75+ Health Assessments: a Randomised Controlled Trial

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July 2001

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Abstract

Preventive care for the elderly originated with a study in Great Britain in 1964 that reported a large number of unmet health needs in the elderly and advocated early intervention. Subsequent randomised controlled trials (RCT) used a broad assessment of health including bio-medical, functional, psychological and social /environmental components but inconsistently demonstrated improved outcome for the elderly. 'Health checks' were introduced for all patients in British general practice in 1990. European and American models of care evolved similarly and justify a multidisciplinary team assessment, thorough training of assessment staff and medical supervision of recommendations. Two literature reviews published in 2000 have not reported sound evidence in favour of health assessments. Medicare funding of health assessments for the Australians aged 75 years and over was introduced in November 1999.

A protocol for conducting 75+ Health Assessment (75+ HA) was developed and a pilot study was conducted in Yarrawonga in 1995 to initiate Australian research of this model of care. A RCT in the Adelaide Western Division of General Practice tested this model of care. The intervention group (n=50) had two 75+ HA one year apart. The control group (n=50) was left to usual care and had a 75+ HA one year later. Demographic data and the Short Form-36 were used to ensure both groups were comparable.

Primary outcome measures did not demonstrate statistically significant reduction in problems nor mortality in the intervention (75+ HA) group compared to the control group. Significant improvements in secondary outcome measures in the intervention group were in self-rated health, depression score and decreased numbers reporting falls.

75+ HAs have been widely taken up by Australian general practitioners. It is no longer possible to conduct a RCT due to the inability to find a legitimate control group. Recommendations arising form this literature review and RCT include; evaluation studies of 75+ HA, concentration on a functional model of health and that nurses or allied health professionals should conduct the assessment in the elderly person's home. A consistent framework for analysis of 75+ HA is proposed.

The elderly can be conceived to occupy one of 3 cohorts defined by their function state: No impairment of Activities of Daily Living (ADL), Impairment of Instrumental ADL only or Impairment of Basic ADL. The elderly without ADL impairment have not been demonstrated to benefit from 75+ HA and should be left to access the acute care stream of health services. The most disabled elderly with Basic ADL impairment have not consistently been shown to benefit from 75+ HA probably because they need a more intense level of community care. They should have Care Plans renewed regularly, as tested in the Australian Coordinated Care Trials. The cohort with Instrumental ADL impairment only seems most likely to benefit from annual 75+ HA.

An evaluation of screening the elderly for Instrumental and Basic ADL impairment and providing appropriate services for each cohort is recommended.

Disclaimer

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, it 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.

Dr Jonathan Newbury

Date

Acknowledgments

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

Pilot study GPEP 334

Funding for the pilot study was provided by the General Practice Branch, Commonwealth Department of Human Services and Health (DHS&H) under the General Practice Evaluation Program. (GPEP) The General Practice Branch also provided administrative advice both before and after receipt of the grant. The Drug Utilization Subcommittee (DUSC) of the DHS&H provided advice on drug coding and disc and paper copies of the ATC and PBS codes.

Advice and support was received from:

The Department of Community Medicine, University of Adelaide

The Department of General Practice, University of Adelaide

Dr Charles Guest, Epidemiologist,

Mr John Moss Health Economist

Mr Neil Griffiths provided programming in Microsoft Access.

Mrs Heather Kelly conducted the telephone evaluation.

Mrs Carol Henderson, Pharmacist, Yarrawonga and District Hospital

Mrs Anne Marley, Dietitian

Sr Wendy Newbury

75+ Health Assessments: a randomised controlled trial GPEP 645

Funding for the RCT was provided by a grant from the GPEP, Department of Health and Aged Care. (DHAC) Support was provided by

Department of General Practice, Adelaide University

Ms Sarah Knight, data entry

Mr Neil Griffiths and Mr. Trevor Wiles MS Access programming

Ms Nicole Pratt, Statistician

Mr Phil Ryan, Statistician,

Mrs Anne Marley, Dietitian,

Research Nurses

Sr Wendy Newbury

Sr Gaynor van de Walt

Sr Heather Temby

Dr Jenny Linn, GP

Mrs Ursula McGowan, English Department

The academic supervision for this Doctor of Medicine thesis at Adelaide University has been provided by:

Professor John Marley

Dr Justin Beilby

The academic support of these two colleagues has been outstanding. Completion of this work without their support would have been impossible.

Chapter One Introduction

1.1 75+ Health Assessment

75+ Health Assessment (75+ HA) describes annual health assessment of the independent living elderly persons aged 75 years or over. It includes a home visit by a nurse or allied health professional who collects assessment data that is interpreted by the elderly person's general practitioner (GP). This model of care had been extensively studied in Europe and the United States of America but it had not been studied in Australia. The study was designed to test this model of care for independent living people aged 75 years and over in Australian.

The Enhanced Primary Care (EPC) package was announced in the 1999 Australian Commonwealth budget. Part of the EPC is new Medicare (Australia's universal health insurance scheme) descriptors for annual health assessments for people aged 75 years and over (i.e. 75+ HA). The Commonwealth Department of Health and Aged Care (DHAC) implemented the EPC from the 1st of November 1999. (1) '75+ HA' will be exclusively used to refer to this Australian model of care throughout this thesis. Similar international examples of this model of care will be described using the names in use in their country of origin or in published works in which they are described.

The work described in this thesis initiated the study of this model of care in Australia.

1.2 Aims

The aims of the study were to:

Compare 75+ HA (intervention) with usual care (control) in a randomised controlled trial (RCT) in the elderly living independently in their own home

Use nurses to perform the data collection phase of the 75+ HA

Conduct 75+ HA in the aged person's home

Evaluate whether there are measurable differences, in defined primary and secondary outcome measures, between control and intervention groups

In both control and intervention groups:

Measure the acceptability to the elderly of this model of care

Categorize the problems uncovered at each 75+ HA

Measure quality of life using the Short Form-36 (SF-36) at each annual visit

In the intervention group:

Follow sequentially the problems uncovered at the first 75+ HA

Categorize problems at the second visit as:

- Resolved
- Persisting and either
  - Resolvable
  - Unresolvable
- New

Evaluate whether there is a measurable difference in primary and secondary outcomes in the intervention group 12 months after their first 75+ HA

1.3 Hypotheses

That in comparison with usual care:

The offer of a 75+ HA is acceptable to aged persons and their established health care providers

A significant number of problems will be identified at each 75+ HA

Problems uncovered will be either amenable to resolution by existing local facilities or unresolvable due to the irreversible diseases of age

The intervention group will have significantly better health outcomes than the control group as measured by primary and secondary outcome measures

Chapter Two Literature review

2.1 Introduction

Demographic predictions for the population make research into ageing an imperative. (2) Ensuring that the health care systems of individual countries can respond to the needs of this aging population is seen as one of the "greatest challenges of our time". (3) The Australian population is ageing. Australia's median age has increased 5.6 years in the last 20 years. (4) The care of the elderly is set to increase both in cost and resource utilization. The extent of this increase in cost is unclear with conflicting estimates reviewed by Gibson and Goss from the Australian Institute of Health and Welfare. (5) General practice is the appropriate element of the Australian health sector to coordinate aged care and GPs are well placed to case-manage the care of the elderly. (6)

This literature review sought evidence in support of a model of care with proven outcome benefits. Recent international and Australian studies were examined to define parameters of a model where maximum benefit had been demonstrated. The evidence relevant to this 75+ HA model of care supports a model that focuses on:

People aged 75 years or older

Elderly people living independently in their own homes

A paradigm of care that includes functional, psychological, social and environmental factors rather than a purely bio-medical model and

Considers care provided by GPs as part of a multidisciplinary team

2.2 Overview of studies of preventive care for the elderly

2.2.1 Early study of unreported needs

Williamson et al proposed anticipatory care of the independent elderly in 1964 following their study of the 65 and over population. (7) They were distressed with the advanced stage of disease in which people were presenting to geriatric units. They advocated that "timely medical and social intervention might have prevented much of the disability". Acknowledging that the GP was the principal person to coordinate the meeting of these needs, they attempted to measure how many of these needs were recognized by the person's GP.

Williamson et al based their study in 3 practices, 2 in Edinburgh and one in a nearby mining town. Their protocol for assessing the elderly was based on a traditional organ system approach to medicine but additionally included poor nutrition, depression, dementia and 'social needs'. Under the 'social needs' category they included mobility, housing, financial needs and social contacts. Their results were a "striking observation of the frequency of multiple disabilities", (7) with an average number of disabilities of 3.26 in men and 3.42 in women. Williamson et al described the frequency of unmet needs, defined as the number of these disabilities unknown to the GP, as 1.87 in the men and 2.03 in women in their sample.

Williamson et al discuss the importance of preventive medicine in the elderly arguing that there are few conditions where early intervention will not be of some help. Given their reported incidence of unmet need they proposed a system of periodic examination to include all old people. This system would depend on an up-to-date practice register; allied health professionals (health visitors) completing "screening on behalf of the GP" and would focus, among other things, on depression, social services, diet, budgeting and avoidance of accidents

in the home. Thirty-five years later in Australia we have instituted a system of care which is very similar to that proposed by Williamson et al in 1964.

2.2.2 Early evaluation trials

The international research that followed the study by Williamson et al, of home visiting of the elderly has been substantial, but there has not been consistent demonstration of benefit for the elderly. Studies discussed in this section were published between 1979 and 1993 but data collection occurred before the implementation of "health checks" in Great Britain in 1990. Important positive and negative outcomes will both be described in this section.

Tulloch and Moore conducted a RCT of geriatric screening and surveillance in general practice. (8) Home visits by nurses were offered to the entire 70 years and over population of a practice in Oxford, UK. Once exclusion criteria were applied (in nursing home, died or moved away and inadvertently still on practice list) 295 patients were included in the study. The study group (n=145) were visited at home by the practice nurse and questioned about "socio-economic and functional problems". They subsequently were sent a medical questionnaire and offered a physical examination at the practice. Both control (n=150) and intervention patients were reviewed by an independent medical team after two years. The review team was blind to the patient's randomisation.

This study had an emphasis on medical problems and 38% of the problems found were previously unknown. These most commonly involved the circulatory, musculo-skeletal and nervous systems. Two thirds of these problems were manageable, half of the manageable problems being improved and half resolved. Admissions to hospital were not decreased in the

intervention group but hospital admissions were significantly shorter. Loss to follow up by the conclusion of the study resulted in only 66% of both groups being available for review. This loss to follow up was due to mortality, moving away or to declining final review. Mortality is not reported separately in this study. The authors formed the impression that the intervention group was more comfortable, less disabled and kept independent for longer. The independent evaluation, as part of the study, however showed that the program had "no significant impact on the prevalence of socio-economic, functional and medical disorders affecting health." (8)

Vetter et al conducted a RCT of the usefulness of a health visitor finding problems in people aged 70 and over. (9) This was conducted in two practices: one rural (Powys) and one urban (Gwent), both in South Wales. They drew a random sample of practice patients aged 70 years and over. In the rural practice, 281 people were randomised to intervention and 273 to control. In the urban practice, 296 were randomised to intervention and 298 to control. All participants were assessed by a structured interview before randomisation and again 2 years later. Randomisation was either to an intervention group who received an annual visit from a health visitor or a control group who received usual care. The health visitor completed a major check-up annually and followed up problems with more regular visits. In the two sites individually no differences were observed between control and intervention groups in physical disability, mobility, anxiety score, depression score and "subjective view of life overall." No decrease in mortality was observed in the rural group.

Vetter et al reported in greater detail, separately, on the urban (Gwent) cohort in their RCT. (10). Significantly decreased mortality had been demonstrated in the urban cohort but no difference was apparent in the rural cohort. (9) The doctors in the urban practice "were

particularly concerned with old people and had a regular visiting schedule to those known to have chronic illness." In the first year of annual visits less than 10 % of the elderly had no difficulties. The doctors knew of the majority of the physical and mental problems but only a small proportion of the social, environmental and carer difficulties. In the second year of annual visits, the health visitor continued to uncover problems that were not trivial but were unknown to the doctor. They concluded that the GPs needed to increase their emphasis on 'overall health and well being' of their elderly patients and that health workers are the group capable of and likely to take on the role of home visiting the elderly.

McEwan et al conducted a RCT of 'screening elderly people in primary care' in Newcastle-upon-Tyne. (11) The sample of patients came from one practice and they were aged 75 years and over. All patients who were eligible and consented were randomised, exclusion criteria being too ill or in hospital (n=11) and declined to participate (n=28). The intervention group contained 151 people and the control group 145. The intervention group received a home visit from a nurse. The intervention assessment included measures of: activities of daily living, social functioning, sensory functions, mental and emotional problems, current medical problems, blood pressure, urinalysis, haemoglobin level and compliance with medication. An independent interviewer evaluated both the control and intervention groups. These evaluations were initial (prior to intervention), interim (7 months) and final (20 months after the intervention). The evaluation used a selection of questions from established instruments designed to measure: physical, social and emotional function, life satisfaction, morale, sleep, physical mobility, energy, pain and social isolation.

At follow up, in the intervention group there was no evidence of better physical functioning

nor improvement in activities of daily living. However they scored significantly better on a morale score, particularly in respect of "attitudes to own ageing" ($p<0.01$) and "loneliness" ($p<0.05$). The authors attributed this to the intervention "improves adaptation to old age and awareness of support systems available". The special attention and education of the screening process may have caused this effect. McEwan argues this may be more important than problem resolution.

Hendriksen's study in Denmark evaluated a more intensive regime of home visiting the elderly in a RCT. (12) All participants were aged 75 years and over. A random population sample of 600 in a suburb of Copenhagen was further randomised into intervention and control groups. These 600 represented half of the local, independent living 75+ population. Those in the intervention group (n= 285) were visited every 3 months at home for 3 years. Visits to each individual were conducted by the same researcher, two of whom were "home nurses" and the third a medical practitioner. The intervention interview was a structured questionnaire on social and health conditions together with a conscious effort to develop rapport. The control group (n=287) was not contacted until near the end of the study. They were then informed and if they consented had a similar interview. Members of the control group who had died or been institutionalised were included in the outcome statistics although they do not seem to have been contacted nor consented to participate. Outcome data were collected centrally from the local community office.

Hendriksen's study demonstrated good results from this intensive intervention. The intervention group had significantly fewer out-of-hours calls to the doctor ($p<0.05$), significantly fewer admission to hospital ($p<0.01$) and significantly lower mortality ($p <0.05$).

They also had fewer admissions to nursing home ($p>0.05$) but this difference was not statistically significant. Conversely, the intervention group received significantly more "social services" ($p<0.05$). These included home help, equipment supplied and home modifications.

Criticism of Hendriksen's study is that there was no measure of the control group prior to commencement hence no certainty that both groups were equivalent. The study population being half the local age-specific population makes this bias unlikely. Danish cultural differences presumably explain the lack of consent of the control group at the beginning of the study and the centralised data collection that facilitated evaluation of the intervention. The interviewers were not blind to the randomisation of individuals when they were conducting interviews. Indeed they report that the good results achieved were in part due to their "understanding of and a devoted interest in elderly people". They also advocate that one person acts as coordinator of multi-disciplinary care, is available every day and has a good knowledge of social and medical systems.

Van Rossum et al conducted a RCT of "preventive home visits" in the Netherlands. (13) Subjects were aged between 75 and 84. The entire age specific population who was not already in receipt of regular home nursing visits was invited to join the study. By this measure, they represent the healthier proportion of the population. Intervention subjects (n= 292) were visited every 3 months at home by a public health nurse. Control subjects (n= 288) received usual care and no unsolicited home visits. At the visits nurses used a checklist of questions, gave information and provided advice. Participants rated their own health on a 0-10 scale devised by van Rossum (0-5 poor, 6-7 fair, 8-10 good or excellent). The groups were compared by postal questionnaire at 18 and 36 months and by independent interviewers who

were blind to their randomisation. Centralised data were collected on all subjects by health and community service organizations blind to the subjects randomisation.

Analysis of van Rossum's results shows neither convincing evidence of improved health nor decreased use of institutional care in the intervention group. Some positive trends were observed in a small subgroup with initial poor self-rated health. Overall, the results of this trial provide no support for the beneficial claims of preventive home visits. They attribute this null effect to the elderly being too healthy to show a positive effect and to the extensive health care system already in place.

Pathy et al conducted a RCT of "case finding and surveillance" in general practice. (14) Patients were recruited from one practice in Cardiff, Wales and were aged 65 years and over. Pathy used a postal questionnaire that concentrated on functional problems, sent to 369 intervention patients. Non-responders were followed up. The health visitor visited patients whose questionnaire revealed one or more problems. Patients reporting no problems (40%) were not visited. The 356 control patients were left to have usual care and the trial was maintained for 3 years.

Mortality was significantly lower in the intervention group (18%) than the control group (24%, $p< 0.05$) The number of hospital admission was similar but length of stay was significantly shorter in the intervention group (difference 4.6 days, $p<0.01$). Quality of life measures were similar but self-rated health status was superior in the intervention group.

Pathy's study is interesting in using a postal questionnaire to identify those patients in the

intervention group with problems (60%). The participants whose questionnaire did not reveal problems did not receive a visit, their only intervention being the questionnaire. Pathy achieved significant improvement in the health status and decrease in the mortality of the intervention group overall despite having to actively intervene in only 60% of the intervention group.

These early evaluation trials had inconsistently demonstrated some improved outcomes for the elderly. The studies by Hendriksen, Pathy and the urban part of Vetter's study had demonstrated decreased mortality in the intervention group. Pathy achieved the best outcomes, by assessing only those 60% of the intervention group who self reported problems. Van Rossum also noted a trend to greater effect in those with poorer self-rated health. The need to consider functional not purely bio-medical problems was reinforced by this series of studies as was the importance of assuming a very personal interest in the care of the elderly participants.

2.2.3 Implementation of 'health checks' in Great Britain

The presumed usefulness of this model of care led to 'health checks' for the elderly being included in the British general practice contracts in 1990. (15) This required GPs to offer an annual health check to patients on their practice lists aged 75 years and over. The contractual obligation was neither clear in terms of how the assessment was to be carried out nor what aspects were to be assessed. An editorial in the British Medical Journal prior to the introduction of 'health checks' stressed the need to assess the elderly for loss of function. (16) Medical screening using multiple laboratory test and measurements had not been shown to reduce morbidity, mortality nor use of services. They suggested that to be effective the 'health checks' would need to be aimed at physical, emotional and social function and the needs of

carers. A system of multidisciplinary assessment in primary care was proposed to be best suited to carrying out this task. This led to a proliferation of studies evaluating the 'health checks'. Some of these relevant studies are described in the next section.

2.2.4 Evaluation of 'health checks'

Brown conducted a process evaluation of 'health checks' soon after their implementation. (17) Twenty practices in one family health service area in Nottingham were included. Data were recorded about organisation of health checks from an interview of one staff member in each practice. Patient notes were searched to record problems uncovered and whether they were previously known or new problems. Analysis revealed that 43% (143/331) of the elderly assessed had unmet health needs revealed by the 'health checks'. These unmet needs were largely amenable to service provision by the existing primary care facilities (3% required hospital referral). Hence, significant functional problems could be solved at relatively small cost and without the initiation of new services.

Further evaluation by the same research team has found variable implementation of the 'health checks'. (18). A postal questionnaire of all practices in Nottinghamshire evaluated the process of offering health checks to the elderly patients registered with each practice. Of the practices that responded, 99% indicated that they did offer annual health checks but one quarter estimated that less than 50% of their patients actually had a 'health check.'

A subsequent study by Brown involved visiting practices and interviewing staff. (19) Stratified random sampling was used to recruit 40 practices within the county of Nottinghamshire. Information was collected on 'health checks' occurring over a 3-month

period. Practices saw a mean of 12% of their patients aged 75 years and over and "44% of patients were found to have at least one problem. Action was taken to help resolve problems in 82% of patients with a problem." The number of physical problems found was larger than expected and conversely the number of functional problems found was fewer than expected. Multivariate analysis did not explain the large variation in proportion of the elderly seen and the proportion found to have problems between the different practices. The authors conclude that finding problems, for which action was taken in nearly half the patients, justifies the intervention. They further argue that a functionally based assessment would find additional problems.

Chew et al also evaluated 'health checks' of the elderly soon after their inception. (20) They conducted a nationwide postal survey of 1000 GPs. From a sample of 150 practices, they interviewed GPs and practice nurses and achieved a response rate of 69% and 76 % respectively. GPs used different methods of selecting patients for a health check. Eighty seven percent used a letter to invite patients for a health check. Many doctors reserved health checks for patients who they did not know well or had not seen recently. Over 70% of GPs claimed to have seen more than 60% of their eligible patients in the first year of implementation. 45% of GPs thought that health checks improved the overall health of the elderly but only 7.4% thought they were of "great value." The GPs reported problems requiring referral to social services but mental health problems were rarely found. They found the health checks useful for providing advice and reassurance to people.

Chew et al also published an evaluation from the consumer's perspective. (21). They approached a sample of 1500 elderly people, 664 (44%) of whom agreed to be interviewed.

