidence-base
   Agree □ Neutral □ Disagree □

7. I have gained knowledge of the management of depression including use of antidepressants and role of psychosocial treatments
   Agree □ Neutral □ Disagree □

8. I understand the importance of medical review in depression and use of psychosocial assessments (including risk assessment)
   Agree □ Neutral □ Disagree □

9. I have developed a greater knowledge of depression assessment tools
   Agree □ Neutral □ Disagree □

10. I have gained experience in using depression assessment tools
    Agree □ Neutral □ Disagree □
11. I appreciate the importance of goal-setting with patients at the outset of treatment

Agree ☐ Neutral ☐ Disagree ☐

12. I appreciate the importance of monitoring of progress

Agree ☐ Neutral ☐ Disagree ☐

13. I have developed skills in goal-setting

Agree ☐ Neutral ☐ Disagree ☐

14. I appreciate the importance of psychoeducation in managing depression and preventing relapse

Agree ☐ Neutral ☐ Disagree ☐

15. I have been provided with a useful psychoeducation resource and had practice in using it

Agree ☐ Neutral ☐ Disagree ☐

16. I appreciate the importance of addressing healthy lifestyle issues in managing depression and preventing relapse

Agree ☐ Neutral ☐ Disagree ☐

17. I have a useful resource for addressing lifestyle issues

Agree ☐ Neutral ☐ Disagree ☐

18. I have developed skills in stress management including relaxation techniques

Agree ☐ Neutral ☐ Disagree ☐

19. I have developed skills in helping patients develop useful coping skills such as using a mood diary, problem-solving and managing panic episodes (slow breathing and cognitive strategies)

Agree ☐ Neutral ☐ Disagree ☐

I have developed sound knowledge of the theory and evidence-base of cognitive-behaviour therapy (CBT)

Agree ☐ Neutral ☐ Disagree ☐

20. I have a useful resource for using CBT with patients

Agree ☐ Neutral ☐ Disagree ☐

21. I have seen modelled and have practiced CBT skills such as identifying negative automatic thoughts, explaining thinking distortions to patients,
helping them identify thinking errors, challenge them and develop more helpful ways of thinking

Agree ☒ Neutral ☐ Disagree ☐

22. I have and understanding of the influence of underlying beliefs on thinking, and how to deal with being a perfectionist

Agree ☒ Neutral ☐ Disagree ☐

23. I have gained knowledge about the important psychological issues in depression, such as self-esteem and loss and grief issues

Agree ☒ Neutral ☐ Disagree ☐

24. I have learned ways of dealing with psychological issues such as raising self-esteem, dealing with grief and managing anger

Agree ☒ Neutral ☐ Disagree ☐

25. I have seen these skills modelled and practiced these techniques

Agree ☒ Neutral ☐ Disagree ☐

26. I have developed further knowledge and skills in risk assessment

Agree ☒ Neutral ☐ Disagree ☐

27. I appreciate the importance of encouraging activity in preventing relapse of depression

Agree ☒ Neutral ☐ Disagree ☐

28. I have developed skills in activity planning

Agree ☒ Neutral ☐ Disagree ☐

29. I appreciate the importance of developing social skills in preventing relapse of depression

Agree ☒ Neutral ☐ Disagree ☐

30. I have developed skills in assertiveness training

Agree ☒ Neutral ☐ Disagree ☐

31. I understand the basis and evidence-base of interpersonal-therapy (IPT) and develop skills in helping patients deal with relationship issues

Agree ☒ Neutral ☐ Disagree ☐

32. I appreciate the importance of identifying early warning signs of depression in preventing relapse
33. I have developed skills in helping patients identify and deal with early warning signs
Agree □ Neutral □ Disagree □

34. I appreciate the importance of following-up patients methodically in preventing relapse
Agree □ Neutral □ Disagree □

35. I have a resource list related to managing depression and anxiety including books and websites
Agree □ Neutral □ Disagree □

Any further comments?
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
_______________________________________________________

Signature:..........................  Date:..............................

Thank you very much for completing this evaluation.
Dear Doctor,

General Practitioners play a major role in managing depression, a serious and often chronic illness. I am a general practitioner (GP), currently a Research Fellow in the Department of General Practice at the University of Adelaide and undertaking a doctorate in the area of depression. I had a year 2000 Churchill Fellowship to study the primary care management of anxiety and depression, and have recently been appointed Co-director of the Primary Care Mental Health Unit within the Department of General Practice.

I have had a long-standing clinical interest in mental health, and have been aware of the difficulties facing GPs in managing patients with depression, and the frustrations experienced by patients by its recurrent nature. GPs are being encouraged to incorporate more psychosocial treatments into their practice. It is my experience that effective, practical treatments that can be readily incorporated into daily practice are needed, and a model of treatment addressing the recurrent and chronic nature of depression.

My doctorate involves the development and implementation of a primary care treatment program aiming to reduce relapse of depression. The program, called ‘Keeping the blues away’, is evidence-based and multimodal in its approach. It involves 10 steps, including education about depression and relapse prevention, and a range of lifestyle, coping and psychosocial (cognitive-behavioural and interpersonal) strategies. Patients are provided with a comprehensive manual, treatment journal and relaxation CD.

I am writing to request your participation in a clinical trial of the program. General practices will be randomized to either carry out the intervention or usual care. The program has been extensively piloted, and has been well received by GPs and patients. GPs participating in the intervention arm of the study will see patients for 6 to 12 regular sessions over the first 3 months (fitting with the Better Outcomes initiative), and then monthly to complete 12 months of follow-up.

GPs in the intervention practices will receive training that has been accredited for Level 2 of the Better Outcomes in Mental Health Care initiative and approved for five Continuing Professional Development points per hour. GPs in the intervention arm will be provided with 20 hours of training to meet Level 2 requirements. For those GPs already accredited, 4 hours of training will be provided. GPs in the control arm will be offered the training and materials at the end of the study.

