



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

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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.⁽¹⁾ 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

background music. These suggestions were acted on for the pilot RCT and a CD was recorded by the researcher.

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

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 psycho-education 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

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PROGRAM: Doctor of Philosophy (Medicine)

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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
The Medical Journal of Australia, 2008; 188(12):138-141.
3. Management of recurrent depression
Australian Family Physician, 2008; 37(9):704-708.

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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
SNRIs – Selective Serotonin and Noradrenaline Reuptake Inhibitors
SSRIs – Selective Serotonin Reuptake Inhibitors
United States of America - USA
VVS - Victorian Validation Study
WHO – World Health Organisation: WHO-QOL – WHO Quality of Life