Only two thirds were aware that they were entitled to a regular ‘health check’ and less than one third thought that they had had a ‘health check’. Fewer than half of these recalled the doctor or nurse discussing findings with them. Although 93% thought that having a health check was a good idea, 82 % did not believe that the health check had improved their health. Elderly people who were in poor health or who lived alone are thought to be at greater risk, but it was this vulnerable group who were less likely to know about the health check being available. Chew et al describe this as an example of Hart’s Inverse Care law which “suggests that knowledge of and access to health care is commonly inversely related to need”. (22)

Jagger et al attempted to categorize people who declined an annual health check in the UK. (23) They surveyed patients of one large practice. This community had also been part of a community survey 2 years earlier that had achieved a 95% response rate. Data from the two surveys could be linked. Thirty six percent of the practice’s patients refused the offer of a home visit. Comparison of the refusal group with the acceptance group revealed that they had similar demographics, had not recently joined the practice and were similar in most health and well being characteristics. Differences that were apparent were higher levels of morale ($p= 0.010$) and less contact with the GP ($p= 0.021$) in the group who declined an annual ‘health check’. This study did not produce evidence of a large “ice-berg” of unmet need existing in the population of elderly who refused an annual ‘health check’.

In 1992, Harris expressed uncertainty about the ‘health checks’ in a British Medical Journal editorial subtitled “the doubt persists”. (24) While accepting that evidence exists of unknown problems in the 75+ population, he was unsure if the evidence suggested that benefits would flow from providing this service to all the elderly. He concluded that flexibility was needed to

permit research into different approaches. This needed to occur to develop evidence based national guidelines together with extensive planning for service provision.

In summary, the 'health checks' had been introduced in Britain in the 1990 general practice contract. The "unreported needs" study by Williamson (7) has been described as a "seminal paper" on care of the elderly living at home. (14) General implementation had followed on from the studies in the 1970s and 1980s that had produced some evidence of positive outcomes from 'health checks'. Evaluation of the 'health checks' in practice had unfortunately not delivered any conclusive evidence of their usefulness for the 75+ population. The British National Health Service was left with an initiative in place that was not necessarily useful. Similarly, the British GPs were unsure if the results were worth the effort that 'health checks' required on their part. In other countries similar assessments were developed and studied in RCTs continuing to look for conclusive proof of their effectiveness.

2.2.5 United States of America

A more intensive system of care has evolved in the United States of America and is referred to as Comprehensive Geriatric Assessment (CGA). (25) CGA incorporates multidisciplinary assessment performed by geriatric assessment units in acute or long-term institutions or in rehabilitation programs. A specialist geriatrician interprets the data collected from home visits by nurses and allied health professionals. This model of care bypasses the primary care physician unlike the model in Great Britain.

Fretwell argues for an emphasis on functional aspects of care in CGA. (25) Function is defined in terms of Katz's Basic Activities of Daily Living (ADL) (26) and Lawton's instrumental

ADL. (27, 28) Fretwell defines Comprehensive Functional Assessment (CFA) as the functional model of care inclusive of the biopsychosocial model. She recommended this "biopsychosocial functional model" of care as the standard approach for all physicians involved in the care of the elderly. CFA consequently could be more available to all the elderly, even those who do not have access to specialist geriatric units.

Paist reviewed the evidence supporting screening and preventive interventions in people aged 65 years and over. (29) Recommendations are made about the interventions that can usefully be applied in primary care. Importance is placed not just on knowledge of what is useful but when it should be recommended. This distinction becomes even more important in the 75+ age group. Paist concludes: "It is hard to make an asymptomatic patient feel better, so it is perhaps most important to make our decisions based on evidence rather than anecdote and personal philosophy."

Primary preventive interventions uniformly recommended by Paist for people aged 65 and over are:

- Exercise for prevention of cardiovascular disease, osteoporosis and falls.
- Smoking cessation, although the rate of smoking has decreased to 8% in men aged 75+.
- Pneumococcal vaccination is recommended every 5 years. The immunised elderly suffer less pneumococcal disease although it has proved difficult to demonstrate a significant antibody rise.(30)
- Influenza vaccination is recommended annually and protection probably lasts 12 months. It is important to immunise late in the autumn so that protection is provided for the late winter peak of influenza.(30)

- Tetanus immunisation is required every 10 years and if never previously vaccinated a primary course should be given. (30) Recommendations published in 2000 suggest less frequent immunisation (31) but all quoted studies have occurred under previous recommendations.
- Aspirin in low dose for prevention of thrombo-embolic disease. A dose of 100mg is currently accepted as providing protection without increasing the risk of haemorrhagic stroke.

At age 75+ primary prevention by lipid and cholesterol lowering is not indicated. Osteoporosis prevention similarly needs to be initiated at a much younger age if it is to be effective.

Paist also cautioned that medical specialist groups might be more aggressive in recommending screening in their field of interest. The design of a 75+ HA instrument needs to be tempered with consideration of the relevance to general population screening. Paist concluded that listening carefully to older patients is the most important skill required by the clinician.

Stuck et al conducted a meta-analysis of CGA trials. (32) They included the results from 28 controlled trials comprising 4859 intervention and 4912 control participants. They grouped the trials into 5 different types of CGA according to predetermined criteria. One type of CGA, which they labelled Home Assessment Service (HAS), is trials of in-home CGA for community dwelling elderly people. HAS trials are directly comparable to 75+ HA. Six trials were included in this category, supplemented with additional unpublished data obtained from the authors. (9, 12, 14, 33-35)

Stuck et al found that HAS decreased long-term mortality by about 14%. The only other positive finding was a favourable effect on "living location". Combined odds ratios of living at home at follow up was 1.20 (95% confidence interval. 1.05 - 1.37) for HAS. Their covariate analysis showed that "programs with control over medical recommendations and extended ambulatory follow-up were more likely to be effective." They did not find consistent evidence in favour of targeting any sub-group. Neither exclusion of "too healthy" nor exclusion of "poor prognosis" subjects increased the likelihood of positive effects being demonstrated.

Subsequently Stuck et al conducted a RCT in Santa Monica, California over a 3-year period.(36) They demonstrated significant difference in the intervention group who had CGA and follow up compared to their control group. Participants were recruited by phone from a voter registration list, by mail and "46 others who asked to participate". Exclusion criteria were impaired cognition, language problems, moving away or into a nursing home, terminal illness and severe functional impairment. This left 414 participants who consented before they were randomised to control (n=199) or intervention group (n=215). The control group received their regular medical care.

This intervention "emphasized reducing the risk factors for disability" (i.e. a functional not a biomedical emphasis). It comprised home assessment by a gerontologic nurse practitioner, review of the assessment and recommendations made by a geriatrician, 3 monthly review visits by the nurse and phone contact if necessary. The assessment included medical history and physical examination, haematocrit, glucose, urine, faecal occult blood, functional status

(basic and instrumental ADL), oral health, cognition, depression, gait and balance, medication, weight, hearing, vision, social network and social support. The recommendations made to the participants were about self-care (51% of total recommendations), problems to discuss with their own doctor (29%) and use of community services (20%). This process of care for the intervention group has been evaluated and reported in a separate publication. (37) Outcomes were measured by independent trained interviewers who visited annually and made phone contact every 4 months.

Statistically significant results at the end of 3 years were:

- The intervention group was less dependent on assistance for Basic ADL (p= 0.02)
- The intervention group was less likely to be permanently admitted to a nursing home (p=0.02)
- The control group had fewer visits to their physician in the second year (p=0.007) and the third year (p=0.001) of the study.

Outcomes for which no significant difference existed between control and intervention groups were:

- The need for assistance with Instrumental ADL,
- The numbers of admissions to acute care hospitals,
- The numbers of short term nursing home admissions (less than 3 months and discharged to own home)
- Mortality (p=0.8)

Stuck et al results confirm their previously published meta-analysis.(32) CGA protocols, for

the independent living elderly, commencing with a thorough home assessment, with an emphasis on preserving functional ability and with regular follow-up are likely to delay the development of disability and decrease institutional care at the expense of more use of health services.

Secondary analysis of this trial has been published separately. (38) Bula et al performed subgroup analysis of the original participants of the trial (n=414). The first subgroup was formed by excluding all participants who were dependant in one or more Basic ADL (n=27) leaving a sample size of 387. The second subgroup was formed by excluding an additional 93 participants who were dependent in one or more Instrumental ADL, leaving a sample size of 294. Functional status was measured at yearly intervals and they assumed that changes had occurred mid way between assessments. Their unit of measurement was the number of days at a particular functional status. One weakness of this secondary analysis is this assumption that change occurred midway between annual assessments.

In neither subgroup analysis was there a difference in mortality between intervention and control group, nor had there been in the whole study population. (36) In the subgroup with no Basic ADL impairment at baseline, the intervention group spent significantly fewer days dependant of both Basic and Instrumental ADL throughout the 3-year study. (p=0.016) In the subgroup with neither Basic nor Instrumental ADL impairment at baseline, there was no significant difference in days spent independent of ADL throughout the study. In the group who had Instrumental ADL impairment at baseline, and no impairment of basic ADL, (n=93) the intervention was most effective (complete dependency intervention group 59 days, control group 233 days, p=0.005).

In summary, Bula et al have demonstrated improvement (decreased time spent dependent) as a result of the intervention, in 75+ people who do not have any Basic ADL impairment initially. This improvement is more marked in the small group who have Instrumental ADL impairment initially but no impairment in Basic ADL.

Bula et al separately report on primary care physicians attitude and cooperation with their in home CGA study.(39) The geriatric nurse practitioners who conducted home CGA rated the physician's cooperation. Physicians with fewer years in practice were more likely to:

- Cooperate,
- See benefits for their patients,
- Rate the program information as useful and
- Discuss the program with their patients.

Importantly higher physician cooperation predicted higher patient adherence to program recommendations. Bula et al suggest that "strategies for increasing primary care physician's (GP) cooperation might improve effectiveness of similar community-based prevention and health promotion programs."

The American studies have succeeded in achieving positive outcomes in preventive home visits for the elderly. This has been achieved by intense intervention with ongoing follow up of recommendations. The costs of providing this level of care have not been considered in these studies but would limit their general applicability for the uninsured American population. Importantly Bula's analysis has suggested a method of targeting a group within the population who is most likely to benefit from health assessments.

2.2.6 Switzerland

Stuck and colleagues have recently published a stratified randomized trial conducted in Bern, Switzerland building on their earlier work in Santa Monica. (40) Participants were all 75 years and over and living in one of 3 Zip code areas (A, B, C). After baseline interview, all participants were assigned to a risk stratum of future nursing home admission. High risk was determined if they fulfilled one or more of 6 predetermined criteria. Criteria used were:

Requires assistance in one Basic ADL (41)

Geriatric Depression Score (GDS 15) greater than 5 (42)

Mini-mental score less than 24 (43)

Impaired gait and balance score (44)

More than 3 self reported chronic conditions

6 or more medications

Within each stratum, one participant was randomised to receive the intervention for every 2 randomised to the control group. The numbers of elderly people randomised are presented in Table 2.1.

Table 2.1 Number of participants (n=791), by risk category and randomisation.

Strata	Control	Intervention	Total
Low risk	296	148	444
High risk	231	116	347
			791

The intervention group received an annual multidimensional geriatric assessment in their homes. Problem lists were created in 24 predefined categories and reviewed by a geriatrician. Recommendations were monitored by 3 monthly home visits including health promotion. One

nurse, with postgraduate public health training, worked in each Zip code area.

Stuck's results, for the entire study population, demonstrated a weaker effect on functional status outcomes than was apparent in their earlier Santa Monica trial. (36) The shorter length of follow-up (2 versus 3 years) may partly explain this result. They had previously reported the length of follow up as a key factor in determining success of geriatric assessment programs. (32) Additionally, the nurse working in Zip code C identified considerably fewer problems.

The intervention group in the high-risk stratum had a higher rate of nursing home admission ($p=0.02$) and a higher, but not significantly so, mortality. ($p=0.23$) Stuck concludes that high risk elderly would be better served with a program combining rehabilitation and care coordination instead of regular preventive home visits.

Stuck et al demonstrated more favourable intervention effects in the low risk group. This is similar to the effects demonstrated in the secondary analysis of their Santa Monica data. (38) Subgroup analysis was conducted of the participants in Zip code A and B, excluding the participants in Zip code C where the nurse identified too few problems. Low risk subjects in subgroup A and B had

Significantly better Instrumental ADL scores ($p=0.005$),

Significantly better Basic ADL scores ($p=0.009$),

Reduced nursing home admission ($p=0.004$) and

Consequently net cost savings in the third year of US $ 1403 per person.

The variability of results across the 3 Zip code areas, due to nurse C identifying fewer problems, defines the need to assess staff performance in delivering health assessments. Stuck's suggestion that the high-risk group would benefit from care coordination will be reviewed later in this chapter in reference to the 'Australian Coordinated Care Trials'.

2.2.7 Italy

Bernabei et al conducted a RCT of integrated care and case management for the frail elderly. (3) Participants were aged 65 years and older and were already in receipt of home health or home assistance programs. They are analogous to Stuck's 'high risk' group. (40) Initial assessment included a modification of the British Columbia long-term care programme, Basic ADL, Instrumental ADL, mental status questionnaire, geriatric depression scale listing of all physical diagnoses and drug treatments. A total of 200 people were randomised to control (n= 100) and intervention (n=100). The intervention group received integrated social and medical care and case management by GPs and the community geriatric evaluation unit. The control group received "conventional and fragmented organisation of services". Outcome measures included admission to institution, cost of health services, physical and cognitive functioning.

There was no significant difference at the outset between control and intervention groups. At the end of one year the intervention group was significantly better than the control group in Basic ADL, Instrumental ADL, (higher ADL scores, $p<0.001$) and reduced decline in cognition ($p<0.05$) and depression scores. This was achieved without an increase in the use of health services. The control group received more home visits by GPs and was more likely to have been admitted to hospital in the 12 months of the study. Per capita costs were 23% lower in the intervention group. This was mostly due to decreased community service costs and

decreased admission to hospital and nursing home.

The authors attribute the decreased costs to lesser physical and cognitive decline in the intervention group. They point to intense training of the case manager's skills and provision of geriatric assessment technology as a likely cause of their success. This training enabled the case managers to design care plans and to integrate care across all agencies. Close collaboration of all allied health professionals was critical to success, as it has been in other studies of home care for geriatric patients. In conclusion Bernabei et al extol the virtue of their model of integrated care and case management for the frail elderly. "In a comparison of this option with a traditional and fragmented model of community care the integrated care approach reduced admission to institutions and functional decline in frail elderly people living in the community and also reduced costs." Bernabei's results support the necessity of integrated care for the identified frail elderly but are not generalisable to the whole age specific population.

Review of these studies since 1964 have enabled an historical perspective on the development of 75+ HA. Outcomes have not been universally favourable, but few negative outcomes have occurred other than increased cost and utilization of services. Stuck's meta analysis in 1993 had been the only attempt to pool the results of studies. Recent attempts at arriving at consensus from published studies will now be discussed.

2.3 Systematic / Literature reviews published in 2000.

Two review articles have recently been published dealing with in-home preventive care of the elderly. (45, 46) Both reviews have been produced by teams of researchers who are

conducting large RCTs of this intervention. They have both reviewed mostly the same literature, some of which has already been described in this thesis. Importantly they have included studies of people aged 65 years and over. The relevance of their reviews for Australian 75+ HA depends on interpretation of their analyses for this older (75+) age group. The evidence about the appropriate age at which to begin this model of health care will be discussed in a following section (See 2.4).

2.3.1 Van Haastregt's systematic review.

Van Haastregt et al has recently published a systematic review of "preventive home visits". (45) Search strategies for selection of articles to be included were those recommended by the Cochrane Collaboration (47), as was an adapted version of the criteria used to assess methodological quality. (48) They reviewed trials of people aged 65 years and over and included 15 trials that studied some or all aspects of preventive home visits to elderly people living in the community. Despite "considerable differences in the methodological quality" they concluded that the quality of these 15 trials was adequate. The heterogeneity of the interventions and of the outcomes reported limited their ability to pool the data. They were consequently unable to produce a meta-analysis of data.

The outcomes of the trials were interpreted and 5 components identified. Only in 'physical functioning' (12/15) and 'mortality' (13/15) are data available from most of the trials. Falls is the least frequently reported component in only 6 of the 15 trials. Analysis of the number of trials reporting on these individual components and the number showing a favourable effect is contained in Table 2.2.

Table 2.2 Number of trials reporting on each component and number with favourable results.

Number of trials =15.	Number of trials containing this component.	Number demonstrating a favourable result
Physical functioning	12	5
Psychosocial functioning	8	1
Falls	6	2
Admission to institution	7	2
Mortality	13	3

The number of trials demonstrating favourable results is small for each component analysed. In 'physical functioning' the best results are achieved with 5 of 12 trials reporting favourable effects. Conversely only 1 of 8 trials reports favourable effects on psychosocial functioning.

Van Haastregt et al conclude that the effectiveness of preventive home visits for the elderly needs to improve, as no clear evidence of benefit has been established. If improvement cannot be achieved, they consider these visits should be discontinued.

2.3.2 Byles' Literature Review

Byles has published a literature review as part of the 70+ Preventive Care Trial (PCT) conducted for the Australian Department of Veterans Affairs (DVA). (46) This is a further work based on previously published reviews of preventive health programs for elderly people. (49, 50)

From an extensive literature search, Byles identified 205 articles of which 50 were identified as possibly providing RCT evidence of the effectiveness of health assessment for the elderly. Methodology was assessed using the 'Critical appraisal worksheet' developed by the Centre

for Clinical Epidemiology and Biostatistics. (51) Reports that dealt exclusively with in-patient care, hospitals in the home or for which no outcome data were available were excluded. Twenty-five reports on 21 RCTs were included in her review. Byles reports that 6 of the trials were assessed as methodologically rigorous, (9, 12-14, 36, 52) where randomisation had produced equivalent groups, losses to follow up were minimal and unbiased, compliance was high and analyses were performed on an intention to treat basis.

Byles reports being unable to produce a meta-analysis of pooled data from the RCTs. The variation in outcomes reported and the inconsistent use of statistical tests across all trials prohibited pooling of data. She concludes that 4 out of the 6 methodologically sound studies report improvements in health and that this analysis is consistent with Stuck's meta-analysis. (32) Studies targeting the frail elderly were not more likely to be associated with positive results. The acknowledged essential components of these trials are cognition, depression, social support, medication review and functional assessment. These components were commonly included both in trials that did and did not demonstrate benefit. This dubious evidence of effectiveness led Byles to speculate that the interaction with the elderly at home may be responsible for the observed effectiveness (the Hawthorne effect (53)). Limitations to the universal implementation of 75+ HA included the generalisability of trials conducted in small samples of the population.

Byles concluded that for Australian 75+ HA to be effective there needs to be:

- A standard assessment tool developed
- Trained health professions to conduct assessments
- Appropriate services available for the health needs identified.

2.3.3 Stuck & Beck.

Another systematic review has been completed by Stuck, Beck et al but is as yet unpublished. (Personal communication JC Beck) They claim to have dealt with the heterogeneity of the data collected in the diverse range of RCTs of health assessment. This had been described as the limiting feature by van Haastregt (45) and by Byles. (46) According to Beck's analysis the essential requirements for successful in-home comprehensive geriatric assessment are:

- Multidisciplinary assessment
- Control over the recommendations and
- Adequate training of the assessment staff.

2.4 Appropriate age for this model of care.

The decision of the age at which to commence home visit for health assessment of the elderly must be made in tandem with the decision about the content of the assessments. While it is appropriate in a 60 year-old patient to remain focussed on their physical health and preventive strategies about medical illness (54), the same does not necessarily hold true with an older person. The older person may already have some established diseases of age for which no solutions exist. They may be unlikely to live long enough to benefit from preventive interventions aimed at stroke and ischaemic heart disease. This is not to say that their health has become less important but that it is time for a change in emphasis. The age at which this change in emphasis is appropriate will not be the same for all individuals. This will depend on their physical health, their cognition, their life experiences and their expectations of their remaining years. Population based screening /preventive programs need to make a considered

assessment of the age at which benefit might be apparent for the population as a whole.

A review of the literature of preventive care reveals considerable differences in the age chosen by investigators. Some studies included 'elderly' people from:

> Age 60 years. (54) This large Australian 'Dubbo study of the elderly', aged 60+ concentrated on the physical health of the sample (54) including cardiovascular disease (55) and mortality. (56)
>
> Age 65 years. (3, 7, 14, 57)
>
> Age 70 years. (8, 9, 35, 58, 59)
>
> Age 75 years. (11-13, 33, 36, 40, 60)
>
> Age 80 years, (61) although this study was specifically about falls prevention.

After the introduction of the obligatory 'health checks' all evaluation studies in Great Britain concentrated on 75 years and over. Consistent results have been more common in studies that included people who have reached the age of 75 and over. (16)

Van Haastregt's recently published systematic review of the RCTs on 'preventive home visits' has been described. (45) They reviewed all trials of people aged 65 years and over. These generally unfavourable results, at age 65+, however appear more supportive of the preventive home visits if only the trials studying people aged 75+ are included. With the exception of the 'physical functioning' component, the proportion of trials returning positive results is increased if confined to 75+ trials. (62) Table 2.3 depicts van Haastregt's analysis as presented in table 2.2 with this secondary analysis in the 4th column.

Table 2.3 Number of favourable trials by component and by age 75+.