It is only with the support of GPs that the effectiveness of programs such as ‘Keeping the blues away’ can be determined. I would greatly appreciate your participation in this study, and I look forward to hearing from you. I can be contacted on 0417867815, or via email cate.howell@adelaide.edu.au.

Yours sincerely,

Dr Cate Howell CSM
Research Fellow
Co-director Primary Care Mental Health Unit
Department of General Practice

Professor Justin Beilby
Head of Department of General Practice

Department of General Practice
Advancing Primary Health Care...
“KEEPING THE BLUES AWAY” STUDY

PATIENT RECORD AUDITS

Practice ID: [Enter Practice ID]

Patient ID: [Enter Patient ID]

Patient participation period: [Enter participation period]

Researcher: [Enter Researcher name] M.O. = 01; W.N. = 02

Practice visit: [Enter practice visit dates]
## 1. Depression symptoms mentioned in case notes (during study period only)

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Notes/specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Low mood, feeling sad, mood swings</td>
<td>Y  N</td>
</tr>
<tr>
<td>02 Loss of pleasure, interest</td>
<td>Y  N</td>
</tr>
<tr>
<td>03 Loss of motivation</td>
<td>Y  N</td>
</tr>
<tr>
<td>04 Irritability, anger</td>
<td>Y  N</td>
</tr>
<tr>
<td>05 Crying easily</td>
<td>Y  N</td>
</tr>
<tr>
<td>06 Emotional numbness, withdrawal from others</td>
<td>Y  N</td>
</tr>
<tr>
<td>07 Anxiety</td>
<td>Y  N</td>
</tr>
<tr>
<td>08 Cognition/concentration/memory/decision-making problems</td>
<td>Y  N</td>
</tr>
<tr>
<td>09 Negative self-thoughts (worthlessness, self-blame)</td>
<td>Y  N</td>
</tr>
<tr>
<td>10 Low self-confidence</td>
<td>Y  N</td>
</tr>
<tr>
<td>11 Alcohol or drug abuse</td>
<td>Y  N</td>
</tr>
<tr>
<td>12 Thoughts of suicide or death</td>
<td>Y  N</td>
</tr>
<tr>
<td>13 Self-harm (cutting, burning)</td>
<td>Y  N</td>
</tr>
<tr>
<td>14 Suicide attempt</td>
<td>Y  N</td>
</tr>
<tr>
<td>15 Sleep problems (trouble getting to sleep, waking early, sleeping too much)</td>
<td>Y  N</td>
</tr>
<tr>
<td>16 Tiredness, low energy</td>
<td>Y  N</td>
</tr>
<tr>
<td>17 Physical aches and pains</td>
<td>Y  N</td>
</tr>
<tr>
<td>18 Agitation or restlessness</td>
<td>Y  N</td>
</tr>
<tr>
<td>19 Slowing down (physical retardation)</td>
<td>Y  N</td>
</tr>
<tr>
<td>20 Appetite/weight changes</td>
<td>Y  N</td>
</tr>
<tr>
<td>21 Loss of interest in sex</td>
<td>Y  N</td>
</tr>
<tr>
<td>22 Nausea, diarrhoea, constipation</td>
<td>Y  N</td>
</tr>
<tr>
<td>23 Menstrual irregularities</td>
<td>Y  N</td>
</tr>
<tr>
<td>24 Other</td>
<td>Y  N</td>
</tr>
<tr>
<td>25 Other</td>
<td>Y  N</td>
</tr>
</tbody>
</table>
From patient notes: treatments/nonattendance/task completion/treatment side effects/noncompliance
(during study period only)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Monitoring condition</td>
</tr>
<tr>
<td>02</td>
<td>Counselling (listening, support, general advice, coping strategies)</td>
</tr>
<tr>
<td>03</td>
<td>Prescribed/increased/reduced/ceased medication</td>
</tr>
<tr>
<td>04</td>
<td>Lifestyle (diet, alcohol, non-exercise treatments)</td>
</tr>
<tr>
<td>05</td>
<td>Recommended/completed exercise</td>
</tr>
<tr>
<td>06</td>
<td>Educated about depression</td>
</tr>
<tr>
<td>07</td>
<td>Recommended/provided/used book/video/website/cd</td>
</tr>
<tr>
<td>08</td>
<td>Psychotherapy (range including interpersonal therapy (relationships), family therapy, narrative therapy, insights)</td>
</tr>
<tr>
<td>09</td>
<td>CBT (related to activity scheduling and thoughts)</td>
</tr>
<tr>
<td>10</td>
<td>Goal setting/problem solving</td>
</tr>
<tr>
<td>11</td>
<td>Breathing/relaxation</td>
</tr>
<tr>
<td>12</td>
<td>Social skills training</td>
</tr>
<tr>
<td>13</td>
<td>Recommended/used journal</td>
</tr>
<tr>
<td>14</td>
<td>Self-esteem-building exercises</td>
</tr>
<tr>
<td>15</td>
<td>Relapse prevention planning (identifying symptoms/high-risk situations, constructing action plan)</td>
</tr>
<tr>
<td>16</td>
<td>Completed step of “Keeping the Blues Away”</td>
</tr>
<tr>
<td>17</td>
<td>Other (i.e. hypnosis, “I will” affirmations, dreams, identity)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Visit date</th>
<th>(a)</th>
<th>(b)</th>
<th>(c)</th>
<th>(d)</th>
<th>(e)</th>
<th>(f)</th>
<th>(g)</th>
<th>(h)</th>
<th>(i)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total visits</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3a. Prescribed depression medication (during study period and 3 months prior)

Medication 1

<table>
<thead>
<tr>
<th>Medication name</th>
<th>1st date ever prescribed</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>No. of repeats</th>
</tr>
</thead>
</table>

Prescription issues during study and 3 months prior

<table>
<thead>
<tr>
<th>Issue date</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>Repeats</th>
<th>Notes/reason for repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medication 2

<table>
<thead>
<tr>
<th>Medication name</th>
<th>1st date ever prescribed</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>No. of repeats</th>
</tr>
</thead>
</table>