Number of trials =15	Number of trials containing this component.	Number demonstrating a favourable result	Number (%) of these favourable studies in 75+ people.
Physical functioning	12	5	1 (20)
Psychosocial functioning	8	1	1 (100)
Falls	6	2	1 (50)
Admission to institution	7	2	2 (100)
Mortality	13	3	2 (67)

For the purpose of conducting this RCT, it was decided to study health assessment in the 75 and over age group. This RCT was initiated to study this model of care in an Australian setting building on the international experience. Prior and subsequent international work has led support to the choice of this age to initiate this model of care.

This does not imply that it is appropriate as the only model of care for all individuals at age 75+. Indeed the results of this RCT and literature review suggest that this model of care is most appropriate for a specific cohort within this age specific population. This concept will be considered further in Chapter 6, Discussion. Having made this arbitrary choice and evaluated this intervention in a random sample, the results are directly relevant to the 75+ HA initiated by the DHAC on 1st November 1999.

2.5 Personnel

2.5.1 Great Britain

Analysis of the literature allows suggestions about which personnel are most appropriate to perform 75+HA. Tremellen evaluated the process soon after the introduction of the 1990 general practice contract in Great Britain. (63) She conducted her evaluation in the Wiltshire Family Health Services Authority that serviced 39,516 patients aged 75 and over and obtained complete data from 73 of the 83 general practices. The practices varied considerably in whether 'health checks' were performed in the home or surgery and whether by the GPs or practice nurses. This study concluded that the patients were more accepting of the offer of an assessment in those practices where they were all performed by the GP (76% versus 57%). Tremellen interpreted that this was because most GP assessments were done opportunistically during routine consultations. Nurses, because of the way their work is organised, needed to more formally invite patients to have a health check. The nurse would then visit them in their home. This impediment would explain the apparent lower uptake of assessments offered by nurses.

Another outcome of Tremellen's study was that practice nurses with specialist qualifications in aged care were more likely than the GPs to perform assessments in the patient's home (85% versus 54%). Tremellen reported the number of referrals for additional services as a measure of the assessment's ability to find problems in the elderly. Referrals were highest in those practices where specialist nurses carried out all or most of the assessments and lowest in those practice where the GPs carried out all or most of the referrals. Nurses were more likely to rate the assessments as important and to see health promotion as a key part of the process, compared to the GPs.

The attitudes of GPs, practice nurses and their elderly patients to the British 'health check'

were reviewed by Chew soon after their introduction. (20) She conducted a postal survey of 1000 practices and an interview survey of GPs and practice nurses from 150 practices. All the practice nurses were female and one third had been employed within the last two years since the contractural obligation to perform the 'health check'. The nurses, more than the GPs, felt the health check was great value and would improve the health of the elderly people. Chew reported, across the participating practices, a general trend from systematic organisation to random /opportunistic screening. The systematic practices were conducting more health checks in the person's home and the practice nurse was conducting these assessments. The GPs in the practices conducting health checks opportunistically were less impressed that they were useful. Nurses took longer to conduct a 'health check', conducted them in the homes and more "felt they uncovered problems".

Other studies have examined the attitudes of medical personnel and subjects for the health assessment. The consistent finding has been that GPs regard case finding as a relatively unrewarding exercise and show little interest in it. By comparison health visitors and trained nurses have a more positive attitude to this type of assessment and generally are more appropriate people for this work. (13, 63) McEwan, in the RCT already described, used nurses to visit the elderly in their home. (11)

The Royal College of GPs in Great Britain produced a set of guidelines on the conduct of the 'health check'. (64) This comprehensive guide covers the preceding research, practice staff, organisation and the content of the 'health check'. They advocate that the "practice nurse, community nurse, health visitor, occupational therapist or link worker" can perform the 'health check'. They remind the GP that they are responsible for the training and supervision

of the quality of the 'health check' and need to be involved in the interpretation of results and implementation of further referral. The GP should supervise the nursing and allied health professions conducting home 'health checks' but may not be the right person to conduct these time consuming home visits and assessments.

2.5.2 Australia

Only one Australian study of GPs performing opportunistic geriatric assessments has been published. (65) This study detailed the whole process from seeking opinions from local experts and developing an assessment instrument, to a pilot phase when the GPs completed assessments on their own patients. The use of nurses for these health assessments does not seem to have been considered in this study and the GPs may have partly been motivated by the 'Practice Assessment' (obligatory Continuing Medical Education) points available if they completed assessments as part of this project.

The Australian DVA has commissioned the PCT, which is a large prospective RCT of home assessment of elderly veterans and their dependants. (58) They have recruited 1500 participants who have been randomised into a control group and three different intervention groups. This trial is ongoing for three years from randomisation and data collection will be completed in 2001. All assessments are occurring in the veterans home and are being conducted by research nurses or allied health professionals. This decision was based on Byles' review of the world literature that noted that assessments were predominantly conducted by non-medical personnel (nurses 8, volunteers 3, health visitor 1 and office staff 1). (46) Of the 10 studies reporting positive findings, 7 had used non-medical personnel to conduct in-home assessments. The studies that used medical practitioners to conduct

assessments have predominantly been based in America.

Nurses conducted all the 75+ HA completed as part of this research investigation. The result of each assessment were seen by a GP, (the author of this thesis) who reported to the participant's own GP.

2.5.3 Denmark

In Hendriksen's RCT, already described, interviews were conducted by 2 home nurses and one doctor (C Hendriksen). (12) Each interviewer regularly visited the same cohort of the intervention subjects. No analysis is presented of differences outcomes achieved by the different interviewers.

2.5.4 United States of America and Switzerland

The RCT in Santa Monica conducted by Stuck, Bula & Alessi has already been described (36-38). They used "gerontologic nurse" for all home based assessments. In their more recent trial in Bern, Switzerland, 3 nurses were used (40). Each nurse visited all the participants within an area defined by a Zip code. All nurses had similar training in public health but despite this nurse C identified significantly fewer problems. Subgroup analysis among low risk patients visited by nurse A & B patients revealed favourable effects. No such favourable effects were demonstrated among the patients of nurse C. Stuck concludes that the intervention's ability to reduce disability depends on the home visitor's performance.

2.6 Australia

There have been several initiatives in Australia which impact on considerations of 75+ HA. These will now be reviewed for their relevance to this research investigation:

Australian Coordinated Care Trials

Dubbo epidemiological study of the elderly (60+)

South Western Sydney

PCT for the DVA

GP education in aged care

Repeat prescribing

2.6.1 Australian Coordinated Care Trials

The Australian Coordinated Care Trials (CCT) arose out of a realisation that health care and community services could be reorganised around provision of three streams of services. (66) These three streams would correspond to the three basic categories of individual need, namely

- a *general* stream for occasional and uncomplicated needs including preventive health, immunisation and GP visits
- an *acute* stream for needs requiring specialised services arising as a consequence of acute episodes
- a *coordinated* stream for people requiring, over a longer period of time, a mix of services for a chronic disease. These services could usefully be coordinated by a care manager.

This third *coordinated* stream focuses on the needs of the individual. A care plan is developed by the individual and a coordinator of care. Flexibility of funding is required to enable purchase of services that address the needs negotiated in a care plan. A mix of services can be purchased from different providers in a cost efficient manner.

The CCTs have been a major experiment in alternate methods of provision of health and community care. The original CCTs were initially established in 9 sites and 4 additional sites were subsequently established in indigenous Australian communities. The CCTs were not uniformly about aged care as some included clients of any age. (66) Some of the CCTs were specifically about community based care of people aged 65 years and over. The CCTs were predominantly about management of known complex health problems. They facilitated care of clients, including the elderly, referred for coordination through the development of 'care plans'.

An interim evaluation of the CCTs has been published. (67) In the Foreword, the director cautions against drawing conclusions yet from this interim publication. Difficulties with the evaluation have included problems with data flow from the multiple trial sites, particularly receiving timely health economic data. The initial CCTs did not all become operational at the same time and the second wave of CCTs in indigenous Australian communities commenced at a later date. As expected the CCTs are generating questions as much as providing answers. A second generation of CCTs is now commencing being a refinement of the initial concepts.

Interim results relevant to this study and against a background of incomplete data are presented, measured against the pre-selected hypotheses of the CCTs. (Part eight, The Hypotheses (67), and Chapter 14 of General Practice in Australia 2000. (6))

> No statistically significant improvement in client health and well being has been measured by use of the SF-36. (68, 69) There are some indicative trends in the intervention group suggesting improvement in physical health. (Hypothesis 1)

No reduction in hospital admissions has been observed at this stage. This is despite the majority of trials focussing on strategies to reduce admissions. (Hypothesis 2)

The majority of clients are elderly, more likely to be socially disadvantaged, of poorer physical health status but their mental health status is only slightly poorer, relative to the Australian population. (Hypothesis 4)

Many trials have not fully utilized care planning due to gaps in service provision and insufficient Information Technology (IT) systems. (Hypothesis 5)

The CCT process is similar to the health assessment process once the client has been identified. (I.e. assessment, care planning, implementation, monitoring, and review) GPs have been central to the care planning process but have tended to focus on the medical aspects.

These CCTs have not involved surveillance nor screening of the general elderly population. In this sense, they represent a complementary model of care for a different cohort of elderly Australians. Care coordination is similar to Stuck's proposal for the elderly at high risk of nursing home admission (40), (See section 2.2.6 'Overview of studies preventive care for the elderly, Switzerland.'). This concurs with Bula's secondary analysis of their Santa Monica RCT. (38) (see section 2.2.5 'Overview of preventive care for the elderly, United States America') Together these models of care represent separate streams of care for the identified high risk elderly (coordinated care) and the general elderly population at low risk (75+ HA).

2.6.2 Dubbo study

The Dubbo study is the largest Australian prospective study of all the elderly (60+) people within a defined community. It was conducted in Dubbo, a large town in central New South Wales and commenced in 1988. The sample population comprised 1236 men and 1569 women who were followed for a median period of 62 months. The main purpose of this study was to "to identify predictors of mortality, hospitalisation and placement in long-term care, with special focus on risk factors for cardiovascular disease." (70). The Dubbo study was thus predominantly about bio-medical illness. It was a prospective study of "non-institutionalised subjects", participants being aged 60 years and over and living in the community. It concentrated on medical problems and known physical risk factors (56).

The study authors reported significant predictors of cardiovascular disease in the elderly as: (55)

- Advancing age
- Prior coronary heart disease
- Use of antihypertensive medication
- Diabetes mellitus
- Serum cholesterol, Low density lipoprotein (LDL) and apolipoprotein B in men
- Triglyceride in women
- High density lipoprotein (HDL) in men
- Lipoprotein A in women
- Poor self-rating of health in men and women
- Isolated systolic hypertension in women (not in men).

The Dubbo study data allowed useful predictions about cardiovascular disease in Australians aged 60 years and over.

2.6.3 South Western Sydney

Shah and Harris conducted a study of GPs providing holistic care of their elderly patients in South Western Sydney. (71) They describe this as an area with high elderly, migrant and English as a second language population. Despite this it is not well provided with aged care services in the community. As such they see the GP as having a larger than usual role in aged care. Shah and Harris explored the GPs perceptions of their own competence in providing care across the spectrum of 'physical, psychological and social' needs. They found GPs felt most competent to deal with physical illness, less so with psychological and least of all with social problems.

Subsequently Shah et al established a method of geriatric assessment of patients selected by GPs for a pilot study in South Western Sydney. (65) The authors stressed the need for general practice to provide anticipatory care for the elderly to maintain functional status. They also argued it needs to be "systematic if it is to be successful" and that "function is more predictive of adverse outcome, than diagnosis per se" and that their review of the literature supported this contention.

Shah et al developed an instrument for opportunistic geriatric assessment in general practice and their publication reports the results of a pilot study of their instrument. (65) Their instrument includes a self-assessment questionnaire that the elderly person completes at home at the suggestion of the GP. At a subsequent consultation, the elderly person has a health

check and the GP audits their case-notes to determine if a new problem has been revealed by the process. This process of care has similarities to the questionnaire used by Pathy. (14) They recommended that the elderly person be reviewed at least once a year. The functional aspects included in their assessment instrument were: “teeth/dentures, feet, falls, tiredness, home circumstances, social networks, community services, financial assistance, equipment and household aids, depression, activities of daily living, mobility, postural hypotension, cognitive function, and medication related issues including compliance.”

In the course of their pilot 41 patients were assessed by 7 GPs. Problems identified were reported as known to the GP or revealed by the assessment. A total of 49 new problems were revealed by these assessments. Shah et al does not report the exact number of the patients who had problems but that “a large proportion having at least one or two problems”. A limitation of this study is not knowing the frequency distribution of problems per patient. The aspect of the assessment that revealed problems and the numbers of problems previously known and revealed by the study have been calculated from their published data. (See table 2.4)

Table 2.4 Components of South Western Sydney opportunistic geriatric screening instrument.

Function	Known to GP (n=41)	Revealed by assessment (n=49)
Loneliness	3	4
Carer ill-health	3	3
Financial problems		3
Mobility	6	2
Other ADL	13	2
Cognition	1	1
Screen suggestive of depression	4	4
Vision	11	5
Hearing	9	2
Teeth	8	5
Feet	10	8
Falls	5	3
Postural hypotension	1	1
Polypharmacy		4
Drug interaction		3

Based on their results, Shah et al argue for a pragmatic approach to the screening of elderly people for problems in their functional status. Improvements in quality of life and prevention of disability are possible with appropriate management of functional problems. GPs have the opportunity to recognise problems as 90% of the elderly consult their GP each year. (72) The elderly may be unaware of the potential for improvement in some functional and mood disorders. GPs are centrally placed in our health system to coordinate care with other health professionals and agencies providing care within the community.

Blakeman et al has recently published a study of the uptake of EPC items by GPs throughout South Western Sydney. (73) They used a fax questionnaire to request information from GPs within the local Divisions of General Practice. Non responders were followed up until they achieved a response rate of 70.6%. Twenty-three percent of respondents had claimed for a 75+ HA and were doing them opportunistically (not systematically). 75+ HAs had been

conducted in the elderly persons home by half of these GPs and it was the most popular of the EPC Medicare item numbers. In conclusion, they see the need for GPs to have a more systematic approach including use of age-sex registers and for there to be more support for GPs and health professionals. Evaluation of all aspects of the EPC is seen as a necessary part of implementation.

2.6.4 Preventive Care Trial

The DVA has commissioned a Preventive Care Trial that is currently evaluating home assessment in a random sample of the veteran population.(58) The project brief for the PCT indicates a sample size of 1500 and a three-year observation period, at a budgeted cost of over $1,800,000. (58) For veterans, data are collected centrally on all services and these data are used for service and health economic analysis.

The assessment instrument for the PCT was developed after reviewing the instrument used in the Yarrawonga pilot study (GPEP 334) and subsequently use in this RCT of 75+ HA (GPEP 645). The specific instrument used in the DVA PCT and the data of frequency of problems identified in the first visit are being published separately. (74)

Specific reasons the DVA study is highly relevant to 75+ HA are:

- Size of sample, being larger than other studies, except that by German. (57)
- Australian, being the only other RCT in Australia
- The nature of service delivery means that it is possible to observe the control group but prevent cross over effect diluting the impact of the intervention.

However its limitations are,

- The veteran population is not representative of the Australian elderly population as a whole being accustomed to additional service provision, more likely to be male and having a higher incidence of smoking. (74)
- Age of the sample is 70 years and over. This may limit the PCT's ability to demonstrate significant effects given the international experience that suggest 75 is an appropriate age to commence annual health assessments.

2.6.5 GP education / RCT

A RCT of GPs ability to positively influence the health of their elderly (65+) patients has been reported by Kerse et al. (75) GPs were recruited for the study from a random sample in Melbourne but only one GP from any one practice was enrolled. The 42 GPs participating were randomly allocated to control or intervention group. A random sample of each GP's 65+ patients (n=10) was audited to assess changes in targeted measures. The intervention group of GPs participated in an educational program to increase their health promotion activities with 65+ patients. The content of the educational package included advice on social and physical activity, prescribing and vaccination.

Patients of the intervention GPs had a significant increase in "physical activity, frequency of pleasurable activity and self rated health." Kerse claims extrapolation of the known effect of this behaviour change makes a 22% reduction in mortality possible. Functional status and psychological well being were increased but did not reach statistical significance. Vaccination rates and medication prescribing were similar in the patients of both the control and intervention GPs. Importantly this study has demonstrated the ability of an educational

program for GPs to have a beneficial effect on their elderly patients. This demonstration of the GPs ability to enhance usual care should be translatable to functional problems found in the course of 75+ HA. (76)

2.6.6 Repeat prescribing

Martin has recently proposed a strategy for identifying patients of GPs who would benefit from 'Care Planning' and to detect the elderly at high risk of nursing home admission. (77) She investigated whether requests for repeat prescriptions for non-psychiatric conditions were an indicator of chronic and complex conditions. Adult patients (over 18 years) only were included in her sample, of which 44% were aged over 65. They completed a SF-36 while waiting to see the GP. The physical disease morbidity in her sample was similar in comparison to other Australian studies of chronic and complex disease burden. (72) The SF-36 data confirmed that these patients of GPs were suffering greater limitations of physical health including pain. As expected this association was weaker for mental health because repeat prescriptions requests were for non-psychiatric conditions. She concludes "GP repeat prescription patients were likely to have high levels of morbidity, worse than people in the general population" and that repeat prescriptions are, "a reasonable but not necessarily a perfect marker for chronic physical conditions." Thus, repeat prescription requests by the elderly as a marker of chronic conditions, may be a useable indicator of need for care planning.

2.7 Design of an instrument for 75+ HA.

2.7.1 Content

A review of articles and editorials was completed to establish the content of the 75+ HA instrument. A consistent framework for 75+ HA had not come into popular use (78) despite opinions suggesting the need and value of consistent assessment instruments (16, 24, 79), and a framework proposed by the Royal College of General Practitioners. (64) The design of the 75+ HA instrument used in the pilot study and subsequently in the RCT was based on this literature as reviewed here. Components of the 75+ HA instrument are listed below. The justification for including each component follows.

Hearing

Vision

Physical Condition

Compliance

Medication

Miscellaneous

Cognition

Activities of Daily Living

Mood /Depression

Mobility

Nutrition

Social

Housing

The implementation of 75+ HA from 1st November 1999 recommends similar content but in a different structure. (1)

2.7.2 Hearing

Iliffe reported that 19.8% of 75+ patients had hearing aids. (80) Among this group use of their aid was erratic but no description is given of why they were not in constant use. Having been assessed as in need of an aid, non-use implies persisting hearing difficulty. Similarly, Tremellen found that 18% of all referrals for action after 'health checks' were for hearing problems. (63)

The Royal College of General Practitioners (RCGP) guide "Health checks for people aged 75 and over" asks only one question to cover hearing. (64) "Do you have any difficulties hearing and understanding what a person says to you (even if you are wearing a hearing aid) in a quiet room if they speak normally to you?"

The frequency of hearing problems, erratic use of hearing aids and its importance to a structured interview justify it being included at the start of an health assessment instrument.

2.7.3 Vision

Visual problems are almost universal at this age with >90% requiring glasses. (63) The RCGP guide to 'health checks' asked one question only to screen for unresolved visual problems. "Do you have any difficulty in seeing newsprint, even when you are wearing your glasses?" (64) Similar subjective questions are asked, together with self-reporting of visual pathology. (Cataracts, macular degeneration, diabetic retinopathy etc) This subjective analysis of vision lends itself to assessment during a home visit.

2.7.4 Physical Condition

Physical problems need to be asked about with an emphasis on whether they have resolved or remain ongoing. Early studies had reported large numbers of medical problems in the 75+ patients. (7) Later studies have emphasized the need to concentrate on functional aspects of the assessment but not to ignore the medical problems. (16)

Self-rated health is a robust predictor of likely future independence in the elderly. Ratings options on a 5 point scale range from ‘very good’ to ‘bad’. Ratings of ‘very good’ or ‘good’ are strongly associated with future independence. (81)

Pulse and blood pressure are included in the recommendations for 75+ HA in the Medicare Benefit Schedule book. (1) Measurement of blood pressure needs to be consistent and reproducible and indications for treatment are based on levels recorded in surgery consultations. (82) Similarly, pulse rate and rhythm need to be checked particularly for atrial fibrillation. It was expected that both of these would not be done at home but left for a subsequent surgery consultation.

2.7.5 Compliance

Compliance with correct dosage and frequency can be reviewed by home visiting. Compliance was assessed with questions about medication difficulties, pre-packaged systems or carer help with correct dosage. Self-reporting of medication side effects and allergy were included in this assessment of compliance.

2.7.6 Medication

Medication in use needs to be reviewed. (83) There is a large literature available supporting the importance of minimising adverse effects and drug interactions in the elderly. (84) Non-prescription medications need to be included in this assessment whether they are over the counter drugs, herbal or naturopathic remedies. Medication use is more accurately assessed by interview of the elderly at home and inspection of their accumulated medication supply than by review of prescriptions by their GP. Significant numbers of prescriptions are not presented to a pharmacist for dispensing. (83)

Jones conducted a RCT of a strategy to reduce use of psychotropic medication by the elderly. (85) The patients in her study were aged 65 years and over and they were recruited from 2 large general practices in Wales. The study team created a register of all patients who had been taking psychotropic medication for more than 3 months. Data were collected from all patients (n=277) using a semi-structured interview before randomisation and again 9 months later. After initial data collection patients were randomised to control or intervention. The intervention consisted of a GP consultation, a practice nurse consultation and an offer of counselling and relaxation sessions all focussed on psychotropic medication reduction. Twice as many patients in the intervention group stopped or reduced their psychotropic medication compared with the control group ($p<0.01$). A majority (81%) of patients who stopped or reduced medication reported feeling the same or better than previously. Regular benzodiazepine use is contra-indicated in this age group. Negotiating an effective strategy for benzodiazepine withdrawal leads to success in a significant number of long term users.

A recent series of publications from a meta-analysis have confirmed the impression that the

elderly are at greater risk of falls when they are on psychotropic medication (86) and some cardiovascular medications. (87) Cardiovascular drugs most likely to be implicated were Digoxin, Type 1A anti-arrhythmics and thiazide diuretics. Additionally this meta-analysis confirmed the association of recurrent falls with being on "more than 3 or 4 different medications".

The authors of the Dubbo study reported medication usage in their initial sampling of participants (60+). Three or more classes of prescription drugs were in use by 18% of men and 25% of women. Similarly, percentages for two or more classes of non-prescription drugs were 29% of men and 44% of women. (88) Among these users of prescribed medication, there was high consumption of non-prescription drugs. The elderly are known to be at increased risk of adverse effects from medication, particularly when multiple medications are used at the one time. "Polypharmacy in the elderly population appears to be predicted by recent hospitalisation, increasing age, female sex and increasing depression. There is potential for drug-drug interaction to occur, but the findings suggest target areas for preventive action." (88)

2.7.7 Miscellaneous

At 75+ not many people are still smoking, so questions were designed to ask about current and past smoking habits. (29) Alcohol consumption is also less in this age group but still a problem in some patients. (89) Specific questions about dentition should be included particularly as dentures become loose with wear and resorption of bone in maxilla and mandible.

Immunisation status for tetanus, influenza and pneumococcus should be investigated. Contemporary advice was to repeat tetanus vaccine every 10 years, pneumococcal vaccine every 5 years and influenza vaccine every year in the immediate pre-winter period. (30) This has now been superseded by advice to repeat tetanus vaccine only once over age 50 if a primary course has been completed. (31)

Questions related to sleep could provide information on a variety of complaints. Depression may manifest as early awakening and nocturia may be a sign of bladder or prostate disease in men or prolapse in women.

2.7.8 Cognition

The Folstein Mini-Mental State (Folstein MMS) has been widely used for 25 years in clinical practice. (43) The Folstein MMS can be interpreted in terms of deficits in certain areas of testing (e.g. recall, orientation, short-term memory etc) or as an overall score.(90) Allowance should be made for acute illnesses (fever, hyperglycaemia or confusion etc) that temporarily impair cerebral function.

Iliffe et al found that 15% of a random sample of the 75+ elderly had Folstein MMS indicating need for further assessment of cognitive state. (89) Folstein MMS scores of 0-18 indicated cognitive impairment and were recorded in 4.6% of the study population. This percentage increased with age from 2.6% in the 75 to 79 age group to 16.7% in the 90+ age group. (89) Folstein MMS scores of 19-24 indicate possible impairment requiring further assessment and were recorded in 10.5% of the whole study population. They demonstrated a more modest increase of from 8.8% in the youngest to 16.7% in the eldest age group. Scores

of 25 or above were assumed to indicate no cognitive impairment.

The Abbreviated Mental Test Score (AMTS) uses only 10 questions but does not yield as much information. (91) The Folstein MMS remains the gold standard of assessment and was used for this research.

2.7.9 Activities of Daily Living

Barthel index of activities of daily living (Barthel ADL) provides a guide to general levels of functioning and is useful for repeated measuring over time. (41) The Barthel ADL was designed to assess the elderly with disabilities from stroke. It is most useful for repeated measurements over time of the same individual. The Barthel ADL assesses independence in ten abilities and these are scored within the ranges specified:

- feeding (0,5,10)
- transfer (0,5,10,15)
- grooming (0,5)
- toiletting (0,5,10)
- bathing (0,5)
- walking (0,5,10,15)
- ascending and descending stairs (0,5,10)
- dressing and undressing (0,5,10)
- continence of bowels (0,5,10) and
- continence of bladder (0,5,10).

The Index score out of 100 is a global measure of independence in ADL. It includes questions

on urinary continence that is frequently under-reported by the elderly. (80). These may be less intimidating when included with other ADL questions.

2.7.10 Mood / Depression

Major depression and significant depressive symptoms remain common problems in this age group. Evidence of mood lowering can be sought with the Geriatric Depression Scale (GDS 15). (42) This is an abbreviated version of an original 30-question depression screening instrument. (92) Fifteen yes-no questions each scoring one point are asked. The GDS 15 is a screening instrument but is not diagnostic of depression in itself. It has been used extensively and its validity confirmed in all aged populations except mild to moderate dementia. (93) This liability was not expected to be a problem in an RCT that is additionally screening for dementia. Validation studies report a sensitivity of 100% for scores of 3+ but low specificity at this threshold. (94) Other studies have advocated a threshold of 5+ as having the correct balance of high sensitivity and specificity. (95) As higher scores are recorded, the likelihood of major depression increases (increasing specificity). The GDS15 in this RCT was used to screen for depression and to report the result to the GP. The GP would then decide if a diagnosis of depression was real and make a therapeutic decision. For this reason, it was decided to use <3/3+ as the cutoff point. 100% sensitivity at this point ensures that the RCT does not miss any depressed people and their own GP decides if the diagnosis is real and plans management. Decisions about psychotherapy or medication with antidepressants require careful clinical appraisal and follow-up.

One study published by Hoyl et al, after the data collection phase of this RCT, advocated a shorter version incorporating only 5 of the GDS 15 questions. (96) This GDS 5 evolved in a

study of community dwelling American war veterans, most of whom were male (98.6%) and physically unwell. Hoyl et al demonstrated that the GDS 5 has equivalent sensitivity to the GDS 15. This shorter version of the GDS may prove clinically useful if its validity is confirmed in a more representative sample of the aged population.

D'Ath and Katona have derived 1, 4 and 10 item GDS versions from the GDS 15 (97) and advocate their usefulness in primary care. (98) Interestingly the only question in common in Hoyl's GDS 5 and D'Ath's GDS 4 is 'Are you basically satisfied with life?' A considerable data set exists on the use of the GDS 15 and these abbreviated versions (GDS 1, 4, 5 and 10) are not yet supported by published literature confirming their validity.

2.7.11 Mobility (Falls Prevention)

The 7 Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) studies are the largest series of trials of prevention of falls and injuries in the elderly. These studies were pre-planned to pool their results by meta-analysis, but each site chose its own intervention. (99) An exercise program was part of all trials but varied in character, duration, frequency and intensity with some trials emphasizing balance training. Individual studies incorporated other preventive strategies including medication review, nutritional supplements, avoidance of postural hypotension, (59) and Tai Chi to improve balance. (100) Most subjects were ambulatory, with intact cognition and aged 60-75 years. Statistical analysis allowed for multiple falls per patient to be analysed. Adjusted falls incidence ratio in interventions incorporating exercise was 0.90 (95% CI 0.70-0.99) and in interventions incorporating balance training was 0.83 (95% CI 0.70-0.98). (99)

The Prevention Of Falls in the Elderly Trial (PROFET) demonstrated that it is possible to decrease the number of falls in an elderly population with simple investigation and minimal follow-up. (101) This RCT occurred in southeast London and was a cooperative venture between the geriatric medicine and the accident and emergency departments. Recruitment of participants was among people aged 65 years and over presenting to accident and emergency following a fall. Falls with or without loss of consciousness were included but excluded if due to "sudden onset of paralysis, epileptic seizures, alcohol excess, or overwhelming external force." Excluded at recruitment were those living in institutions, those with dementia (AMTS <7) (91), those unable to be traced and those not consenting to be part of the study.

Assessment of the cause of the fall involved a general medical examination and an occupational therapy assessment.

> Medical examination focussed on visual acuity (including poor binocular vision), balance (inability to stand on one leg for more than 10 seconds.), cognition (Folstein MMS (43)), affect (modified geriatric depression scale (42)), and prescribing practice. The physician made appropriate referrals for problems discovered, including referral to the day hospital. Drug modification was achieved by contact with the GP.
>
> Occupational therapy assessment occurred in a single home visit. Instruments used were the Barthel index of ADL, (41) functional independence measure (102) and the falls handicap inventory (FHI). (103) Advice, education and minor home modifications were made as a consequence of the visit. Follow-up was done by postal questionnaire 4 monthly for 12 months but without any further face to face contact with participants.

Statistically significant findings in the intervention group were:

Decrease in the number of falls, (p=0.0002)

Decreased risk of falling, (odds ratio 0.39, 95% CI 0.23-0.66)

Decreased risk of recurrent falls (odds ratio 0.33, 95% CI 0.16-0.68)

Decreased admissions to hospitals (odds ratio 0.61, 95% CI 0.35-1.05) and

Lesser decline in the Barthel score. (p= 0.00001)

The PROFET study utilized a similar process to a 75+ HA but with outcome measure confined to those related to falls and admissions. Similarities include

Participants were living independently in their own homes (not in institutions)

However, participants were aged 65 years not 75+.

Assessment used similar instruments to those used in 75+ HA.

Intervention group had one assessment and no further prompting of their usual health care providers (GPs)

Comparative measures were completed 12 months after enrolment.

Campbell et al conducted a RCT of strength and balance retraining to prevent falls and injuries. (61) They realised the risk of injury from falls increased with age and was worse for women. Participants were women aged 80 years and over. The study was based in Dunedin; New Zealand and participants were living independently at home. The intervention group (n=116) received a program of physical therapy incorporating exercise delivered in the home by physiotherapists. The control group (n=117) received an equal number of social visits. Both groups were followed for 12 months. After one year, there were 152 falls in the control

group and 88 in the exercise group. The intervention group was significantly better than the control group in:

Mean (SD) rate of falls (intervention 0.87 (1.29) vs control 1.34 (1.93))

Relative hazard for the first 4 falls (0.68, 95% CI 0.52 to 0.90)

Relative hazard for first fall with injury and (0.61 95% CI 0.39 to 0.97)

Balance as measured by balance score at 6 months (0.43 95% CI 0.21 to 0.65).

Campbell has established that exercise training is possible in 80+ women and that it had the desired effect of improving physical function. Importantly this has had a measurable effect on reducing falls and preventing injuries.

The effect of exercise on physiological functioning, cognitive functioning and mood has also been investigated. (104) Participants were women, aged 60 years and over, living in the community. The control group had no intervention nor group social contact throughout the 12 months of the study. They were tested at the beginning and end of the trial. The exercise group (n=94, initially) were offered exercise classes including home exercise routine for one year. The 71 women who completed the program attended an average of 59.0 classes. At the conclusion of 12 months, the exercise group had improvements in reaction time, strength, memory span, measures of well being and mood. Improvement in mood was inversely proportional to initial mood measures. Williams and Lord conclude that exercise has a beneficial effect on physiological function, cognitive function and mood in subjects initially suffering from high depression, stress or anxiety levels.

2.7.12 Nutrition

Nutrition can be assessed using the Australian Nutrition Screening Initiative (ANSI) checklist.

(105) The ANSI was developed from the American version: the 'Nutrition Screening Initiative' (NSI). (106) Items for potential inclusion were derived from previous research into nutritional well being of older people. Items were analysed against 2 criteria set to identify under-nutrition. One criterion was intake of nutrients that would provide 75% of recommended daily intake (RDI). The other criterion was subject's perceived health on a 5-point scale. Regression analysis was used to derive item weights that would predict under-nutrition. The NSI committee chose a cutpoint of 6. This is equivalent to RDI below 75% for 3 nutrients or 'fair' or 'poor' perceived health.

The 12 questions in ANSI are substantially the same as the 10 questions in NSI. Some questions have been rephrased slightly, one question expanded into 2 and one question added about "adequate fluid intake." ANSI questions include weight loss, alcohol consumption, 3 or more medications and whether subjects eat alone. There is overlap among these ANSI questions with questions that may be asked in other parts of the 75+ HA. ANSI is very sensitive, as answers suggesting risk to any two of the questions places the person in the 'moderate risk' group. ANSI has been validated in a large study but is not diagnostic of poor nutrition only an indicator of risk. (107) In the Australian Longitudinal Study of Women's Health, 43% of the 70-75 years age group have moderate or high nutrition risk. (108) Interpretation of the risk category, further assessment requirements with a dietitian and consideration of ability to bring about change in patient's nutrition will influence decisions about how to proceed.

2.7.13 Social

Iliffe et al published a study to answer the question "Are the elderly living alone an at risk

group?" (60) They conducted a secondary analysis of data from a community survey of 239 elderly (75+) people living alone. They did not confirm the notion that they are an "at risk" group. They were more likely to

Use community health professionals,

Use social services and

To have difficulty summoning help by day and night

They were no different than those living with someone "in measures of cognitive impairment, numbers of major physical diagnoses, impaired mobility or use of GP or hospital services." They conclude that they do warrant "specially targeted services".

Questions designed to explore subject's social situations were included in the 75+ HA. Does this person live alone or with partner or children? Do they have support available from neighbours, friends or nearby family. Are they in the role of carer, or cared for or is it a mutually supportive role. Sometimes one partner is physically disabled and the other has impaired cognition. Even if support is adequate at present, it may change suddenly with illness or absence of a carer. Apart from human contact, do they have phone numbers or an alarm system for emergencies? Loneliness is a frequent problem, and if found, social suggestions can be made which may be taken up. Some of this age group is gainfully employed at work. Sport, frequently lawn bowls, is an important part of their social network and appropriate levels of exercise is just as important as at a younger age. (104)

2.7.14 Housing

Gill et al studied the home safety devices in a group of community living people aged 72 years and older. (109) Over half the bathrooms were hazardous (59%). The incidence of

hazards in other rooms was not as high, ranging from 23%-42%. Housing specifically for the elderly was less hazardous than community housing. They also examined the ability of elderly people in transfers, balance and gait and considered the environmental hazards in their homes. Environmental hazards were as common in the homes of people with specific physical disabilities as in the non-disabled elderly. The only exception to this being "grab bars" in the tub /shower. (110) In some cases, hazards were more prevalent in the homes of the physically disabled.

2.8 Overview of structure of 75+ HA

2.8.1 Disablement process

Verbrugge and Jette's defined the term "disablement process" to incorporate concepts both of 'disability' and 'functional limitation'. (111) These terms had been used throughout the literature they reviewed but without a consistent definition. Verbrugge and Jette have attempted to define "disablement process" by describing both the,

- Mechanism by which acute and chronic conditions affected function in body systems, physical, mental activities and activities of daily living and
- Factors that influenced how disabled one became in terms of risk factors, interventions and exacerbations.

They were left with a definition as "Disability is defined as difficulty doing activities in any domain of life".

2.8.2 Functional Status Decline

Subsequent to the initiation of our RCT, Stuck et al published a review of the international

literature on risk factors and consequently introduced the term "functional status decline". (112) This term incorporates both the difficulty of doing activities of daily living and physical function limitation. Having delimited the terminology, they then categorised 14 domains of risk factors for functional status decline. They found strong evidence that certain predictors within 11 of these domains are associated with functional status decline. These 11 domains are:

Cognitive impairment

Depression

Disease burden (co-morbidity: number of prevalent chronic conditions)

Body Mass Index (BMI) either increased or decreased

Lower extremity functional impairment (gait, balance, falls risk)

Low frequency of social contacts

Low level of physical activity

Alcohol (no consumption compared to moderate level of use)

Poor self-perceived health

Smoking

Vision impairment

Stuck et al also noted a shortage of published research in 2 areas: Nutrition and Physical environment. Immunisation is well supported in the literature but is not included in Stuck's domains.

Table 2.5 contains Stuck's 14 domains (column 1) and the predictors of high risk in 11 of these domains (column 2). The 75+ HA instrument used in this study was designed in 1995 before Stuck's publication. The components of the 75+ HA instrument are compared with

Stuck's domains and predictors (column 3). There is general agreement between the concepts covered in Stuck's domains and the components of the 75+ HA instrument. Concepts consistent across both lists include affect / mood, alcohol, cognition, co-morbidity, falls, function (activities of daily living), hearing, medication, nutrition, self-rated health, smoking, social contacts and vision. Physical activity was not included in the 75+ HA instrument and immunisation and physical environment in Stuck's domains.

2.8.3 Process of care

Alessi et al (37) describe the analysis of the process of care they used in the preventive in-home CGA trials by Stuck et al. (36, 38, 40) She reports they classified problems into 4 broad areas.

Medical (organ system diseases, including dementia)

Physical functioning (ADL and falls)

Mental Health (mood disorders, substance abuse, anxiety)

Social /Environmental. (unsafe home, social isolation financial problems)

She also classifies the recommendations arising from problems identified into,

Self-care activities

Referrals to a physician or

Referrals to a non-physician professional or service

Table 2.5 Domains, predictors within each domain and comparison with the 75+ HA instrument.

Stuck's Domains (alphabetically)	Predictors within domain	75+ HA instrument
Affect	Depression	9. GDS 15 6. Miscellaneous. (Sleep)
Alcohol	None compared to moderate	6. Miscellaneous. (Alcohol)
Cognition	Cognitive impairment	7. Folstein MMS
Co-morbidity	N of prevalent chronic conditions	3. Physical condition
Falls		10. Mobility
Functional limitation	Lower extremity impairment	8. Barthel ADL
Hearing		1. Hearing
Medication		4. Compliance 5. Medication
Nutrition	High /low Body Mass Index	11. ANSI
Physical activity	Low level of activity	
Self-rated health	Poor	3. Physical condition
Smoking	Currently smoking	6. Miscellaneous. (Smoking)
Social function	Low frequency of contacts	12. Social
Vision	Poor self-reported vision	2. Vision
		13. Housing assessment
		6. Miscellaneous (immunisation)

2.9 Enhanced Primary Care Package.

The 75+ HA implemented in Australia conforms to the model evaluated in this literature review. Crucially they are:

For elderly people aged 75 years and over

For elderly people living independently in the community

Inclusive of a home visit for collection of assessment data

Conducted by nurses or allied health professionals

Supervised by their regular GP and

An encouragement for the GPs to plan to provide coordinate care

Alessi's categorization of problems is similar to that described in the Medicare Schedule which was subsequently used to design protocols for assessment in Australia. (113, 114) As described previously, Australia is now in the same situation as Great Britain in 1990. Widespread implementation of 75+ HA is occurring and further RCTs would face the difficulty of creating a valid control group. Evaluation studies are commencing. (73) A consistent framework for reporting these studies will enable comparison of different evaluations and meta-analysis of results. This would avoid the insurmountable problem reported by Byles (46) and van Haastregt (45) with heterogeneous data. Alessi's analysis of the process of care in preventive in-home CGA could be adopted as a standard to facilitate comparison of the imminent Australian evaluation trials.

2.10 Summary of the literature

The literature review has found:

The origins of this model of care in the "unreported needs" study of Williamson et al 1964.

Extensive RCT evidence prior to, and evaluation evidence after, the introduction of the British 'health checks' in 1990. Results of these studies have not consistently shown positive outcomes for the elderly.

Systematic reviews of the literature published in 2000 confirming positive trends in some studies but not universal justification for implementing this model of care in the general population.

The importance of comprehensive functional assessment of the independent elderly not limited to the bio-medical aspects.

The age (75+) at which comprehensive assessment should become the emphasis of primary care of the elderly.

The ability of nursing and allied health professionals to competently complete the data collection phase of health checks. Medical practitioners have consistently interpreted the data collected and better results are achieved with medical supervision of recommendations.

The relevant Australian research into:

Bio-medical illness of people aged 60 years and over,

Preventive care for 70+ DVA veterans currently under trial,

Opportunistic screening by GPs in South Western Sydney,

The ability of education for GPs to bring about change in health behaviour among their elderly patients

Justification for the 75+ HA instrument developed in a pilot study and used in this RCT.

The components that should be included in a 75+ HA instrument and the process of reporting consistent with the work of Verbrugge, Stuck, Bula, Alessi and others.

This RCT aimed to fill the apparent gap in the literature by completing an RCT of 75+ HA in Australia.

Chapter Three Pilot study

Yarrawonga Home Assessment of the Elderly Pilot Study (YHAEPS)

3.1 Introduction

This pilot study was initiated to explore ways of adapting the international experience to the Australian context. It was intended to develop a method for a more complete RCT. Methods used in this pilot study were largely based on the British model of 'health checks'. This was the predominant model described in the literature at the time. To facilitate design of the pilot study links were established with the:

- University of Wales, Cardiff, which had responsibility for overseeing the cost effectiveness of this intervention in the British National Health System and
- Department of General Practice, University of Nottingham, who were researching attitudes among doctors and utilization of this service.

No specific assessment instruments were in common us in Great Britain. Components of various assessments were collected into an assessment instrument. Valid instruments were preferred if available and an attempt was made to avoid repetition and duplication. This was not always possible without altering already validated instruments.

The British and European experience had already shown that a large number of simple functional problems are uncovered. (24) A pilot study to develop a method of 75+ HA was a necessary first stage of testing the hypotheses of this thesis. The pilot study was funded by the General Practice Evaluation Program (GPEP, grant number 334) and was entitled the

'Yarrawonga Home Assessment of the Elderly Pilot Study' (YHAEPS). This pilot study initiated Australian research to establish whether a similar system of health assessments would be of significant benefit to elderly Australians.