Prescription issues during study and 3 months prior

<table>
<thead>
<tr>
<th>Issue date</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>Repeats</th>
<th>Notes/reason for repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medication 3

<table>
<thead>
<tr>
<th>Medication name</th>
<th>1st date ever prescribed</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>No. of repeats</th>
</tr>
</thead>
</table>

Prescription issues during study and 3 months prior

<table>
<thead>
<tr>
<th>Issue date</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>Repeats</th>
<th>Notes/reason for repeat</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Medication 4

<table>
<thead>
<tr>
<th>Medication name</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; date ever prescribed</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>No. of repeats</th>
</tr>
</thead>
</table>

Prescription issues during study and 3 months prior

<table>
<thead>
<tr>
<th>Issue date</th>
<th>Dose</th>
<th>Admin. frequency</th>
<th>Repeats</th>
<th>Notes/reason for repeat</th>
</tr>
</thead>
</table>

3b. Other depression medications noted in patient records (during study period and 3 months prior)

<table>
<thead>
<tr>
<th>Medication name</th>
<th>Date(s) mentioned</th>
<th>Dose</th>
<th>Admin. freq.</th>
<th>Notes</th>
</tr>
</thead>
</table>

SSRIs
- Fluoxetine (Prozac, Lovan, Fluohexal)
- Sertraline (Zoloft)
- Paroxetine (Aropax, Paxtine, Espar)
- Citalopram (Cipramil)
- Escitalopram (Lexapro)
- Luvoxamine (Luvox, Movox)

SNRIs
- Venlafaxine (Efexor)
- Reboxetine (Edronox)
- Mirtazapine (Avanza)

Tricyclics
- Dothiepin (Prothiaden)
- Doxepin (Deptran)

Monoamine Oxidase Inhibitors
- Moclobemide (Aurorix, Clobemix, Arima)

Mood stabilisers
- Lithium carbonate
- Epilem or sodium valproate

Anxiety/sleep medications (benzodiazepines)
- Valium (Diazepam)
- Kalma (Alprazdam)
- Serepax (Oxazepam)
- Nitrazepam (Mogadan)
- Normison (Temazepam)
4. Referrals to/evidence of treatment by other professionals (during study period only)

Any treatment by others? □ No
□ Yes (see below)
□ Possibly/unsure (see below)

<table>
<thead>
<tr>
<th>Referral Date(s)</th>
<th>Other evidence of treatment by professional (besides referral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>01 Counsellor</td>
<td>Y N</td>
</tr>
<tr>
<td>02 Psychologist</td>
<td>Y N</td>
</tr>
<tr>
<td>03 Social worker</td>
<td>Y N</td>
</tr>
<tr>
<td>04 Psychiatrist</td>
<td>Y N</td>
</tr>
<tr>
<td>05 Naturopath</td>
<td>Y N</td>
</tr>
<tr>
<td>06 ACIS</td>
<td>Y N</td>
</tr>
<tr>
<td>07 Other (specify)</td>
<td>Y N</td>
</tr>
<tr>
<td>08 Other (specify)</td>
<td>Y N</td>
</tr>
</tbody>
</table>

5. Evidence of depression relapse (during study period only)

Any evidence of relapse? □ No
□ Yes (see below)
□ Possibly/unsure (see below)

01 Relapse or recurrence (increased feelings/symptoms of depression)
02 Medication dose increase after previously being stable (not normal adjustments)
03 Second medication added
04 Medication change (not due to side-effects)
05 Referral to specialist (psychiatrist, psychologist, ACIS)
06 Hospital admission
07 Medication recommenced (after time without)
08 New symptom development
09 Suicidality
10 Other
<table>
<thead>
<tr>
<th>Date</th>
<th>Evidence (codes)</th>
<th>Notes/specify “other”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
B15 - Relaxation CD script

Welcome to the Keeping the Blues Away relaxation CD. It is provided as part of this depression relapse prevention program, and for you to enjoy.

It is divided into 3 parts
- The first involves a general relaxation technique
- The second a colour meditation
- The last is a mindfulness meditation.

You may find that one technique suits you better than another - once you have learnt the basic techniques you can tailor relaxation to suit yourself.

When using the CD choose a comfortable position, seated or lying down, and make sure that the lighting and temperature are right. Remember that when you relax there is always part of your mind looking after you, so that you feel safe - you can ignore distractions, but attend to anything important.

Part 1 – general relaxation techniques
A good place to start in any relaxation technique is with physical relaxation. Make yourself comfortable in a warm and quiet place, either sitting or lying down. Let your eyes close.

When we relax, the muscles in the body loosen and lengthen, letting go of tension and feeling more comfortable. Sometimes we hold tension in one particular place, such as the neck and shoulders or tummy. As we now scan the different parts of the body be aware of any tension and gradually let it go.

- To begin, be aware of the muscles of the face. There are muscles across the forehead and around the eyes. It might help you to move the forehead muscles up and down to get a sense of how they feel. Gradually loosen them, letting go of any tightness or tension, simply let it drift away.
- Now relax the muscles around the eyes, into the cheeks around the mouth and into the jaw, letting go of any tightness or tension.
- The jaw is another place where tension can be held so that the teeth sit slightly apart, let the jaw muscles loosen and relax.
- When moving your forehead muscles you might have become aware that the scalp felt tense. Let the scalp muscles loosen and relax.
- The scalp joins with the muscles at the back of the neck. Make sure your head and neck are well supported and let the neck muscles loosen and relax, just as if you had a nice massage of the neck muscles.
- Focus on the shoulder muscles. Again you may want to move the shoulders to help you get a sense of the muscles loosening. Let go of any knots or any tightness in the shoulder area and down into the shoulder blades.
- Let relaxation flow down through the arms now – down through the upper arm muscles, down through the forearm into the hands and fingers. Let go of any tension out through the fingertips, let it go. As the arms loosen and relax, notice how they feel, sometimes when we relax they feel a bit heavier or lighter or different. That’s okay, just go with that feeling, a nice pleasant relaxed feeling.
Loosen and relax the chest area with nice gentle easy breathing. Breathe in what you need each time, breathe away any tension.

Loosen all of the back muscles from the top of the spine all the way down to the base of the spine. Again make sure you’re in a comfortable position so that your back is well supported. Let those muscles loosen and relax - they don’t need to do any work right now. Relax the buttock muscles.

And the tummy muscles - let the tummy move with your breathing, gently relaxing.

Now take a moment to notice how the upper part of the body feels compared to the legs. Even a few minutes relaxing can bring about quite a difference.

Then let the relaxation flow down through the legs, down and down through the thigh muscles so they are loose and relaxed and comfortable, down through the calf muscles right down into the feet and the toes. Again you might want to wiggle your toes to let go of any tightness or tension.

And it’s a nice feeling to feel more comfortable from head to toe. Makes you feel good, it’s good for your health, and well-being. So enjoy.

You can return your attention to any part of the body that needs a little bit more time, let the tension ease away, drift away.

And if you feel ready to, and if you want to, you can focus attention back on the chest and on your breathing. There are lots of different breathing techniques that are used in relaxation and meditation. When we breathe with our diaphragm, taking air into the base of the lungs, this is called yoga or belly breathing. Breathing in this way can help you relax more deeply. Let the tummy move with your breathing, breathing in what you need each time down to the base of the lungs, breathing away any stress or tension.

Breathe at a gentle, easy rate, in 2 3, and out 2 3. It is good to breathe in through the nose let the air warm, breathe out, let go, relax. With each breath, relax that little bit more, feeling comfortable and peaceful.

And you’ll notice that your mind is gradually clearing through the relaxation. Let go of any thoughts, let them drift away like clouds floating across the sky. Simply enjoy the moment, peaceful and relaxed.

We are going to explore another relaxation technique, using your imagination. Imagine a gentle path that leads to a pleasant and special safe place. It might be somewhere familiar or somewhere you would like to spend a while. Some people like to go to the beach, the hills or to a tropical rainforest. Others simply want to sit in their garden or on their bed reading a book. It really doesn’t matter, whatever suits you.

And it is good to tap into all of your senses as you head along the path, gradually becoming aware of your special place and of what you can see, smell, feel, touch, and hear in this special place. You can do what you want to do - some people like to sit quietly, others like to walk or run or swim or whatever it is they want to do. Some people like to be alone, some like to have someone or even a dog with them. Spend some time in this special place and enjoy, getting in touch with positive feelings and thoughts.

It is a good spot to give yourself some encouragement, some positive affirmations, about what you can think, and feel, and do, and achieve yourself. Even the tiniest achievements are special. So relax and enjoy for a few moments. Feeling good, always peaceful and safe.

The techniques that we’ve looked at so far in this general relaxation technique have been

- physical relaxation, relaxing the muscles throughout the body
• using your breathing to relax more deeply
• visualizing or experiencing a special place.

You can use one or all 3 of these whenever you choose to and whenever it is safe for you to do so. As I said there is always a part of your mind looking after you, so that if there is anything important you need to come out of the relaxation for and attend to, you will always be able to do that. You can use these techniques to help with sleep, drifting off to sleep from the relaxed state and awakening refreshed when you need to.

Equally at the end of a daytime relaxation, and we will go through this now, it is always important to re-orientate to the here and now. So if you’ve been imagining a special place, you come back along the path, or if you’ve been relaxing the muscles, or breathing and relaxing, just gradually reorientate to the day. It is good to count 1 up to 5, on the count of 5 knowing that you’ll be alert and refreshed and feeling good.

So I’ll count for you… 1 - comfortable throughout, any unusual feeling from the relaxation heaviness or lightness or anything disappearing. 2 - plenty of energy for the rest of the day. 3 - still a sense of calmness within, growing confidence day by day, feeling good. 4 - eyes getting ready to open, coming close to the here and now, and 5 - as you’re ready, eyes can open, alert, refreshed, feeling good.

Part 2 – a colour meditation

This relaxation technique is based on colour meditation. Over the years I have found that many people find meditating on colour a relaxing and positive experience.

As before, make yourself comfortable and allow your eyes to close. Let the body relax from head to toe, more comfortable with each moment, let the mind clear, more and more peaceful.

And as we go through this meditation, you can visualize the colours from a special place such as a garden, or you can simply let the colours come into your mind. Whatever works for you.

To begin with, imagine the colour blue - the blue of the sky, or the blue of the ocean; a beautiful clear blue. It is a cleansing and clearing colour. It is a good colour to begin with, to clear and cleanse the mind and body. Let the blue surround you, or you can breathe it in and let it move through the mind and body to cleanse and clear away any tiredness, stress or negativity. Enjoy the colour blue.

And then meditate on the colour green. Green is the colour of trees, grass and nature. It is a healing colour. The healing of good food, of being at one with nature. Again, imagine green, visualize it if you can and surround yourself with green, or breathe it in, taking it through the body, to heal...the colour green.

The next colour is pink, or a pinky-red, the colour of a beautiful rose or a wonderful sunset. This is a very special colour, a colour to raise self-esteem or self-love. Surround yourself with the colour pink, an acknowledgement that each and every one of us is special, just like the rose. Take pink into your mind, into your body - into your heart. Enjoy pink and feeling good about yourself.
The next colour is a lovely white or golden white. It is almost like a light, the sort of light you see reflected on ocean waves on a lovely sunny day, or the beams of light from a star. Imagine a white, golden light beaming towards you, and let yourself receive this light. It is a special energy to energize and refresh you and to give you energy to move forward. Whenever you need a sense of energy, simply imagine this golden white light, beaming towards you, surround yourself with it and breathe it in. All the energy you need.