3.2 Methods

3.2.1 Sample

An age-sex register (75 years and over) was printed from the computerised account records of the Denis Medical Clinic, one of two general practices in Yarrawonga, Victoria. This practice comprised 4 full-time GPs who collectively delivered a broad range of general practice skills. The age-sex register was refined by not including patients not currently residing in Yarrawonga or Mulwala, known to be living in an institution (Hostel, Dementia Hostel and Nursing Home) or deceased. The remaining patients were assumed to be living independently at home. A random sample was drawn by selecting every 10^{th} name on this register. Members of this random sample were offered a 75+ HA in their home.

Initially the research nurse contacted the elderly by telephone and offered them a 75+ HA. The nurse then forwarded a written explanation of the study. (Appendix 1 'Letter of Invitation' 1995) A relative, friend or spouse was always invited to be present and this offer was frequently taken up. Each interview began with a verbal and written explanation of the study. (Appendix 2 'Information Sheet' 1995) A consent form was signed and one copy was left with the patient and the other copy retained by the research team. (Appendix 3 'Consent Form' 1995)

75+ HAs were conducted by a research nurse specifically employed and trained for that

purpose. Data were collected in a standardised form and transferred to a computerised database. A report of each 75+ HA was forwarded to the GP the elderly person nominated as their usual doctor for detailed follow up. Reports from the GP at a later date answered questions about whether the problems uncovered were unrecognised or previously known and whether they were amenable to resolution by existing local facilities.

Ten home assessments were conducted using our original standardised interview and the results entered in a computer database constructed in Microsoft (MS) Works. A 'form' view of the database was printed for each patient. These were delivered to their nominated GP. Advice was sought after the first ten interviews from the Departments of General Practice and Community Medicine, University of Adelaide. Significant refinements to the protocol were made and this refined instrument is the one described above. The standardised interview was rewritten so that answers were collected as much as possible as yes/no or numerical values with avoidance of free text. This enabled results to be more amenable to analysis.

3.2.2 75+ HA Instrument

A 75+ HA instrument was developed based on the literature reviewed and the 'health check' instruments in use in Great Britain and Europe. A description of the 75+ HA instrument follows and the print version is included in the appendices (4-15). This represents the final form used throughout this pilot study. One other module was added for the RCT described later. Aspects assessed were:

'Demographics': Usual demographics (name, age, address, date of birth etc.) plus

information about the persons usual GP. (Appendix 4)

'Hearing': Questions about hearing were intentionally placed first to facilitate the conduct of the assessment. The 4 questions used allow a description of the ability of the person to hear well enough for daily activity. Included are questions about the problems frequently observed in clinical practice. (Hearing aid not used or flat batteries) (Appendix 5)

'Vision': Subjective information about the adequacy of vision together with information about how recently correction had been prescribed or checked. Specific visual pathology common in the elderly was listed. (Appendix 5)

'Physical Condition': Self-rated health was asked on a 5-point scale. This section also recorded relevant recent medical conditions. Questions were included to elucidate common problems among the elderly. Did they attend and did they discuss all their worries with their GP? (Appendix 6)

'Compliance': A series of questions focussing on whether prescribed medication was actually being taken as prescribed or likely to be interacting with non-prescribed medication or medication prescribed for someone else. (E.g. spouse) (Appendix 7)

'Medication': All medication in use by the person was inspected and recorded. Special note was taken of whether the medication had been prescribed for the patient or another person.

Options for coding of medication history were explored including the Victorian Hospitals Association codes and the Chemdata commercial codes used in retail pharmacy. The most appropriate system for our purposes was the Anatomical Therapeutic Chemical (ATC) classification index together with the Pharmaceutical Benefits Scheme (PBS) codes. The ATC codes generic drug names only and, as a product of the World Health Organisation, is in use worldwide. It is hierarchical in nature, codes drugs in several different places if they have different indications (e.g. aspirin, angiotensin converting enzyme inhibitors) but does not code tablet size or preparation. The PBS codes mesh with the ATC and allow recording of tablet size and trade name /manufacturer if required. The drug data has been entered in the database using trade names to facilitate communication between patients, GPs and the research team. Trade names allow checking for drug interactions and manual coding risks erroneous recording of data. Prescribing software for GPs in Australia was in its infancy in 1995 and not in use in the Denis Medical Clinic, Yarrawonga at this time. (Appendix 8)

'Other drugs' listed non-prescription medication being used. (Appendix 7)

'Miscellaneous': This category includes questions about tetanus immunisation, dentures, tobacco and alcohol. (Appendix 9)

'Sleeping' Sleep questions were designed to ask about sleep patterns, depression, nocturia and anxiety about lack of sleep. (Appendix 9)

'Cognition'. The 'Folstein Mini-mental state' score has been in use since 1975 (43) and provides an easy, reproducible assessment of organic cerebral function. (90) For our purposes it reliably assesses early dementia and produces a global score (0-30). An alternative way of reporting the mini-mental result is to describe areas of deficit in function. E.g. attention, recall etc This is not as amenable to statistical analysis, hence our use of global scores. (Appendix 10)

'Barthel Index of Independence of Activities of Daily Living' (Barthel ADL) was incorporated in the questionnaire. The Barthel ADL Index has been extensively validated in geriatric populations over many years (24) Other measures of ADL (e.g. Katz (26)) were reviewed but were seen to be less sensitive when looking for early loss of function in an elderly but independent population. (Appendix 11)

'Mobility': Aspects assessed included driving, walking and history of falls. A list of community services, available in Yarrawonga, that were being used, was included. (Appendix 12)

'Nutrition' was assessed by the Australian Nutrition Screening Initiative (ANSI). This scores dietary habit into nutritional risk categories (low, moderate or high risk). (105) It had been derived from an American dietary screening instrument (106) and was being evaluated throughout Australia during 1995. (Appendix 13)

'Social': Questions were asked about living alone or with family in the house or nearby. The availability of assistance day or night and the amount of social contact

usually experienced were inquired about. (Appendix 14)

'Housing Assessment': The housing assessment was conducted by accompanying the person around their home looking for obvious risk of falling. Particular attention was paid to the bathroom and toilet. (Appendix 15)

3.2.3 Electronic database

A computerised record of all interview data that allowed potential for analysis necessitated the use of a relational database. A database in MS Access was designed and was identical to the questionnaire. This enabled direct data entry into a portable computer as a future option. The relational database structure designed incorporated four 'tables':

'Demographics' contained patient data that did not change with time (e.g. name, birthday),

'Interview demographics' contained patient data at the time of interview that might change with time (e.g. age, address, and own doctor),

'Questionnaire' contained all the answers collected at one home visit and

'Outcome' contained present status of each patient in the study.

The relationship between the 'key fields' of each 'table' connects all the data from each interview. This allows separate but comparable records of sequential interviews of the same patient. It places no limit on the number of interviews nor number of patients. In this form the database allowed easy entry of records and was suitable for fieldwork with a portable computer. A structured electronic assessment instrument facilitates consistent and reproducible data collection by the research nurses. Additional data could be collected for

expansion of the interview by insertion of extra ‘tables’ linked by ‘key fields’. Writing of ‘queries’ to generate ‘reports’ in Access allows association of any fields (questions) in the database. The ‘report’ to a patient’s GP was generated using a standard ‘query’ that extracted data from their interview record. To this was added ‘fields’ describing all the problems uncovered at each interview. The ‘fields’ in this ‘query’ were merged in a form letter in MS Word giving the GP an accurate report of the 75+ HA of their patient. (Appendix 16)

Ethics approval to conduct a pilot study was sought and obtained from the University of Adelaide Committee on the Ethics of Human Experimentation (Approval H/32/94). This is a body convened in accordance with National Health and Medical Research Council guidelines.

Analysis of data was performed in MS Access and Excel. Basic statistics were calculated using Epi Info.

3.3 Results of the Pilot Study

3.3.1 Demographics

Forty (40) elderly people living independently at home were offered a 75+ HA. After explanation of the project, 3 people declined the offer. One declined to be involved when first contacted by phone and two declined to proceed with the interview when visited by the nurse. These three took no further part in this study. Thirty-seven complete 75+ HA were recorded between March and August 1995.

This pilot demonstrated that this intervention has a high acceptance rate of 92.5% (37/40), among the sample population.

The female to male ratio among 37 subjects interviewed was 24/13. The mean age was 80.7 and age range was 75-89. These data are contained in Table 3.1.

Table 3.1 Demographics of sample.

	Male	Female	Total
Number	13	24	37
Age range	76-88	75-89	75-89
Mean age	81.0	80.5	80.7

No interviews were incomplete although the time taken for completion varied between 45 and 135 minutes (average 90 minutes). The average total time taken for each patient interviewed was 150 minutes and comprised:

15 minutes to arrange the assessment by phone and print questionnaire,

90 minutes to conduct the interview,

30 minutes for data entry and

15 minutes to deliver reports to the G P and if necessary discuss the results with him/her.

3.3.2 Problems identified

Problems uncovered were grouped as follows and assessed as whether they were previously known (or uncovered by this study) and whether they were amenable to resolution by existing local services.

Hearing: 7 (19%) elderly reported their hearing as poor or deaf, yet 2 did not have a hearing aid and 2 reported problems with the function of their aid.

Vision: 6 (16%) said their glasses prescription was more than 5 years old although 4 had had the prescription checked, 2 complained of black spots, one was known to have a cataract and the other subsequently found to have a cataract.

Physical condition: 6 (16%) volunteered they had problems they had not discussed with their doctor but only one had not been to see a doctor in more than 12 months.

Compliance: 7 (19%) people were using a dosette but 5 of these still required supervision. No one was using a Webster pack (blister packaging of all medication prepared by a pharmacist) or similar.

A ‘query’ constructed in MS Access found three people who had a Folstein score <25 but did not have their medication packaged in a dosette nor supervised.

Medication: 2 (5%) elderly men were found to have large stores of medication, most of which they were not currently using. Some of this medication was in the name of their deceased wife and there were multiple bottles of some drugs.

A hospital pharmacist reviewed all medication lists and reported 6 (16%) people with potential interactions or omissions. These omissions/ interactions were:

Diuretic (frusemide) without potassium supplements,

Two diuretics (frusemide and indapamide),

Inadvertently omitted eye drops after surgery,

Probable interaction between digoxin and diltiazem,

Two incompatible antidepressants medications and,

Inhaled beclomethasone on a p.r.n. basis.

These omissions/ interactions were subsequently reviewed by the patient's usual GP.

Miscellaneous: Dentures were a problem for 10 (27%) people.

24 people reported problems with waking at night; 7 of who were worried by this and 6 couldn't get back to sleep.

The level of tetanus immunity was inadequate in 23 of 37 people. Nine people did not know when they had last had a tetanus immunisation. Fourteen people knew that it was more than 10 years since their last tetanus immunisation.

Cognition: Folstein Mini-mental scores <25 were recorded in 6 (16%) people. These 6 people warranted further investigation.

ADL: Barthel ADL scores of less than 80 were recorded in 6 (16%) elderly people. Impairments were mostly in ability to move independently (bed or steps) and in urinary continence. Of these, 4 remained at home only because they had a spouse who lived with them and the other 2 had daily visits from a daughter. Clearly an able-bodied relative living nearby or in the home facilitates the frail elderly remaining independent.

Mobility: 25 (67%) admitted to walking problems but 14 of them did not have any aid (stick or walking frame.) 16 had had significant falls and 4 had been unable to get themselves up after a fall. Most of these falls had occurred despite mobility aids being in use at the time.

Nutrition: ANSI scores revealed

16 (41%) at high nutritional risk (score 6+)

12 (32%) at moderate nutritional risk (score 4-5) and only

9 (27%) at low nutritional risk (score 0-3).

Social: 16 elderly people were living alone and 5 of these had no relatives living nearby. 12 had no regular outings and 4 of these wanted more regular outings.

Housing. On inspection of their homes 24 hazards were noted and 16 (43%) of these were in people who had reported walking problems.

Table 3.2 summarizes these data of the more serious problems, which were previously unknown.

Table 3.2 Number of serious problems, previously unknown by the GP.

Hearing	4	Deafness, without a functional hearing aid.
Vision.	1	Unrecognised cataract.
Medication	6	Drug interactions and omissions
Cognition	6	Folstein scores <25
Compliance	(3)*	Folstein <25, but medication unsupervised
ADL	6	Barthel scores < 80
Nutrition	16	High nutritional risk
Housing	16	Walking problems and obvious hazards in their homes
Total	55	

*these 3 included in 6 in cognition

3.4 Evaluation

Process and Impact evaluation of this pilot study, as described by Hawe et al (115), was considered throughout the course of the study. Outcome evaluation will be a main feature of the subsequent RCT.

3.4.1 Process evaluation:

3.4.1.1 Elderly person's opinion

To ensure that the assessment was targeting the needs of the 75+ population the research team met with two focus groups of elderly people. This gave the elderly an opportunity to express their perceived needs of services to help them remain independent at home. These discussions were held at the Adult Day Activity and Support Service (ADASS) involving 10 women all over 75 and the Uniting Church Fellowship involving 15 women and 2 men, (mostly 75+ and some carers). These groups were not constructed to be representative sample of the elderly population. Their female preponderance was not considered to invalidate their opinion on aged health care. Members of the groups indicated that the intention of the study to keep the elderly independent and in their own homes was in agreement with their own wishes. No major deficiencies in service provision in the community were revealed by these focus groups nor did they reveal additional needs that were not already being assessed by the pilot study. Clearly the most useful facility to allow the elderly to remain in their own homes is daily contact with a younger relative /carer.

3.4.1.2 Acceptability

Acceptability of this intervention was assessed by phone interview of half the participants after their interview (Appendix 17 'Telephone Evaluation Form'). This was conducted by a

local social worker, not otherwise connected with the study. She contacted the first 10 people assessed, about 5 months after their visit and the last 10 assessed soon after their visit. Several evaluations were incomplete due to poor memory of the 75+ HA.

Generally, there was good acceptance of the assessment:

60% (12/20) could recall that the assessment had been helpful,

85% (17/20) thought the visit was of the right duration and

75% (15/20) said they would like to have an annual visit and that the service should be expanded to include all the elderly.

The social contact of the interview was particularly appreciated. None of the 20 people in the phone evaluation expressed any reservations about having been involved in this pilot study.

3.4.2 Impact evaluation

55 major problems, previously unrecognised, were uncovered in 25 of 37 (68%) elderly people interviewed (See Table 3.2). Twelve of the 37 (32%) did not have any problems recognized by the assessment. These 12 represent the active, healthy aged. They have been similarly recognized in the other trials of aged health assessments. Twenty-five of the 37 had one or more problems. All of the categories defined in constructing the assessment instrument recorded problems. Thus, none of the categories were seen to be not worth including in the subsequent RCT.

The numbers of problems uncovered by this pilot is an indication of the importance of this research. This pilot study sample was not large enough, nor has a valid random sample been sought, to produce reliable descriptive statistics about problems uncovered, however, the

pilot study has developed a method of conducting a 75+ HA of the elderly.

3.5 Discussion

This study has established a method of 75+ HA. The trial of content of the interview and development of software to manage the data produced pre-empts the next phase, that is a larger trial of this intervention.

3.5.1 Software

The Pilot Study allowed development of a relational database that was functional by the completion of the study. The power of this software to search an established database justifies the considerable effort expended on its establishment. The modular nature of Access allows for the development of different 'tables' that could be incorporated to research different aspects of the independent elderly. For example:

A 'table' of questions about the use of a 'personal alarm' comparing other methods used to obtain help in an emergency. This could answer questions about the cost effectiveness of personal alarms.

A separate 'table' to record more detailed medication data would allow tablet size, dosage and manufacturer details to be included. Drug coding could be added although for reasons previously discussed it has not been incorporated in this pilot study. Development of drug prescribing software may allow electronic data entry and reduce the risk of errors.

Screening for depression could be achieved using a rating scale and recorded in a

depression ‘table’.

A separate ‘table’ could list all the GPs and their contact details in a particular division of general practice. Our pilot study has only involved the 6 local GPs in Yarrawonga.

The Access database has unrealized potential and in this pilot study was not fully utilized. As developed it is functional and has demonstrated it’s potential for research. Future use may involve modifying the database to record data necessary to answer particular hypotheses. If additional data needed to be collected to test a particular hypothesis then questions could be added to the Questionnaire table. The established Demographics, Interview demographics and Outcome tables and all the table relationships would remain unaltered.

3.5.2 Cost and Time

Indicative costing for the service aspect of a further study has been calculated. (Appendix 18) Data could be collected by direct entry into a portable computer, multiple interviews of the same person being feasible in the already developed software. As previously described the total time for each assessment, including prior arrangement and generating of report, averaged 150 minutes. This time could be reduced by 30 minutes using a portable computer. The quoted retail price for a colour screen notebook included sales tax (1995 prices). Data entry directly into the database and the avoidance of paper, other than for the report to the doctor, would save significant amounts of time and increase efficiencies of effort.

It has been difficult to find suitable times to visit this age group; mostly they have preferred an interview about 10 am or after lunch, e.g. 1pm. Two interviews per day are probably all

that is feasible. A research nurse working 20-25 hours per week could complete ten 75+ HAs per week. Travel costs for a study based in small towns such as Yarrawonga, or for nurses based in local practices, would be small at approximately 5 km. per visit. The cost per assessment and the annual cost of interviewing 10 people per week have been estimated. The cost of a notebook computer is more than offset by the savings in nurse's wages. (See appendix 18)

3.6 Study design

This study has established a method of 75+ HA that is both feasible and inexpensive to apply. This pre-empts the next phase, which is a larger trial of 75+ HA.

Outcome evaluation would be the most important measure of the usefulness of 75+ HA. RCTs have been performed in Great Britain (8, 9, 11, 14, 33), but are no longer possible. The obligation on all British GPs to offer annual 'health checks' to all people aged 75+ on their practice lists (15), precludes the establishment of a valid control group.

3.6.1 Cohort study

The format of an evaluation could include all the local age specific population. Yarrawonga and the surrounding district had a population of about 6000 and a population aged 75 years and over of 524 at the 1991 census. (116) A study based at this location would have the advantages of an easily accessible study group. This has obvious advantages of cost containment and completeness of including all the age specific population. The census data, the age-sex registers of the two general practices and the electoral role could be compared to

ensure high penetration of the target population.

A practical study design therefore is:

Include all the age specific population of Yarrawonga and district and offer annual assessments to all of them.

Continue to report problems to local doctors for action by local services.

Repeat assessments after one year and record problems uncovered as:

Resolved problems that were present at the 1st but were not present at the 2nd 75+ HA.

Persisting problems that were present at the 1st 75+ HA and still present at the 2nd 75+ HA. These could be further subdivided into:

Resolvable problems, that potentially could be resolved.

Un-resolvable problems that clinically could not be expected to resolve. (E.g. emphysema)

New problems that have arisen since the 1st 75+ HA

The difficulty with a cohort study design would be in finding a valid control group. Finding a control group elsewhere would create the difficulty of ensuring both groups were similar enough to be comparable. Even if initially comparable they may have different services available which would influence outcome measures unevenly. Alternately randomizing half the population to each of control and intervention groups would result in considerable cross over effect.

3.6.2 Urban or Rural site

Yarrawonga has above average numbers of medical facilities compared to many Australian

rural towns. A study of an inner city suburb might produce interesting comparisons; elderly city dwellers are often very isolated and removed from medical facilities despite their close proximity. The British 'health check' has been based on RCTs performed in cities (8, 11-14) and some have included adjacent rural areas. (7) Only one study has reported separate analysis of the urban and rural cohorts. (9, 10)

3.6.3 Randomised Controlled Trial

The evaluation that would establish the worth of 75+ HA would be the measurement of problems uncovered and subsequently resolved compared to usual care. This approach necessitates comparing randomised control and intervention groups. A legitimate control group would have to be created and left to usual care. The intervention would be a 75+ HA at home reported to the elderly person's nominated GP. Randomisation would need to produce two comparable groups. This could be checked by demographic and other measures of health status that did not directly impact on the intervention. Comparing the control and intervention group by using a different measure would ensure that:

Equivalent groups were being compared and

The ethical problem of assessing the control group but not offering them any intervention would be avoided.

A RCT could collect data at 2 successive annual 75+ HAs and measure the ability of the intervention to resolve the problems revealed. Contamination of effect from the intervention group (e.g. by education of the GPs) would have to be minimised. This would be most easily achieved in a large population centre where an adequate sample could still be a small percentage of the age-specific population. Sampling a small percentage of each participating

practice's list would minimise contamination. Additionally GPs would remain blind to which patients had been sampled for the control group.

Offering a 75+ HA to the control group in the second (final) year of the RCT would enable comparison of health status of the two groups. This would not contaminate the control group but would measure the number of health status problems in the control group for comparison with the intervention group. Differences in the health status might then be attributable to the intervention.

The Yarrawonga Home Assessment of the Elderly Pilot Study has established a 75+ HA instrument and developed computer software for the collection of these data and its analysis. On a sample of 37 independent elderly it has proved to be acceptable and has uncovered a range of health status problems. It has initiated this type of research in Australia and enabled comparisons with international research in this area. Importantly it has considered cost and design for a subsequent study to evaluate this intervention if applied to a larger group of independent living elderly people.