And so you've experienced the cleansing of the blue, healing green, self-nurturing pinky-red, and energy from the golden white light beaming towards you. Some people like to finish with that golden white light, others like to focus on a purpley violet colour. This is a colour that is associated with the spiritual side of life. All aspects of life are important, and for some people there is a spiritual context, whether that is a sense of nature or a sense of a higher power or god.

Only imagine this colour if you want to - the colour of violets, a deep purple. And a sense of meeting spiritual needs through this colour, getting in touch with your own sense of spirituality that's important for you. And surrounding yourself with that colour, a strengthening and fulfilling colour.

Spend as long as you would like enjoying the colours
...And when you are ready counting
1 - comfortable throughout, 2 – plenty of energy for the rest of the day, 3 – a sense of calmness, and confidence, feeling good, 4 – gradually coming closer to the here and now, and 5- as you’re ready, eyes can open, alert, in the here and now, feeling good.

Part 3 – a mindfulness meditation
In Keeping the Blues Away, the concept of mindfulness was discussed. It is about being aware and paying attention in the present moment. A meditation based on mindfulness follows. Approach it with a sense of enjoyment and curiosity.

Make yourself comfortable in a warm and quiet place, and allow your eyes to close.

Take a little while to become aware of the sensations in the body, and let yourself be still. Become aware of the parts of the body touching the chair or bed, allow yourself to relax into the chair or bed.

Be aware of each part of the body and let go of any muscle tension, from the muscles in the face down through the shoulders and arms, the chest and tummy, down through the legs to the feet and toes. Allow relaxation to flow through the body, letting go of any tension, let it ease away.

Be aware if your mind wanders away from your focus on muscle relaxation. That is okay and happens from time to time. Be patient with yourself and gently refocus your attention on letting go.

For a while too, be aware of the breath - as you gently breathe in and out. Feel the air warm as you breathe in through your nose, feel the air pass down through the lungs, using your tummy breathing, and then breathe out and let go, relax.
Now practice mindfulness of sounds. Bring your attention to your ears and your hearing. Listen to the sounds around you. Simply be open to sounds as they arise. Let the sounds come into your awareness. Equally you can let go of the awareness of sounds.

Be aware of any thoughts that come into the mind, observe them and sit with them for a while. Be curious about your thoughts and where your mind leads. You can be aware of thoughts and you can let go of them - just as you would observe clouds floating across the sky and then disappearing into the distance. There are some helpful thoughts and some that are not helpful. You have choice with thoughts, to take them on board or to watch them pass.

Spend as long as you want relaxing
And when you are ready to be alert simply be aware of the body again and slowly open the eyes as you are ready, comfortable and in the here and now.
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Keeping the Blues Away</strong></td>
<td><strong>Activity Guide</strong></td>
</tr>
<tr>
<td><strong>Step 1 - Getting Started</strong></td>
<td>8</td>
</tr>
<tr>
<td>Assessment &amp; Goal Setting</td>
<td>8</td>
</tr>
<tr>
<td>Psychological Assessments</td>
<td>9</td>
</tr>
<tr>
<td>Goal-Setting</td>
<td>9</td>
</tr>
<tr>
<td>Monitoring Progress</td>
<td>13</td>
</tr>
<tr>
<td><strong>Step 2 - Information about depression and relapse prevention</strong></td>
<td>16</td>
</tr>
<tr>
<td>What is depression?</td>
<td>17</td>
</tr>
<tr>
<td>Why does it happen?</td>
<td>20</td>
</tr>
<tr>
<td>How is it treated?</td>
<td>25</td>
</tr>
<tr>
<td>Family and friends</td>
<td>39</td>
</tr>
<tr>
<td>Anxiety</td>
<td>42</td>
</tr>
<tr>
<td><strong>Step 3 - Healthy lifestyle issues</strong></td>
<td>46</td>
</tr>
<tr>
<td>Healthy eating</td>
<td>47</td>
</tr>
<tr>
<td>Exercise</td>
<td>49</td>
</tr>
<tr>
<td>Sleep</td>
<td>51</td>
</tr>
<tr>
<td>Stress</td>
<td>55</td>
</tr>
<tr>
<td>Avoiding drugs</td>
<td>67</td>
</tr>
<tr>
<td><strong>Step 4 - Useful coping skills</strong></td>
<td>69</td>
</tr>
<tr>
<td>Mood diary</td>
<td>69</td>
</tr>
<tr>
<td>Problem solving</td>
<td>70</td>
</tr>
<tr>
<td>Relaxation</td>
<td>77</td>
</tr>
<tr>
<td>Dealing with panic episodes</td>
<td>84</td>
</tr>
<tr>
<td><strong>Step 5 - Helpful thinking or cognitive strategies</strong></td>
<td>94</td>
</tr>
<tr>
<td>5 steps to tackle unhelpful thinking in depression</td>
<td>96</td>
</tr>
<tr>
<td>(a) Keeping a thought diary</td>
<td>97</td>
</tr>
<tr>
<td>(b) Understanding thinking errors</td>
<td>98</td>
</tr>
<tr>
<td>(c) Identifying thinking errors</td>
<td>100</td>
</tr>
<tr>
<td>(d) Challenging unhelpful thinking</td>
<td>101</td>
</tr>
<tr>
<td>(e) Developing more helpful thoughts</td>
<td>102</td>
</tr>
<tr>
<td><strong>Step 6 - Dealing with psychological issues</strong></td>
<td>115</td>
</tr>
<tr>
<td>Self Esteem</td>
<td>115</td>
</tr>
<tr>
<td>Loss and Grief</td>
<td>124</td>
</tr>
<tr>
<td>Managing anger</td>
<td>131</td>
</tr>
<tr>
<td>‘Letting go’</td>
<td>137</td>
</tr>
<tr>
<td>Suicidal thoughts</td>
<td>140</td>
</tr>
<tr>
<td><strong>Step 7 - The benefits of activity</strong></td>
<td>147</td>
</tr>
<tr>
<td>List of enjoyable activities</td>
<td>149</td>
</tr>
<tr>
<td>Activity planning</td>
<td>151</td>
</tr>
<tr>
<td><strong>Step 8 - Fostering social support &amp; skills</strong></td>
<td>158</td>
</tr>
<tr>
<td>Developing assertiveness</td>
<td>160</td>
</tr>
<tr>
<td>Identifying supports</td>
<td>170</td>
</tr>
<tr>
<td><strong>Step 9 - Developing a plan for managing early relapse symptoms</strong></td>
<td>172</td>
</tr>
<tr>
<td>Three vital steps</td>
<td>174</td>
</tr>
<tr>
<td><strong>Step 10 - Reassess, review &amp; helpful resources</strong></td>
<td>180</td>
</tr>
<tr>
<td>Resources – where to go for help</td>
<td>194</td>
</tr>
<tr>
<td>Emergency numbers</td>
<td>202</td>
</tr>
</tbody>
</table>
Keeping the blues away

December 2004 Newsletter

How to contact us:
Department of General Practice,
University of Adelaide.
Phone: 8303 3400   Fax: 8303 3511

Recruitment phase extended

Thank you for your recruitment efforts to date. Recruitment is moving along, but we need more participants in the study. To facilitate your efforts we have extended the recruitment phase until the END of DECEMBER. So keep thinking of KBA for your patients with depression.

When recruiting, please remember that your patient does not have to be suffering from his/her first episode of depression, nor does this episode have to be newly diagnosed or newly recognised.

Current Recruiting versus Required Recruiting

<table>
<thead>
<tr>
<th></th>
<th>Controls</th>
<th>Interventions</th>
<th>Total Needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruiting</td>
<td>51</td>
<td>57</td>
<td>120</td>
</tr>
<tr>
<td>Required</td>
<td>0</td>
<td>20</td>
<td>120</td>
</tr>
</tbody>
</table>

You might find that, during the Christmas season, some of your patients re-present with their condition worsening or recurring. Please consider these patients for the Keeping the Blues Away study.

Light Therapy

Light therapy is used for seasonal affective disorder. It is generally used in the morning and stimulates the production of melatonin, which helps synchronise the sleep-wake cycle. The KBA Manual talks of light box for depression (page 34 near the bottom). Light boxes are available overseas, and soon to be available from Flinders University (School of Psychology – Prof Leon Lack, phone: 8201 2391, email: Leon.Lack@flinders.edu.au).

Cate and Wendy want to wish you a safe and happy Christmas!

Patient follow-up is vital

The KBA treatment program incorporates strategies shown to be helpful in managing chronic disease. A vital part of the program is FOLLOW-UP. Recent studies have shown that telephone follow-up is effective in improving outcomes for patients with depression.

The KBA program incorporates regular review appointments during the 12 months of the study. At times you may want to consider TELEPHONE review, for example if it is difficult for the patient to attend the surgery. One practice has involved the practice nurse to assist with this process, so feel free to do what works for your practice. Just document the process on the KBA summary sheet.
B18 – Interview Questions

*KBA - Interview of GPs and participants at the end of the trial*

**Questions for the intervention GPs**

My name is …………… and I am carrying out this telephone interview on behalf of Dr Cate Howell. Thank you for being involved in Dr Howell’s Keeping the Blues Away’ project, which involved a trial of a program designed to prevent relapse of depression. I have a series of questions to ask you. Please indicate if there are any questions that you do not want to answer. The interview should take 20-30 minutes.

1. **What did you think of the content of the program?** The content was -
   - Not relevant
   - Of little relevance
   - Moderately relevant
   - Highly relevant
   - Extremely relevant

   Comments
   
   __________________________________________________________________________
   
   __________________________________________________________________________

2. **Can you explain which parts of the program were most helpful for patients?**
   - Step 1
   - Step 2
   - Step 3
   - Step 4
   - Step 5
   - Step 6
   - Step 7
   - Step 8
   - Step 9
   - Step 10
Which parts of the program were least helpful?

- Step 1
- Step 2
- Step 3
- Step 4
- Step 5
- Step 6
- Step 7
- Step 8
- Step 9
- Step 10

Comments

___________________________________________________________________
___________________________________________________________________

3. Do you think the program had an appropriate amount of information in it?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If no, did it have

- Too little
- Too much

Comments

___________________________________________________________________
___________________________________________________________________

4. Do you think the program was the appropriate length?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If no, was it

- Too short
- Too long

Comments

___________________________________________________________________
___________________________________________________________________
If there were patients who did not complete KBA, what were the main reasons for not completing the program? Prompts as follows -

- decided not to continue treatment
- insufficient time to continue the program
- not presented for follow up despite reminders
- found the treatment program too difficult
- decided to see another doctor
- been advised not to continue treatment
- decided to pursue a different treatment
- had difficulties getting to the practice
- been unable to afford to attend the practice for further appointments
- had a relapse of depression
- developed another medical condition
- moved away from the area
- experienced a major life upheaval
- participant has died
- other commitments which preclude them continuing with the program
- gone away temporarily for work/holiday
- had changes in personal circumstances
- no known reason

Comments
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________
___________________________________________________________________

5. Did you think the manual was an appropriate resource?
   Yes †  No †
   If no, why not?
___________________________________________________________________
___________________________________________________________________

6. Was the manual presentation appropriate?
   Yes †  No †
   If no, why not?
___________________________________________________________________
___________________________________________________________________

7. Were the drawings appropriate?
   Yes †  No †
   If no, why not?
___________________________________________________________________
___________________________________________________________________

8. Did you think the CD was an appropriate resource?
   Yes †  No †
   If no, why not?
___________________________________________________________________
___________________________________________________________________

9. Did you think the journal was an appropriate resource?
   Yes †  No †
If no, why not?

10. How would you rate your overall level of satisfaction with the KBA program - on a scale from 1-5,
    where 1 is extremely dissatisfied
    2 is low satisfaction
    3 is satisfied
    4 is highly satisfied
    5 is extremely satisfied?  ________________