Chapter Four Methodology

4.1 Study design

The first stage of this work had been to develop the 75+ HA instrument, as described in Chapter 3 Pilot Study (117), and described in a recent publication. (118) The assessment protocol developed is very similar to the content subsequently recommended in the Medicare Schedule. (119) A number of trial designs were considered for the next stages of development and evaluation. A RCT design was chosen to test the ability of the intervention to find problems and facilitate their resolution by notifying the patients nominated GP.

A RCT was chosen as it represents the 'gold standard' trial design to test the problem resolution capability of this unproven intervention. A RCT would establish if the intervention was a reliable method of finding the unmet health needs of the elderly and whether this led to a reduction in the number of health needs one year later. It also depended on the GP's ability to coordinate local services to respond to the problems revealed. The control group was left to usual care after randomisation and had a 75+ HA one year later. The intervention group had two 75+ HAs one year apart. This study design conforms to the model of service implemented by DHAC. (Annual 75+ HA home visit by nurse, reviewed by own GP)

The elderly are a particularly vulnerable group within our society. (120) They tend to be physically frail. With physical frailty comes emotional insecurity. A significant minority of them has impaired memory. These factors were considered in the design of this study. The scientific rigour of the study design was balanced with the ethics of conducting research on

this vulnerable population.

To measure if control and intervention groups were similar, participant demographics and the SF-36 were used to compare the groups. (68) A 75+ HA of both groups would have been the most complete way to ensure that both groups were comparable at the start of the study. However, it would have been ethically indefensible to assess the control group initially and not report problems to their GP's. The 75+ HA of participants in both groups 12 months after randomisation was used to measure if the health status of the intervention group was different from the health status of the control group.

At the first visit, the research nurse gained written informed consent for the study. This included consent to collect data at the end of the study, from the participant's health care records and contact a nominated carer to gain any missing data about health events which occurred during the year. After obtaining informed consent, the research nurse opened a sealed randomisation envelope to obtain the participant's study group. The research nurse then completed a SF-36 quality of life questionnaire by interviewing the participant. The control group was then left to 'usual care' and no further questions were asked. For the intervention group, the nurse completed the 75+ HA and this was reported to their "own GP'. This approach allowed for recruitment of a usual care control group and avoided the ethical dilemma of identifying problems but taking no action.

Twelve months after the first visit a SF-36 and a 75+ HA was carried out on participants in both groups. Research nurses, who had been trained in the administration of the established instrument, conducted all assessments. The research nurse who conducted the second visits

was, as far as possible, blinded to the study group to which the participant had been randomised. After the second visit, the nurse collected health data from the records of GPs to complete missing data for the previous 12 months. (Appendix 19 Flow chart)

At the completion of the two annual visits (twelve months after randomisation), data were available:

For both groups on the:

Acceptability of the 75+ HA to the participants and their health care providers

Quality of life (SF-36) at two points 12 months apart for comparison of the effect of the intervention.

Number and nature of problems, grouped as specified in the 75+ HA

For the intervention group only analysis of problems as:

Resolved problems that were present at the 1st but were not present at the 2nd 75+ HA.

Persisting problems that were present at the 1st 75+ HA and still present at the 2nd 75+ HA. These could be further subdivided into:

Resolvable problems, that potentially could be resolved.

Un-resolvable problems that clinically could not be expected to resolve. (E.g. emphysema)

New problems that have arisen since the 1st 75+ HA

4.2 Sampling frame

The RCT of 75+ HA was based in the northwestern suburbs of Adelaide, within the Adelaide Western Division of General Practice (AWDGP). The Division's eastern boundary, Prospect

road, runs north form the central business district of Adelaide to the Port River. In the opposite direction, the Division's boundary is the Anzac Highway that runs southwest, until it reaches the coast at Glenelg. The western boundary is the coast. (Appendix 20 Map of AWDGP)

This Division was chosen because:

It had been active since early in the general practice reform process,

AWDGP's projects have been well managed and consequently they have a well-established infrastructure. This infrastructure was useful in recruiting practices to be involved in patient randomisation.

It is representative of urban Australia. Demographically the AWDGP covers old established suburbs where there is a high proportion of elderly people (e.g. Woodville) and the more affluent beachside suburb (e.g. North Haven). (4)

4.3 Restrictions /limiting conditions

An age limit for the study was set at aged 75 years or over on the day of commencement of recruitment. (1st August 1998) This meant inclusion of people born on or before 1st August 1923. The age at which functional assessment in the independent living elderly become more significant than bio-medical illness alone, is supported by the literature reviewed.

The YHAEPS pilot study demonstrated good acceptance by the 75 years and over population of this intervention. (See Chapter 3, Pilot Study) In YHAEPS 92.5% of the elderly people approached accepted the offer of a home functional assessment.

4.4 Location of the GP practices

A convenience sample of practices was chosen. A random sample of patients was chosen from each practice, sampling every 20th patient on the 75 years and over age-sex register. The AWDGP provided a list of practices that had been active in the division program. They were thought to be amenable to a request for research to be carried out on patients from their practice lists. The AWDGP list was used as a source of the first two practices approached who both agreed to be involved. A broader range of practices was needed within the AWDGP. Practices in geographically separate parts of the division were sought (northwestern corner and southern corner) from the telephone book.

The principle researcher approached a doctor at each practice. The RCT 75+ HA was explained and an expression of interest was sought. If a desire to be included was expressed then a meeting was arranged. Suggested meeting times were to coincide with the next regular practice meeting if possible. The principal researcher offered to attend each practice to explain the study. Four of 6 practices that agreed to the study were content for this face-to-face visit to be with the research nurse. On the other 2 occasions the principal researcher attended. Once the study had been explained and the GPs were agreeable to being involved, an age-sex register was created from their practice records. This was achieved in all practices despite considerable variation in the time and effort required.

Three practices were approached by phone but declined to be involved in the RCT of 75+ HA. Reasons given included:

A perception that there were not many elderly patients in the practice

Not enough office space for the research nurse to search patient records for creation of an age-sex register

Inability to achieve consensus among all the GPs whether they should be involved

No interest, among the GPs, in this type of research

Analysis of the 6 practices from whom patients were recruited revealed a broad range of practice type and style. They will all be described individually to illustrate these differences.

4.4.1 Practice One

(One computer system)

This practice had been in existence for many years. It was located in an inner city suburb with a stable population. It was conducted in a surgery building attached to the back of the elder GP's residence. The elder GP was near to retirement and the younger GP had been part of the practice for many years. She performed the bulk of the consultations. This practice was situated on one site only. Patient accounts were computerised but no prescription or medical records were generated electronically. The commercial accounting system was 'Medical Spectrum'. Creation of an age-sex register was accomplished by one of the practice staff within 10 minutes, without any outside advice.

4.4.2 Practice Two

(Two-computer systems)

This practice was in a beachside suburb but close to the industrial part of Adelaide. The practice building was in a shop front in a small suburban shopping centre on a main road. It was well established and one of the GPs was chairman of the AWDGP. Two GPs worked full time in this practice. Medical accounts were handled by a computer system in the reception area. The two consulting rooms were equipped with a different computer system for prescriptions and recall functions. The two-computer systems were in no way linked and the patient list on each system was separate. The reception computer system was used to produce an age-sex register. This was achieved within 15 minutes with the help of the 1800 freecall advice from the software supplier.

4.4.3 Practice Three

(Manilla cards in envelopes)

This long-established practice was near a major public hospital and close to the intersection of two main roads. It is in an older stable part of the AWDGP. The two remaining GPs have been in practice here for many years. They had outlasted their more senior partners who had retired. They remain unable to attract young GPs to join the practice. The practice records were on manilla cards with each patient's cards and correspondence stored in a manilla envelope. The patient's date of birth was recorded on the top right hand corner of the front card within each envelope. There was no computer within the practice. The creation of an age-sex register necessitated the research nurse manually searching through all the envelopes filed as active. This process required three working days to complete. The two GPs retired

during 1999 and a younger GP took over the practice. Their patients sought ongoing care from a variety of different GPs.

4.4.4 Practice Four

(Card index)

This practice was in a beachside suburb. Three GPs worked full time, two being partners and the third an employee. They worked from one site in a renovated house on a main road. There were no computers in the practice. A card index of patient's details was used to produce an age-sex register. Manual searching of the card index, checking the birth date on each card, produced an age-sex register.

4.4.5 Practice Five

(Unique computer system)

This practice was also in the older established part of the AWDGP. Two full time GPs worked at one practice address. Practice accounts were the only function computerised and the son of one of the GPs had written the software. The practice regularly referred patients to one local pathology provider. The pathology provider had given them an electronic list of all patients they had referred for pathology. This list had been used as the basis of their patient registration. It was constantly being updated with new patients and changed patient details. They had not previously produced an age-sex register but were able to with some additional programming by the system designer.

4.4.6 Practice Six

(Computerised multi-site practice)

This group practice was the largest used in this study. It employed 8 full time GPs and operated from 3 different sites. The main practice had computerised patient registration data for all sites. This software produced an age-sex register and also indicated whether patients were archived, casual or inactive /deceased. Patient records were kept in RACGP style A4 size manilla folders.

4.5 Sampling technique.

4.5.1 Sample size calculation.

The pilot study found that 67% (25 of 37) elderly people assessed had at least one or more major, previously unknown, but potentially resolvable, health problem. (117). It was assumed that in the control (usual care) group, a similar number and nature of problems would be found at their only 75+ HA at the end of the study period. In the intervention group, it was expected that problems identified at the first assessment would have been resolved before the second assessment, but some new problems would have arisen in the 12 months interval. In this group, the minimum clinically important outcome would be the reduction in number of elderly people with problems by 50%, i.e. only 33% of the group will be found to have one or more potentially resolvable health problems at the second assessment. The sample size necessary to detect this difference if it existed, at an alpha level of 0.05 and a beta of 0.1, was 40 subjects per group. (121). To achieve this number of completions at the 12 months point, assuming a loss rate of 20%, 50 subjects per group were needed.

4.5.2 Patient lists.

An age-sex register was obtained from each practice as described above. This was assumed to be a 'raw' list with a significant number of errors. An attempt was made to 'clean' the list before a sample was drawn. The practice reception staff was asked to help trim the list of obvious errors. The research nurse supervised this process.

The staff, including GPs, had a natural tendency to introduce bias into the sample. They volunteered comments about patients such as "I hope you don't have to visit him!" or "She would be a good one for your study!" and "There is no way he will agree to participate." All these type of comments were disregarded in the compilation of the 'clean' age-sex register with a gentle reminder that research protocol required an unbiased list and a reassurance that only a sample would be invited to join the study. Acceptable ways of reducing errors are listed in Table 4.1

Table 4.1 Process of cleaning age-sex register.

Errors in raw Age-sex registers	Actions taken
Duplications of individuals	All but one deleted
Deceased patients still listed	Deleted if known
Spelling errors and duplications due to spelling errors	Spelling checked from another source
Patients known to be admitted to institutions (Hostels, Nursing Homes etc.)	Not included in this study

The cleaned age-sex register was used to produce the sample required for this study. Every 20th name was selected starting from the first name on each practice's list. The protocol for

contacting patients was as described in 'Recruitment of individual participants'. (Section 4.7.1) An invitation to join the study was posted, printed on the letterhead used by the practice. Several days later the research nurse phoned and inquired if they were interested in being visited as part of the study. An appointment was made with patients agreeing to be involved at this stage. Every 20th patient who could not be contacted was replaced with the next patient on the practice list. This commonly occurred, as practice lists were inaccurate. Patients who declined to be involved were not replaced with the next on the list.

4.6 Materials

The content of the 75+ HA was as used during the pilot study with one additional module. A full description of the development of the assessment instrument occurred in the Chapter 3 'Pilot Study'. The Geriatric Depression Scale (GDS15) was added to assess significant mood alterations / depression in the participants. (42) (Appendix 21) The GDS15 has been validated as a depression screen in the elderly in a variety of situations. Its main shortcoming is its' inability to detect depression in the presence of mild to moderate dementia. (93) It has recently been validated for use in 'health checks' of patients aged 75 years and over in Great Britain. (94)

The functions assessed in order were:

Hearing

Vision

Physical condition

Compliance

Medication

Miscellaneous

Cognition (Folstein mini-mental state)

Activities of Daily Living (Barthel ADL Index)

Mood (GDS 15)

Mobility

Nutrition (Australian Nutrition Screening Initiative)

Social Contacts

Housing

The results of each assessment were entered into an MS Access database constructed and tested during the pilot study. Results were reported to the person's nominated GP at the conclusion of the visit.

No interval assessment was conducted between the annual visits to either group. Interval visits were not planned to be part of a future service delivery project. Although it would have been helpful to measure the rate of resolution of problems identified, it would not have been ethical to identify a persisting problem at an interval visit and disregard it. Every effort was made to determine the outcome in all subjects' twelve months after randomisation. This included contacting relatives and carers in the event of a death or institutionalization during the study period.

4.7 Procedures

4.7.1 Recruitment of individual participants

Recruitment of participants began once an individual practice had agreed to participate in the study. This meant that the research nurse was visiting patients of only one practice at any one time.

Initial contact with patients was in the form of a 'Letter of Invitation' (Appendix 22) printed on letterhead stationery of the individual practices. This letter was signed by the research nurse but had clearly come with the consent of the GPs in the practice. Letters of invitation were followed with a phone call to ascertain if the person was interested in participating in the study.

If they declined to participate in the study, a reason was sought and no further contact was made.

If the research nurse received a positive response by phone, then an appointment for a visit was arranged. Usually this followed within a few days. Occasionally it was postponed until after a holiday, a funeral or until a date when it was convenient for a family member to be in attendance. Participants were encouraged to have a member of their family or a close friend present during the visit.

If at the initial visit, despite agreeing to the visit, they declined to be involved, they were not enrolled in the study. A reason was sought and they took no further part in the study.

If they could not be contacted (moved or incorrect address), were deceased (but still

on their practice register) or were not aged 75 years or over (incorrect birthday on practice records) they took no further part in the study. The next name on the practice list was sought and offered the enrolment process.

The protocol was followed until every 20th, or subsequent, patient was contacted on each practice list. This sampling method was adhered to until 100 patients had consented to join the study.

4.7.2 Consent

Each visit began with a verbal explanation of the study and a written 'Information Sheet'. (Appendix 23) If the patient consented to involvement in the study they were asked to sign a 'Consent Form' (Appendix 24). A signed copy of the Consent Form and the Information Sheet was left for each participant. A signed Consent Form was retained for each participant.

4.7.3 Ethics

Ethical approval was obtained from the University of Adelaide Committee on the Ethics of Human Experimentation. (H/41/97) This is an Ethics Committee convened in accordance with the National Health Medical Research Council guidelines. Ethical approval was maintained throughout the study by the provision of annual reports to the committee.

4.7.4 Randomisation

The study protocol required randomisation of 100 people. This was achieved using random numbers and adhering to basic statistical principles. (122) To ensure that equal numbers were

in the control and intervention group if the trial was aborted early, it was decided to use block randomisation to create 5 groups of 20. Each group had 10 participants randomised to each of control and intervention.

Random number tables were used. (122) Two-digit numbers were sought (00-99). The first group of 20 was sought from line 110 of the table. The first 10 two-digit numbers between 00 and 19 become the controls in the first group of 20. This process was repeated for subsequent groups, starting at line 120 for the second group of 20 (the first 10 numbers between 20 and 39 became the next 10 controls.) For each group, the first 10 numbers found became the control group. Thus, 100 numbers were randomised into control or intervention with each group of 20 having an equal number of control and intervention randomizations.

The allocation sequence was generated by the author alone. Instructions were placed in sequentially numbered, sealed envelopes to complete a SF-36 only for the control group or the 75+ HA and SF36 for the intervention group. The research nurse conducting interviews was blind to randomisation until consent had been obtained at the home visit. She then opened the next sequentially numbered envelope and proceeded to the control or intervention protocol.

4.7.5 Short Form 36

The SF-36 is a measure of quality of life. It has been extensively validated internationally (68, 123) and in Australia. (69, 124) Population studies have established normal values and standard deviations in a South Australian population. (125) These data, specifically for the 75 years and over population sample, were used for comparison with the sample in this RCT.

Specifically the SF-36 has been evaluated in a sample of elderly people living in the community. (126) Hill's sample of the elderly was accessing community services for either of two specific problems (mental health or incontinence). For these specific conditions, it was found not to be a good discriminator of change when compared with a structured interview. This is attributed to the presence of other co-morbidities in the elderly and to the SF-36's lack of detail. Hill concludes that the SF-36 "masks rather than illuminates patients views of outcome." For this reason, the SF-36 results were not expected to show positive change in the intervention group as a consequence of the intervention.

Hill however sees it as useful for assessing population health status, particularly for summarising change in relatively large and homogenous groups. In this RCT it was used to compare the control and intervention group and to ensure that randomisation had produced comparable groups. Thus we compared the two groups at enrolment (Control 1998 and Intervention 1998), the change within each group over the course of 12 months (to look for confounders) and the two groups at their 2nd visit. (Intervention 1999 and Control 1999)

If the 75+ HA had been performed on the control group at the initial visit that would have been a more precise comparison of the two groups. It would however have been ethically unacceptable to find problems in the control group and not notify their GP about problems apparent. Use of the SF-36 in both groups, at both visits, allowed a measure of their health status without pre-empting any of the questions / components assessed in the 75+ HA. This enabled the testing of the Intervention (75+ HA, notified to own GP) in a RCT whose control and intervention group's comparability was measured by the SF-36. Thus, use of the SF-36 allowed comparison of control and intervention group without contamination.

4.7.6 Report to nominated GP

A report was written for each participant's GP after each 75+ HA. This was after each visit to a participant randomised to intervention in the first year and to both intervention and control group in the second year. A de-identified sample letter is Appendix 16. This report was generated from the Access database and included:

- Patient demographics,
- Scores for

  Folstein mini-mental,

  Barthel ADL

  ANSI,
- List of prescribed medication
- List of "over the counter" medication.

To this report was added manually individual problems that had been identified by the 75+ HA. These problems were listed, counted for each participant and separately recorded as the "number of problems" found by the assessment. This report was generated after the visit and mailed or delivered to the GP.

The reporting of what constituted a 'problem' was based on the clinical experience of the principal investigator. This enabled consistency to be achieved by one GP reporting all the assessments. In the first year of visits, the investigator was not blind to randomisation of each participant because only the 'intervention' group was receiving 75+ HA. In the second year of visits, the investigator remained blind to randomisation until after the reporting of each assessment.

4.7.7 Second visit

The second visit for all participants enrolled in the study occurred 12 months after their first visit. Both Control and Intervention groups were offered a 75+ HA. A different research nurse was employed to conduct the second visits. This strategy was employed to enable the research nurse to be blind to randomisation. In as many instances as possible she remained blind to the group to which participants had been randomised. It was accepted that some participants would comment about the second visit and inadvertently reveal the group to which they had been randomised. She was asked to ignore comments such as "You didn't ask that last year" and "This is taking longer than last year". She was trained to administer the 75+ HA in the identical manner to the first research nurse. To ensure consistency in the assessment, training was provided by the principal investigator, who had trained the first research nurse.

Prior to the second visit, participants were contacted by mail. (Appendix 25 'Second Visit Letter') They were offered a second visit as previously promised. Included in the letter was another copy of the original 'Information Sheet'. Several days later they were phoned by the research nurse to arrange an appointment for the second visit. The participants were again encouraged to have a friend or family member present during the 75+ HA.

Consent for two annual visits had been obtained in the original Consent Form. The second visit began by a verbal review of this consent and repeating information about the study to ensure that the participants were fully informed and consenting to their continuing involvement. A SF 36 was administered prior to the 75+ HA as previously.

A letter was sent to all the GPs who had patients in the study prior to the participant's second visit. (Appendix 26, 'GP letter/2nd visit') This included all GPs whose practices had agreed to involvement in the study and other GPs who had been nominated as a participant's "usual doctor" at the first visit. This letter reminded GPs about the nature of the study and that they would soon be receiving a report of a 75+ HA on one or more of their patients. This letter did not remind them about which of their patients had been visited 12 months previous. It was mailed at the time when the first of their practice's participant's second visit was being arranged. This letter did not specifically remind GPs about problems that had been reported in these patients. The study had been designed to not include any interval reminders to GPs of problems revealed.

In several instances, participants had changed GPs during the course of the year. If the new GP had not been involved in the study previously, a letter was sent explaining the nature of the study (Appendix 27, 'Letter to new GP') and a copy of the 'Information Sheet' for the patients.

The GPs had received an assessment report on all patients visited who had been randomised to the Intervention group. They had not been notified of patients who consented to participate but had been randomised to the Control group. This design was employed so the study could examine the effect of the simplest intervention possible (i.e. 75+ HA and report to GP). It neither compromised the study ethically nor diluted the effect of the intervention.

Second visits were planned to occur in the same month of the year as the first visit 12 months previous. Visits recommenced in the first week of August 1999 and were completed by the

first week of February 2000.

4.8 Data management

4.8.1 Access database

The development of the Access relational database was described in Chapter 3, Pilot Study.

4.8.2 Microsoft Excel

MS Excel spreadsheet was used for cleaning, tabulating, summing and averaging data. Data were either entered manually or exported from the Access tables.

4.8.3 Outcome measures

Primary outcome measures were:

- Number of problems in each group,
- Number of participants with problems (%) and
- Mortality.

Secondary outcome measures were:

- Physical function (self-rated health and Barthel ADL scores),
- Psychological function (Folstein MMS and GDS 15 scores),
- Falls (number of participants reporting falls) and
- Number of participants admitted to a long-term institution.

4.9 Statistical treatment

4.9.1 Epi Info 6, SPSS and SAS

Quantitative data analysis required use of Epi Info 6 (127) Statistical Package for Social Scientists (SPSS) and Statistical Analysis Systems (SAS). Data obtained from the 75+ HA was in the form of dichotomous variables, means and continuous variables.

Dichotomous variables analysed to compare control and intervention groups were:

- Number of deaths
- Number of participants living in an institution (At enrolment all participants were living independently, numbers admitted to an institutions was used to compare the change occurring within control and intervention group)
- Self-rated health ('Very good' and 'good' compared to 'fair', 'poor' or 'bad'. This is a continuous variable but reports of 'very good' or 'good' have been strongly associated decreased mortality (56, 128), hence this was analysed as a dichotomous variable
- Self-reported falls (number of participants reporting falls compared to those not reporting falls)
- Folstein MMS scores were analysed as a dichotomous variable. Clinical interpretation of these scores had been based on the work of Iliffe who categorised scores as 'normal', needs investigation' and 'dementia'. (89) Because of the small numbers, analysis was based on 'normal' versus 'needs investigation' and 'dementia' combined.

Chi squared test and P values were used to compare dichotomous variables and necessitated the use of Fishers exact test if the variables were <5. P values and odds ratios were used to measure the significance of the difference between control and intervention group.

Means were calculated for:

- numbers of problems per participant
- numbers of drugs per participant

Means were compared using a t-test and reported as P values and 95% confidence intervals.

The non-parametric Wilcoxon rank sum test was used to compare continuous variables between control and intervention groups. These scores were not normally distributed (e.g. Folstein MMS and Barthel ADL scores mostly at high end of scale, GDS 15 scores mostly at the low end) hence the need to use non-parametric tests

Comparison of change in the intervention group's dichotomous variables required use of McNemars test. This facilitated comparison of the paired data of 1st and 2nd 75+ HA and was reported as P values.

4.9.2 SF-36 software

Raw data from SF-36 requires considerable manipulation for interpretation. Data were entered into an Excel spreadsheet and checked for accuracy. Analysis was performed in accordance with the SF-36 instructions (68, 123) in SAS.

The sequence of functions performed in analysis is:

Raw ('untransformed') data entry

Range checking of data

Dealing with missing data according to SF-36 documentation.

Transformation of data (reverses or re-calibrates individual scores)

Calculation of scores

A selection of scores was also checked manually. Specifically, range checking and treatment of missing scores was recalculated manually. No discrepancies were found with the scores calculated by SAS program.

The 10 scales produced are:

Physical function

Role physical

Bodily pain

General health

Vitality

Social functioning

Role emotional

Mental health

Summary physical health

Summary mental health

For each scale, statistics are produced for mean, standard deviation and range.

Chapter Five Results of the RCT of 75+ HA

5.1 Definitions

Recruitment of practices and participants began on the 1st August 1998. An age-sex register was created in the first practice. Sampling of potential participants and mailing of 'Letter of Invitation' began as described in the methodology. Subsequent practices were recruited progressively in time to provide a continuous workload of 75+ HA. All the first round visits were completed between 1st August 1998 and 15th February1999 (referred to as **1998 visits**). The control group consented and had a SF-36 recorded. The Intervention group consented, had a SF-36, a 75+ HA and a report delivered to their nominated 'own doctor'.

The second annual visits began on 1st August 1999 and were completed by 3rd February 2000 (referred to as the **1999 visits**). Both control and intervention group had a SF-36 and a 75+ HA in the second round. All 100 participants enrolled were successfully traced. Data were compared and contrasted between:

Control and intervention group

Intervention group 1998 visit and 1999 visit

5.2 Recruitment

5.2.1 Participants

Recruitment of every 20th (or subsequent) patient on the practice age-sex registers continued until 100 patients had consented to enter the study. This coincided with completion of sampling in the 6th practice.

The numbers of patients sampled, contacted and consenting / declining were as follows:

- 200 patients were sent letters and subsequent attempts were made to contact them by phone.
- 36 no trace could be found. These represent practice records that were out of date (n=34) and people who had very recently moved away from the study area. (n=2)

This meant that the research team made contact with 164 patients from the practices who were assessed for eligibility to enter the RCT. The numbers recruited are contained in the Flow Diagram, figure 5.1. Of these 164:

- 45 patients who were contacted declined to enter the study

  44 of these declined when phoned by the nurse after the 'Letter of Invitation' had been posted to them

  1 declined to consent at the research nurse visit (change of mind)
- 4 aged less than 75, their date of birth was incorrect on the practice records
- 10 were deceased but inadvertently still on practice records
- 2 were suffering from dementia and unable to consent to the study
- 2 were in Nursing Homes and 1 was in an acute hospital bed thus ineligible

Ineligible patients were replaced with the subsequent name in the age-sex register. Patients who declined were not replaced in the sampling.

- 100 patients consented to enter the study and were randomised to control (n=50) or intervention (n=50).

5.2.2 Participants by practices

Table 5.1 details the number of patients sampled from each practice. The numbers recruited from each practice varied between practices. This was dependent on size of a practice's age-

sex register, on how accurately it contained active patients of the practice and on the number consenting from each practice.

Column 2 contains the number of potential participants posted and invitation from each practice. Column 3 contains a code number for each individual GP, the first digit being the practice number (column 1). Column 4 contains the number of patients consenting per GP and per practice (column 5). Column 6 contains the number of patients declining and column 7 the number un-contactable per practice.

Able to contact patients on practice list:

The number of patients unable to be contacted varied between practices and is a measure of how well organised the age-sex register was in the practice. Practice 4 had a large list, from which 51 names were sampled. However 34 of these could not be contacted and were clearly no longer regular patients of the practice. Practice 3 had no patients in the sample who could not be contacted.

Figure 5.1

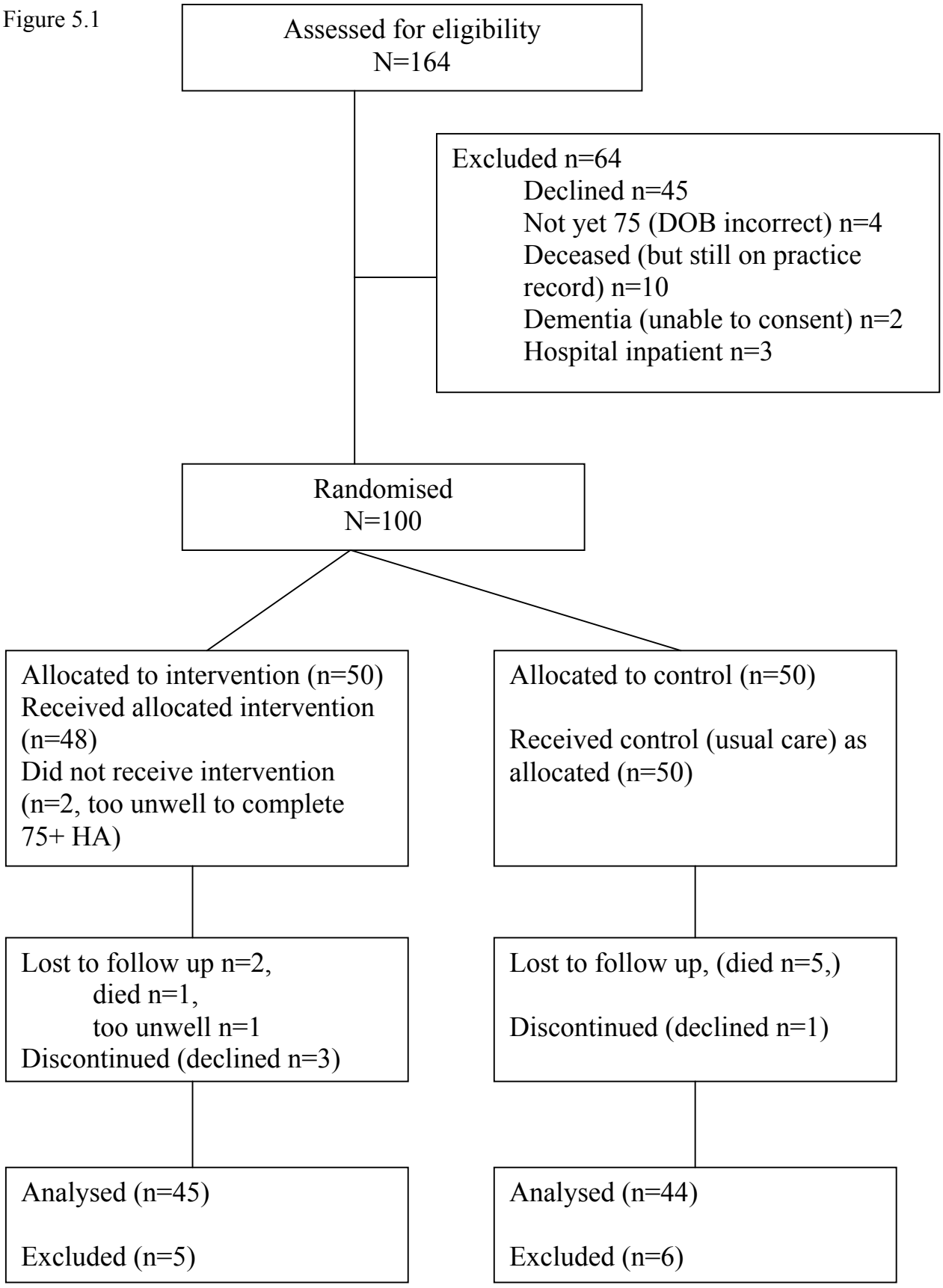
Assessed for eligibility
N=164
Excluded n=64
Declined n=45
Not yet 75 (DOB incorrect) n=4
Deceased (but still on practice record) n=10
Dementia (unable to consent) n=2
Hospital inpatient n=3
Randomised
N=100
Allocated to intervention (n=50)
Received allocated intervention (n=48)
Did not receive intervention (n=2, too unwell to complete 75+ HA)
Allocated to control (n=50)
Received control (usual care) as allocated (n=50)
Lost to follow up n=2,
died n=1,
too unwell n=1
Discontinued (declined n=3)
Lost to follow up, (died n=5,)
Discontinued (declined n=1)
Analysed (n=45)
Excluded (n=5)
Analysed (n=44)
Excluded (n=6)

Table 5.1 Numbers of participants recruited, declining or un-contactable by GP and by practice

Practices	Patients posted an invitation	Individual GPs (code numbers)	Patients consenting per GP (n of controls)	Patients consenting per practice	Patients declining per practice	Unable to contact, deceased or admitted.
One	27	101	12 (6)			
		102	5 (1)			
		103	1 (0)			
				18	6	3
Two	13	201	7 (4)			
		202	5 (3)			
				12	0	1
Three	23	301	10 (7)			
		302	1 (0)			
		303	2 (1)			
				13	10	0
Four	51	401	1 (1)			
		402	2 (0)			
		403	1 (1)			
		404	1 (0)			
		405	1 (0)			
		406	1 (1)			
		407	1 (1)			
		408	1 (0)			
		101	1 (1)			
				10	7	34
Five	57	501	17 (11)			
		502	10 (2)			
		503	1 (0)			
				28	18	11
Six	29	601	3 (2)			
		602	3 (1)			
		603	3 (2)			
		604	3 (2)			
		605	2 (0)			
		606	1 (0)			
		607	1 (1)			
		608	1 (1)			
		609	1 (0)			
		610	1 (1)			
				19	4	6
Total	200		100 (50)	100	45	55
Percentage of total						27.5%
Percentage of patients contacted				69%	31%	

Patients declining to enter study:

Of the patients contacted, a variable proportion agreed to enter the study. Practices 3 and 5 had the highest proportion of contacted patients declining to enter the study. Practice 2 had the highest proportion (100%) accepting the offer to join the study.

Individual doctors:

Once a patient had consented to enter the study, they were asked who was their usual GP. The patients recruited from practice 4 listed 9 GPs and from practice 6 listed 10 GPs as their regular provider. Several of these GPs were not working in the practice from which their patient's name had been sampled. These GPs were provided with a separate explanation of the RCT, as they had not been part of the initial practice recruitment phase. One patient from practice 4 claimed a GP from practice 1 as their regular GP. Conversely practices 1, 2, 3 and 5 had only zero or one patients sampled who did not claim one of the practice GPs as their 'own doctor'.

5.2.3 Refusals of Recruitment

Reasons for negative responses were recorded. There was not a lot of detail in the refusals, merely a statement that they did not wish to be involved.

5.3 Demographics

Table 5.2 shows the age-sex distribution of the all the participants enrolled and the Control and Intervention group individually.

Table 5.2 Age-Sex ratio of whole sample, control and intervention group.

	Whole sample	Control group	Intervention group
Male (%)	37 (37)	17 (34)	20 (40)
Female (%)	63 (63)	33 (66)	30 (60)
Sex ratio (male:female)	1:1.70	1:1.94	1:1.50
Age range in years, (at enrolment)	75-91	75-91	75-86
Mean	79.86	80.76	78.96
SD		3.76	3.49

5.4 Participant tracing for 2nd visit

Randomisation produced two groups containing 50 participants.

Despite consenting, 2 intervention participants were unable to complete 75+ HA in1998. One was physically unwell and the other extremely anxious. Both agreed to have a nurse visit and were agreeable to enter the RCT when it was explained. They each signed the consent form, completed the SF-36 but were unable to continue with the 75+ HA. They were both retained in the RCT, as it would invalidate the sample to not include them once they had consented to participate.

All 100 participants enrolled were successfully traced prior to a 2nd visit. Table 5.3

summarizes data on group size completeness of 75+ HA and participant tracing.

Table 5.3 Participant tracing for 2nd visit (1999).

	Control group	Intervention Group	Odds ratio (95% CI)	P
Enrolled in 1998	50	50		
Completed 75+ HA 1998		48		
2nd Visit 1999				
Deceased	5	1	0.18 (0.0 to 1.76)	0.20*
Declined second visit (alive)	1	3	0.37 (0.01 to 4.25)	0.62*
Incomplete assessment / unwell	1	1		
Completed 75+ HA in 1999	43	45		
Total of 1999	50	50		

(* Fishers exact two tailed)

One of the primary outcome measures chosen was mortality. Six participants had died and the cause of their death was obtained from their relatives and their GPs. Five of these deaths were in the control group and one in the intervention group. This difference is not statistically significant; Odds ratio (95% CI) 0.18 (0.0 to 1.76) p= 0.20, Fisher exact two tailed).

None of the participants who died had had a 75+ HA in 1998. The patients in the control group had not completed a 75+ HA so no detail is known about the state of their health or the existence of these conditions at enrolment. The one patient in the intervention group who died had not completed a 75+ HA. He had consented to enter the study and completed a SF-36. He was unwell and could not continue to complete the 75+ HA. The research nurse tried on another occasion but could not complete a 75+ HA. He was included in the study because he

had consented to enrol, but no 75+ HA data were obtained. (See table 5.4)

Table 5.4 Cause of death in both groups.

Cause of death in the control group were		Age
1	Breast cancer	80
2	Myocardial infarct / sudden death	88
3	Cardiac failure & liver failure	84
4	Cerebro-vascular accident (CVA)	88
5	Post operative complications of knee replacement	91
Cause of death in the intervention group was		
6	Gastrointestinal bleed in hospital	76

These deaths were unlikely to have been prevented by a 75+ HA. Modification of risk factors may have delayed death but this sample size is unlikely to demonstrate this effect. Individually analysed the natural history of these conditions would have been:

1. Breast cancer. Slowly developing over many years.

2, 3 & 4 Atherosclerotic vascular disease. These elderly people were aged 88, 84 and 88 years. Risk factors and co-morbidity would have contributed to their fatal disease over a long period of time. Treatment of risk factors in established disease is unlikely to have a profound effect at this age.

5 & 6 Complications of knee replacement (5) and deterioration during a medical admission to hospital (6) are deaths occurring despite medical intervention being readily available and are attributed to frailty in this aged population.

Four participants declined to have a 2nd visit. No 75+ HA data were obtained for these 4 other than a brief description of why they declined. All 4 declined because they felt they didn't need another visit.

For two participants it was impossible to complete a 75+ HA at their second visit (1999).

- One had had a CVA (intervention) and
- One had developed dementia (control)

Some components of the assessment were completed with the help of carers (e.g. medication) and where data were available, they were included. None of the participants revealed to the research nurse their randomisation to control or intervention protocol.

The denominator for comparison of data in each group is contained in table 5.5.

Table 5.5 Denominator in each group and year.

Group	Number
Intervention 1998	48
Control 1999	44 (43 some components)
Intervention 1999	45
Intervention group, paired data (1998 & 1999)	44

The sample size calculation in the research plan assumed a loss rate of 20% (i.e. 40 completed second assessments in each group). The loss rate has been less than assumed and did not compromise the sample size calculated to detect significant effects.

5.5 Problems reported to the GP

The data arising from the reports to the GPs at the conclusion of the 75+ HA are presented in table 5.7. These are raw data, as reported by the research team to the GP, while still blind to each individual's randomisation. Inconsistencies exist in this data from 1998 to 1999. As

previously described the research team had difficulty reducing the complexity of the life of the elderly to quantitative data. The 75+ HA is necessarily subjective, as is the whole of the craft of general practice. Further analysis of these data will be presented in this chapter. Firstly this will be by individual category (See 5.6 Results by individual category), and secondly by tracking of each reported problem in the intervention group from the 1st to the 2nd 75+ HA. (See 5.39 Problem resolution in Intervention group) No statistical analyses of these raw data have been attempted for this reason.

Table 5.6 details the number of problems in each group at each 75+ HA. These are the problems reported to the GP as a result of the 75+ HA. As such, they represent the clinical assessment of the individual by the research team at the time of the visit.

Table 5.6 Number of problems reported to the GP.

	Intervention 1998	Intervention 1999	Control 1999
Hearing	12	11	9
Vision	8	5	7
Physical condition	6	12	9
Compliance	3	4	1
Medication	2	7	6
Miscellaneous	46	36	35
Cognition	18	5	16
Depression	10	12	13
Activities Daily living	4	6	6
Mobility	23	10	15
Nutrition (ANSI)	20	18	21
Social	3	0	2
Housing	20	11	7
Total Number of problems	175	137	147
Number with no problems	5	1	5

5.6 Results by individual category

5.6.1 Hearing

The frequency of subjective report of hearing ability is listed in table 5.7. No participants described themselves as deaf.

Table 5.7 Hearing self report

	Intervention group 1998	Intervention group 1999	Control group 1999
Deaf	0	0	0
Poor	6	3	5
Fair	19	22	16
Deaf/Poor/Fair (%)	25 (52)	25 (55)	21 (47)
Inadequate aid if hearing Deaf/Poor /Fair (%)	15 (60)	16 (64)	15 (71)
Good	20	19	19
Very good	3	1	4
Denominator	48	45	44

Similar numbers of people reported problems with hearing in each group and they represent nearly half the population in this age group. Across all groups, those with impaired hearing did not have effective hearing aids in 60-71% of cases. There was no significant difference between the groups in numbers with inadequate hearing aids. There was no decrease in this number in the intervention group 1999 despite reporting this to their GP one year previous.

5.6.2 Vision

Data on self-reported vision are contained in table 5.8 ‘Self reported vision’. In the intervention group there is a decrease in the numbers who reported impaired quality of vision in the second year. This decrease approached statistical significance. (p=0.06) The

participants in the control group reported impaired vision in similar numbers to the intervention group in second year. Table 5.39 'Resolution of problem and cause /agency' describes this observed visual improvement due to prescription of glasses (n=4) and cataract surgery (n=3) in the Intervention group. (See 'Problem resolution in Intervention group')

Table 5.8 Self-reported Vision by group and year.

	Intervention group 1998	Intervention group 1999	Control group 1999	Change in intervention group
Blind	0	0	1	
Poor	4	3	3	
Fair	20	11	14	
Total of blind, poor or fair	24	14	18	RR 1.45 (0.98 to 2.13) p= 0.06*
Good	18	28	24	
Very good	6	3	2	
Total	48	45	44	

* Mantel - Haenszel

Visual pathology was specifically inquired about by the research nurse and is listed in table 5.9. Glaucoma and cataracts / intra-ocular lenses (IOL) were the most frequently reported pathology. In 1999, fewer people reported that they had IOLs, presumably this was an error in the collection or recording of this data.

Table 5.9 Self reported visual pathology by group and year.

	Intervention group 1998	Intervention group 1999	Control group 1999
Diabetic retinopathy	0	0	0
Glaucoma	7	5	9
Cataract	16	8	8
Field defect	1	1	1
Macular degeneration & other retinal problems.	1	1	4
Other (incl. IOL)	7	1	2
Total	48	45	44

Self reported impaired vision was compared with other components within the 75+ HA, specifically retention of a 'driving license' and 'self reported falls.' These data are contained in table 5.10.