11. Can you make any suggestions about topics that should be added to the program?

12. Can you make any suggestions about topics that should be deleted from the program?

13. Can you please comment on your overall perceptions of the KBA program?

14. Do you have any final comments on the KBA program?

Thank you very much for your time. We greatly appreciate your participating in this interview.
We would also like to interview a number of patients who participated in the study. They have already consented to being approached. Would you be able to suggest a couple of patients and perhaps contact them to let them know that we would like to speak with them. I am happy for you to give them my number ..........and they can ring me to set up a time for the interview.
**B19 – Additional interview results**

**GP and Patient comments during semi-structured interviews**

<table>
<thead>
<tr>
<th>What did you think of the content of the program?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP</strong></td>
</tr>
<tr>
<td>The more I used the program, the more I was able to find the parts relevant to the individual patient.</td>
</tr>
<tr>
<td>Most people (maybe 80%) with anxiety and depression can benefit from this type of program.</td>
</tr>
<tr>
<td>The book was very handy, lots of detail. Simple to understand.</td>
</tr>
<tr>
<td>Patients found it helpful</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Which parts of the program were most/least helpful for you?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP</strong></td>
</tr>
<tr>
<td>Used all of them; depending on individual patient</td>
</tr>
<tr>
<td>all were helpful</td>
</tr>
<tr>
<td>In the local population (middle class population) (health lifestyles are covered in normal practice).</td>
</tr>
<tr>
<td>2 &amp; 5 were extremely helpful, and stand out from the rest. None were unhelpful, some were a bit repetitive.</td>
</tr>
</tbody>
</table>
| None were not helpful.                                     | Activity is difficult as I am in a wheelchair."
|                                                            | None were not helpful. |
|                                                            | Knowledge is power, I read them but didn't go back to them. |
|                                                            | Needed more practical help from the GP than theoretical help. |

<table>
<thead>
<tr>
<th>Do you think the program had the right amount of information in it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP</strong></td>
</tr>
<tr>
<td>Depended on patient, assumes patient can engage and depends on intellect, language skills. Good to choose</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do you think the program was the right length?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP</strong></td>
</tr>
<tr>
<td>Able to select relevant parts.</td>
</tr>
<tr>
<td>Possibly a bit long for some patients. OK though for most.</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>What were the reasons for not completing the program?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>GP</strong></td>
</tr>
<tr>
<td>Those with mild depression can engage, but stopped coming when better over 2-3 visits. Severely depressed can't engage. Some already well informed; need</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
motivation.
- One patient moved away. GP was disrupted by death of partner. One patient found some parts too challenging and probably may not have completed the whole program.
- "Difficulties getting to the practice. Multiple life crises. Found too threatening - might actually help problems."
- One moved interstate, but had completed up to maybe Step 6.
- 3 finished the program, 1 didn’t complete, had other family issues and found it difficult to come back.

chapter. Now back to it since GP back at work.

- Completed the program.
- Completed the 10 steps and follow-up. Still referring to the program at each GP visit.
- Completed 10 steps, and follow-up, but this took longer than 12 months.
- Completed the program.
- Completed the 10 steps and follow-up for 12 months.
- I still talk to Dr when needed.

### Did you think the manual was helpful/useful resource?

- Quite helpful, still uses it with some patients.
- Went back to it many times.
- It was alright. I'm not a big textbook person; we jumped around a bit.
- Difficult to fit in to life at the time. Discussions with GP were more beneficial.
- I keep going back to it.

### Was the presentation appropriate?

- Used simple language.
- Good everyday presentation.
- Language used was easy, not childlike, not too much like a medical textbook.

### Were the drawings appropriate?

- No comments.
- Loved them.
- Can't recall.
- My first impression is they were a bit childish. After that I didn't take any notice of them.

### Do you think the CD was a helpful resource?

- Fabulous.
- It would be better for the different parts to be separated into tracks so the patient could select the one that suits.
- The CD is beautiful.
- Still using it.
- Didn't like it at all. It aggravated me more.
- Still hasn't listened to it. Still finds it hard to get time to listen to it; no CD player in bedroom, which is her preferred place.
- Didn’t like the colours part.
- The CD was no help to me. I can't lie down with music - issues from childhood. I would prefer it without music.

### Do you think the Journal was a helpful resource?

- Definitely very good.
- People were too lazy to use it. 1 did, 2 didn't.
- Depends on patients. Some found it useful, others didn't. Depends on patients being used to writing things down.
- Very useful.
- Started out using it, but didn't use it much.
- Didn't use the journal, not one for writing things down.
- Didn’t use it - just too much to do at the time. With post-natal depression there was not time for this.
- For keeping up with appointments.
- Started to use it, but didn’t keep on with it. I put together my own achievement folder - using copies of goals etc.
- I'm not good at writing, better at talking with Dr. I got better as time went on and found that having to write it down was really beneficial.

Can you make any suggestions about topics that should be added to the
<table>
<thead>
<tr>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety information could be expanded no</td>
<td>Anxiety management as a standalone step. (Co-morbid) In introduction: I wonder about explanatory notes about acknowledging past issues, but CBT focuses on future. Program was pretty good. One patient had schizophrenia too, maybe more information on this, although I recognise that this is not the main focus.</td>
</tr>
<tr>
<td>Can you make any suggestions about topics that should be deleted from the program? Some were too detailed and could be cut down e.g. goal setting. no</td>
<td>No. It is a well-rounded program. Walking every day. It covered what was needed. No, from my experience No</td>
</tr>
<tr>
<td>Overall perceptions of the KBA Program? Good program, used it, but tailored it to patient. Certain parts better for certain patients. I liked the idea of a structured program; with CBT clearly spelled out. Lifestyle things were important. It was well put together. Individualising program, despite very structured. It is time consuming. Patients should read chapters beforehand, wouldn't do homework. Found it very good, a good resource. I still use certain parts with patients.</td>
<td></td>
</tr>
<tr>
<td>Final comments on the KBA Program? Good program, useful tool. Pat on the back for the KBA team. And thanks for our support/care for her when needed. Very, very happy to be involved as opposed to standard therapy. Looking at people involved, they still refer back to it as needed. Patients still use their books. They are well educated because of KBA. Gives them strategies. No further comment</td>
<td></td>
</tr>
<tr>
<td>The program was very helpful, concise; I liked the way it was developed, the steps were logical. It is supportive, and enlightening. Easily understandable. You can take what counts, or is needed at the time. Well planned program with something for everyone. Good program. It helped me. KBA helped me. It opened my eyes. It was good reading, increased my understanding. Medication helped along with the program. KBA helped to sort out the way to go with treatment. See Question 15 for overall comments. It was very interesting, with good bits that helped me. Good progress. Found all aspects of the program excellent. I found it really useful at the time, and even now I go back to it.</td>
<td></td>
</tr>
<tr>
<td>I really appreciated the opportunity to participate. I loved the CD. I still refer to the program and the journal from time to time as needed. It is of ongoing benefit. Discuss more about side effects of medication - don't experience as much joy or sadness. No. It possibly helped the doctor to work out methods and treatment options available too. The program was great, but the most beneficial part was to talk to GP who was happy to give advice to take time out. It was more the 1 on 1 sessions with GP that were useful, but difficult to make time to get to Dr. Suffered from post-natal depression.</td>
<td></td>
</tr>
</tbody>
</table>
- No
- Personally I've gained a lot from the program. Possibly because I was willing to.
- I was very thankful to have it at the time, it really did help, made me stop and think. I do go back to it now. It was very good at the time.
You are invited to attend the official launch of

Keeping the blues away
A guide to reducing the relapse of depression
by Dr Cate Howell

Keeping the blues away is a primary care treatment program aiming to reduce the severity and relapse of depression. The program was developed and studied here in South Australia. The treatment manual and CD have now been published and will be:

- Launched by the SA State Minister for Mental Health & Substance Abuse
  Hon Gail Gago MLC

- & officiated by the Executive Dean, The Faculty of Health Sciences, The University of Adelaide, Professor Justin Beilby

Where:
Relationships Australia Bookshop
49A Orsmond St
Hindmarsh SA 5007

When:
Friday 30th March, at 5.15pm

Please complete and return: Fax to Discipline of GP 83033511

☐ Yes! I will be attending the launch of ‘Keeping the blues away’

Name: .................................................................

Contact Details
Phone: ...............................................................

Email: ...............................................................
B21 - Letter to Premier re launch

Premier Mike Rann
GPO Box 2343
Adelaide SA 5000

3rd January, 2007

Dear Premier Rann

In the past few years I have been carrying out a research study on preventing depression relapse. As you are aware depression is a very common problem which frequently relapses. The study involved a new primary care treatment program called 'Keeping the blues away' which aimed to reduce the relapse rate and severity of depression. It utilized a 200 page treatment guide and relaxation CD specifically developed for the study.

The project was supported by BeyondBlue, the Royal Australian College of General Practitioners, the Primary Care Research Fund and the University of Adelaide. The study is now complete and has some promising results, which are yet to be published in an academic journal. The GPs and participants involved in the study were very positive about the program.

The treatment guide is due to be published in early March. Moneys raised will primarily support further mental health research in our Discipline at the University. The CD has been available for some time and last year over 500 were sold.

We are planning a launch of the Keeping the blues away book and CD in late March or April and I am hoping that you (or a representative) would be able to attend the launch and speak. The launch will be held at the Relationships Australia Bookshop in Hindmarsh. A date has not been set until your availability is known. I look forward to hearing from you.

Yours Sincerely

Dr Cate Howell CSM, Churchill Fellow
BMBS, BAppSc (OT), FRACGP, FACPsychMed, Dip Clin Hyp, Dip HSM

cc Executive Dean Professor Justin Beilby
B22 – Publicity about KBA

NOTE:
This figure is included on page 371 of the print copy of the thesis held in the University of Adelaide Library.
NOTE:
This figure is included on page 372 of the print copy of the thesis held in the University of Adelaide Library.
References


42. Dade Smith J. Educating to improve population health outcomes in chronic disease: a curriculum package to integrate a population health approach for the prevention, detection and management of chronic disease when educating primary health care workforce in remote and rural northern Australia. Darwin, Australia: Menzies School of Health Research; 2005.


58. DATIS. Drugs and Therapeutics Information Service Review of Management of Depression in General Practice; 2006.


92. United States Agency for Health Care Policy and Research. Depression is a treatable illness: a patient's guide. [cited; Available from: http://mentalhealth.com


149. Australian General Practice Network. Chronic Disease Management. 2008 [cited
150. Wagner EH. Chronic disease management: What will it take to improve care for
151. Lewis R, Dixon J. Rethinking management of chronic diseases. British Medical
152. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with
153. Scott J, Thorne A, Horn P. Effect of a multifaceted approach to detecting and
managing depression in primary care. British Medical Journal. 2002 26 October
2002;325:951-4.
155. Simon GE, Von Korff M, Rutter C, Wagner E. Randomised trial of monitoring,
feedback, and management of care by telephone to improve treatment of depression
effectiveness of a collaborative care program for primary care patients with persistent
157. Kessler D, Bennewith O, Lewis G, Sharp D. Detection of depression and anxiety in
158. Flinders Human Behaviour and Health Research Unit. Chronic condition self-
159. Battersby M. Key note address: The integration of chronic condition self-
management into health systems - a world view. Guiding us Forward: National
Chronic Condition Self-Management Conference; 2003: Australian Government
Department of Health & Ageing; 2003.
160. Funnell MM. Helping patients take charge of their chronic illnesses. 2000 [cited 15th


239. GlaxoSmithKline. Signals II. Sydney, Australia: OCC Australia Pty Ltd.
266. Page A, Page C. Assert yourself! How to resolve conflict and say what you mean without being passive or aggressive: Gore & Osment; 1996.