The group with impaired vision also continued to drive. Across the 3 groups 22-42% continued to drive. Most of these reported they had reduced their driving, only drove with their spouse's assistance or limited their driving to daylight hours only. The decrease in numbers driving with impaired vision in the intervention group is not significant (p=0.65)

The number of participants reporting falls is described across the 3 groups. Among the visually impaired 54-80% of falls were assessed as being at least in part due to impaired vision, mostly due to tripping on unseen hazards. (Table 5.11) No differences were discernible comparing the 3 groups.

Table 5.10 Blind /poor /fair vision, 'Still driving' & 'Falls' due vision impairment.

	Intervention group 1998	Intervention group 1999	Control group 1999
Blind /poor /fair	24	14	18
and still driving (%)	10 (42)	4 (28)	4 (22)
Falls	11	5	4
Vision contributed to cause of falls (% of All falls)	6 (54)	4 (80)	3 (75)
Total	48	45	44

5.6.3 Physical Condition

Self-rated health was analysed as a dichotomous variable by comparing the sum of "Very good" and "Good" answers with the sum of "Fair", "Poor" and "Bad" answers. Table 5.11 contains these data. Although the intervention group in 1999 had more participants rating their health as good or very good, this difference was not statistically significant. Odds Ratio 0.72 (95% CI, 0.28 to 1.87) p= 0.51.

Table 5.11 Self rated health.

	Intervention group 1998	Intervention group 1999	Control group 1999
Bad	0	2	0
Poor	4	0	1
Fair	20	13	17
	(24)	(15)	(18)
Good	20	25	25
Very good	4	5	1
	(24)	(30)	(26)
Total	48	45	44

Analysis of the paired data of intervention group was by McNemars test. This revealed a

significant improvement in the self-rated health at the 2nd 75+HA compared to the 1st 75+HA. (p= 0.033) This paired data is presented in table 5.12.

Table 5.12 Paired data of self-rated health, intervention group

	Fair, poor or bad at 2nd visit (1999)	Good or very good at 2nd visit (1999)	Total
Fair, poor or bad At 1st visit (1998)	11	11	22
Good or very good at 1st visit (1998)	3	19	22
Total	14	30	44

The conditions from which they were suffering were grouped by the International Classification of Primary Care (ICPC) chapter and are listed in table 5.13. The 4 commonest conditions (arthritis, hypertension, heart disease and non-insulin dependant diabetes mellitus (NIDDM)) were listed separately from the other conditions within their chapter. Asthma and emphysema were the only respiratory conditions reported. They were grouped together, as there is considerable imprecision in the use of these two diagnostic labels by this age group. The self-reported data collected did not allow a distinction to be made between these two conditions. Self-reported diseases varied in the intervention group from 1998 to 1999. This group reported more heart disease and diabetes in 1999 but less hypertension and respiratory disease. Tests of significance were not done on these data because of the subjective nature of self-reported disease. Eye and ear conditions were inquired about separately and are not recorded in this table. Urinary incontinence was specifically asked in the ADL questions and is not recorded here in Urological or Male /Female Genital chapters. The incidence of urinary incontinence is reported separately in ADL.

The common conditions were reported in similar numbers in the control and intervention group. These frequencies are comparable to other studies reporting the prevalence of disease in Australia. (72) Self reported length of time since last doctor's visit was recorded. All groups reported regular attendance, 2/3 (67-68%) within the last 4 weeks. Small numbers had not seen a doctor for 3 months and none for greater than 6 months. These data are presented in table 5.14.

Table 5.13. Self-reported diagnoses by ICPC Chapter

Chapter	Description	Intervention group 1998 n=48	Intervention group 1999 n=45	Control group 1999 n=44
A	General		2	3
B	Blood	1	1	1
D	Gastrointestinal		4	1
F	Eye			
H	Ear			
K	Circulation			
	Heart	10	15	11
	Hypertension	23	20	12
	Other			2
L	Musculo-skeletal			
	Arthritis	28	28	18
	Other			2
N	Neurological	1	4	2
P	Psychological		1	1
R	Respiratory	9	6	8
S	Skin		1	
T	Endocrine			
	NIDDM	1	4	4
	Other		2	1
U	Urological		1	1
W	Family planning			
X	Female genital			
Y	Male genital			
Z	Social problems			

Table 5.14. Time since last doctors visit.

Time in weeks (cumulative %)	Intervention group 1998	Intervention group 1999	Control group 1999
0-1	17 (35)	16 (36)	15 (34)
2-4	15 (67)	15 (68)	15 (68)
5-8	8 (87)	8 (87)	8 (86)
9-12	3 (90)	4 (96)	4 (95)
13-26	5 (100)	2 (100)	2 (100)
>26	0	0	0
	48	45	44

5.6.4 Compliance

Poor compliance with medication is a cause of significant morbidity in the elderly. (83) These compliance questions sought to determine if medication was being taken as prescribed by inquiring into likely problems and the use of available reminder packaging systems.

Questions included:

Pre-packaged system in use,

Supervision of medication by carer,

Need to be reminded about medication,

'Other medication' not prescribed (over-the-counter, natural remedies and laxatives) and

Allergies, intolerance or side effects of particular medication

Additionally lack of supervision of medication was compared with cognition (Folstein mini-mental state, reported elsewhere) on the assumption that impaired memory makes incorrect dosage likely in the absence of supervision.

Table 5.15. Medication / non prescribed medication and unsupervised / cognition impaired.

	Intervention group 1998	Intervention group 1999	Control group 1999
No regular medication	4	0	1
'Other medication'	12	29	24
Medication unsupervised (n with impaired cognition)			
Folstein MMS <19	1 (1)	0 (0)	1 (2)
Folstein MMS 19-24.	6 (9)	3 (5)	7 (8)
Folstein MMS 25+	41	42	36
Total	48 (10)	45 (5)	44 (10)

The majority of participants with impaired cognition do not have supervision of their medication. The intervention group had a smaller percentage of participants who had impaired cognition and were not supervised in taking their medication in the second year. It was not statistically significant compared with the intervention group 1998 (p=0.56 Fishers exact one tailed) or the control group (p=0.40).

Medication allergies and side effects have been reported together. Each group reported a similar range of adverse drug effects. The commonest problems were with

Penicillin

Other antibiotics

Aspirin and non-steroidal anti-inflammatory drugs (NSAIDs)

Codeine and narcotic analgesics

Problems with other drugs were reported in small numbers. Penicillin allergy is well known and its potential seriousness well known to the public.

Table 5.16. Allergies and other drug side effects.

	Intervention group 1998	Intervention group 1999	Control group 1999
Penicillin	10	7	4
Other antibiotics	3	3	1
Aspirin / NSAIDs	2	3	2
Codeine / narcotics	3	1	3
Thiazides	1	1	
Warfarin	1		
ACE inhibitors	1		
Anticonvulsants	1		
Statins		1	
Inhaled steroid		1	
Others	1	1	
Unknown*	1	1	2

* Participant reported an allergy but could not recall drug name.

5.6.5 Medication

The number of prescribed medications was counted for each participant. Polypharmacy in the elderly was reviewed in the Literature review Chapter 2. Both groups were similar in having large numbers of people on multiple medications. No reduction in drug numbers was recorded in the intervention group in the second year

Table 5.17 Number of medications per person, by group and year

Number of medications	Intervention group 1998	Intervention group 1999	Control group 1999
0	3	0	0
1	6	5	3
2	5	10	9
3	12	5	8
4	10	11	12
5	4	3	3
6	2	3	5
7	4	6	2
8	2	1	1
9		1	
Total drugs taken	168	176	160
Denominator	48	45	44
Range	0-8	0-9	0-8
Mean number of drugs / person	3.50	3.91	3.63

Means were compared by T test. The control group 1999 were no different from the intervention group 1999 (Difference in means 0.28, 95% CI –1.11 to 0.56, p= 0.51) nor were the intervention group 1998 different from the intervention group 1999 (difference in means 0.41, 95% CI –1.3, 0.45, p= 0.39)

Medications taken are presented in table 5.18, grouped by the ATC class and further grouped by type of medication.

Table 5.18 Number of medications in each class by group and year

	ATC class	Medication groups	Intervention 1998	Intervention 1999	Control 1999
A	Alimentary	H 2 antagonist	7	5	6
		Proton pump inhibitor	2	7	1
		Other e.g. IBS	5	3	3
		NIDDM	3	5	5
		Cations	4	4	5
B	Blood	warfarin	7	7	5
		Aspirin	19	21	18
		Fe, folate, B12	3	4	
C	Cardiovascular	Digoxin	3	3	3
		Nitrates	4	4	6
		amiodarone			2
		methyldopa	1	1	2
		prazosin		1	1
		ACE	15	11	4
		Diuretics, non-loop	9	9	6
		Loop diuretics	8	5	8
		Beta block	10	7	5
		Ca Channel Block	8	6	10
		A II	1	1	1
		Statins	7	7	1
		Fibrates		1	1
D	Dermatological	Steroid	1	1	
G	Gynaecological	Oestrogen	1	2	2
H	Hormone	Steroid	2	2	1
		Thyroxin	6	3	6
J	Antibiotics			2	1
L	Malignancy				2
M	Musculoskeletal	NSAID	7	6	4
		Osteoporosis		2	1
		quinine	2	2	1
		allopurinol			3
N	Neurological	Codeine + other	1	2	3
		Anticonvulsants	2	3	0
		benzodiazepines	14	12	14
		Other	1	1	2
	Antidepressants	Tricyclic	3	4	6
		SSRI			1
P					
R	Respiratory	Nasal allergy		2	3
		Bronchodilator	6	7	0
		Steroid	4	4	1
		Other inhaler	1	2	1
		Antihistamine	1		1
S	Eye drops	Glaucoma	4	4	6
		Dry eyes	1		3
		Allergy incl. steroids		1	4

Abbreviations in table 5.18

IBS	Irritable bowel syndrome
Cations	Calcium, magnesium, sodium
A II	Angiotensin II converting enzyme inhibitor
ACE	Angiotensin converting enzyme inhibitor
NIDDM	Non- Insulin Dependant Diabetes Mellitus
NSAID	Non-Steroidal Anti Inflammatory Drugs

5.6.6 Miscellaneous

Tetanus

Large numbers of participants self-reported that they were 'overdue' or 'did not know' if they were immunised against tetanus. Despite reporting this to their GP similar numbers of the intervention group reported 'overdue' or 'did not know' at the second annual 75+ HA. Tetanus remains infrequent in Australia but is commoner in the elderly and has a high case fatality rate. (31)

Current smokers

Seven participants were current smokers of the 93 on whom we have at least one set of data. The rate of smoking in this 75+ sample is 7.1%. All current smokers were female. The 4 in the intervention group who were smoking in 1998 were still smoking in 1999. There were 3 smokers in the control group in 1999. Number of cigarettes smoked averaged 9.7/day with a range of 4-20.

Past smokers

Large numbers of participants in each group reported having smoked in the past, indicating that more had ceased than had continued to smoke. The total numbers of current and past smokers was approximately half the sample. (42-50%)

Alcohol

Large numbers of both groups admitted to regular consumption of small amounts of alcohol. None of the control group admitted to being a heavy drinker in the past. In the intervention group, 5 participants admitted to past heavy alcohol consumption at each annual assessment. Interestingly it was not the same 5 participants on both occasions. Three participants admitted to past heavy alcohol consumption twice and an additional 2 said yes in 1998 and a different 2 said yes in 1999.

Table 5.19 Tetanus, Smoking and Alcohol by group and year

	Intervention group 1998	Intervention group 1999	Control group 1999	Total (%)
Tetanus overdue (self report)	21	19	23	41
Current smoker	4	4	3	7
Past smokers	20	20	16	36
Ever smoked, current + past. (%)	24 (50)	24 (50)	19 (43)	43 (46)
Current alcohol	16 (33)	31 (68)	26 (59)	57 (61)
Past heavy alcohol intake	5	5	0	8
Total	48	45	44	93

Sleep.

Subjective sleep problems were common in both groups. Initial insomnia was complained of by similar numbers in each group and was slightly more common in the intervention group in 1999. Waking too soon (during night or too early in morning) was similarly very common and no different between groups.

Nocturia was a common cause of sleep interruption and was analysed by sex in 1999 (n= 89 completed 75+ HAs in 1999) Nocturia as a cause of sleep disturbance was significantly more common in females than males. (9/35 males, 26/54 females, relative risk (95% CI) 0.53 (0.29 to 1.00), p=0.035 Mantel-Haenszel) A small number of participants in each group reported no sleep problems. (See table 5.20)

Table 5.20. Analysis of Sleep problems by group and by year

Sleep problems	Intervention group 1998	Intervention group 1999	Control group 1999	Both groups 1999
Initial insomnia	14	17	13	
Wakes too soon	36	21	26	
Initial &/or wakes too soon	40	29	29	
Nocturia				
male	15	3	6	9
female	25	14	12	26
total	40	17	18	
Worried by sleep problems	9	10	11	
No sleep problem	5	13	11	
Total	48	45	44	
Sex				
male	20	18	17	35
female	30	27	27	54

5.6.7 Cognition

The Folstein MMS proved simple to administer. The length of time it took was not a problem. Assessment of memory impairment in the elderly is a sensitive issue due to the implications of a failing memory. There was no apparent unease among the participants caused by the testing of this sensitive area. Participants did not fail to complete the Folstein MMS, nor did they fail to continue the 75+ HA at this point. Incomplete data from one 75+ HA only was due to severe physical impairment in one individual.

Data are not available for 5 participants in the intervention group in the 2nd year. These are one person in the 'demented' group who died, the 3 people who declined a 2nd interview and the one person who was too unwell to complete a 2nd 75+ HA. Analysis of the changes in the Intervention group reveals that 2 people moved from the 'needs assessment' score into the 'normal' score.

The control group assessed in the 2nd year was limited to the 44 participants who remained in the study.

Folstein MMS scores were analysed in bands (18 or less indicating cognitive impairment, 19-24 requiring further assessment and 25 or greater being normal). (90) See table 5.21. Because of the small numbers in the lower bands ('assessment indicated' and 'dementia') these two were grouped together and analysed versus the normal score group, creating a dichotomous variable.

Table 5.21 Folstein Mini-mental State scores by group and year.

Folstein MMS	Intervention group 1998	Intervention group 1999	Control group 1999	Interpretation
30	2	11	6	Normal
29	3	13	10	
28	6	13	8	
27	13	2	2	
26	7	1	6	
25	7	0	2	
Total 25-30 (%)	38 (79)	40 (89)	34 (77)	
24	2	2	5	Assessment indicated
23	4	3	2	
22	3		1	
21				
20	1			
19				
Total 19-24 (%)	10 (21)	5 (11)	8 (18)	
18 or less (%)	0	0	2 (5)	Dementia
Total	48	45	44	

The Control group shows a trend to lower scores than the intervention group in 1999. This was not statistically significant. See table 5.22.The relative improvement in the Folstein MMS scores in the intervention group (larger number in normal group in 1999) was not statistically significant.

Table 5.22 Significance of difference in Folstein scores.

Folstein MMS Scores	Intervention group 1999 (95% CI)
Control group 1999	OR 0.43 (0.1 to 1.54) p= 0.17
Intervention group 1998	p = 0.13*

* McNemars test

5.6.8 Activities of Daily Living

Barthel ADL scores in each group tended to be high. The Barthel ADL was designed for assessment of individuals in rehabilitation settings or long-term care particularly after stroke. (41) Table 5.23 contains the Barthel ADL scores of participants within each group.

Table 5.23. Barthel ADL scores (cumulative %) by group & year

Barthel ADL	Intervention group 1998 (%)	Intervention group 1999 (%)	Control group 1999 (%)
100	33 (68)	24 (53)	18 (40)
95	6 (81)	13 (82)	13 (70)
90	4 (90)	5 (93)	8 (88)
85	3 (96)	2 (97)	2 (93)
80	1 (98)	1 (100)	0 (93)
75 or less	1 (100)	0	3 (100)
Total less than 95	9	8	13
Total	48	45	44

There is no significant difference between the intervention and control groups in 1999 (p= 0.16 Wilcoxon rank sums)

Analysis of the impaired participants (<95) within the intervention group is difficult because of the small numbers (n=9). Of the 9 with scores <95 in 1998, 2 refused a second visit and of the remaining 7 with two sequential Barthel ADL scores;

2 improved their ADL score, one moving from 90 to 95 (not impaired)

3 remained on the same ADL score and

2 had lower ADL scores in 1999.

These results were analysed as a continuous variable using a *t-test* to compare means and revealed no significant difference between the intervention group 1998 and 1999; difference in means (95% CI), -0.8, (-9.4 to 7.8), p= 0.36.

Positive answers to the individual questions within the Barthel ADL were analysed for each group and are presented in table 5.24.

Table 5.24. Individual questions indicating impairment by year and group.

		Intervention group 1998	Intervention group 1999	Control group 1999	Total
1	Feed self	0	0	1	1
2	Transfer	0	0	1	1
3	Grooming	1	0	3	4
4	Toilet	0	0	1	1
5	Bathing	1	2	3	6
6	Walking	2	1	1	4
7	Stairs	10	8	15	33
8	Dressing	1	1	3	5
9	Continence bowels	3	2	3	8
10	Continence urine	9	13	17	39
	Total	48	45	44	

Analysis of the Barthel scores indicates that:

Barthel ADL scores were generally high in this population; in each group 70-82% of participants scored 95 or 100. One question accounted for most the scores reduced to 95. (Q10 occasional urinary incontinence.) Urinary incontinence is a significant problem but it is not a serious disability at this level of occasional incontinence (complete incontinence as only problem would score 90).

Almost all participants scoring <95 reported needing help /being unable to ascend /descend stairs. Thus, scores of 90 or less were taken to represent significant disability. All but one of the significantly disabled in 1998 remained so in 1999. This distinction will be discussed further in Chapter 6, Discussion.

The 4 severely disabled participants (scores <80, table 5.22) were responsible for most of the affirmative answers in question 1-6.

The Barthel ADL index discriminated several elderly people who were severely impaired and in need of (and receiving) considerable support to remain in their own home. It proved easy to apply despite having been originally designed to be a report by nursing staff on ability over the proceeding few days.

5.6.9 Mood / Depression

The GDS 15 has a measured sensitivity of 100% for scores of 3 or more as described in the literature review (Chapter 2). (94) The specificity of the GDS 15 score increases with increasing score. The number of participants clearly not depressed in the intervention group increased from 23 to 29. Other authors have recommended using 5 or more as an indicator of likely depression. (95) All groups had similar scores using this cutpoint. The GDS 15 scores for the groups are presented in table 5.25.

The intervention group 1999 has a cluster of 3 scores at 10. Analysis of these 3 individuals revealed the likely cause /consequence of their (presumed) depression as:

Loneliness, poor nutrition and impaired cognition

Severe emphysema and poor nutrition

Emphysema, poor nutrition and impaired physical function

Insufficient data were gathered to decide if these comorbidities were causing the presumed depression or a consequence of it. Clearly, a high GDS 15 score is associated with significant morbidity as expected.

Table 5.25. GDS 15 frequency of scores by group and year

	Intervention group 1998	Intervention group 1999	Control group 1999
0	9	12	2
1	9	10	14
2	5	7	8
Total <3	23	29	24
3	7	7	5
4	5	1	6
Total < 5	35	37	35
5	5	1	3
6	3	2	4
7	2	1	1
8	2	1	0
9	1	0	1
10	0	3	0
Total 3+	25	16	20
Total 5+	13	8	9
Total	48	45	44

The difference between the control and intervention group was tested by Wilcoxon rank sums for a non-parametric variable. The Intervention group scores (median 2, range 0-9) were lower than the control (median 2, range 0-10) in 1999 but not significantly so ($p = 0.10$). The intervention1998 scores (mean 2.0, SD 2.5) was compared with the intervention 1999 scores (mean 2.5, SD 2.8) Wilcoxon signed rank test, difference in means (95% CI), –0.5 (-3.95 to 2.95) $p = 0.50$. Although there was no significant difference between the control and intervention group, there was a significant improvement (lowering) in the GDS 15 scores of the intervention group from 1998 to 1999.

5.6.10 Mobility

'Mobility' data included:

Driving,

Walking,

Falls and ability to get up unaided and

Use of community services.

The number of participants still driving has been reported previously in relation to their vision. (Table 5.10) The prevalence of walking problems and use of walking aids was similar in all groups. These data are contained in table 5.26.

Table 5.26 Number of people reporting falls and number unable to get up by group and year

	Intervention group 1998	Intervention group 1999	Control group 1999
Walking problems	16	17	21
Uses stick or frame	13	19	17
Number reporting falls	22	12	17
Number unable to get up after fall	8	3	5
Total	48	45	44

More participants in the control group reported falls than in the intervention group 1999. This difference was not significant: Odds ratio (95% CI) 0.58 (0.21 to 1.55) p= 0.32. The intervention group demonstrated a significant improvement from 22 reporting falls in 1998 to 12 reporting falls in 1999. (McNemars test of paired data p = 0.033)

Services used were listed for each group. Podiatry services were the commonest used

followed by possession of a Taxi concession voucher (see table 5.27).

Table 5.27 Community services used by group and year.

	Intervention group 1998	Intervention group 1999	Control group 1999
District nurse	2	1	2
Meals on wheels	1	2	1
Home help	4	6	5
Podiatry	13	18	19
Day care centre	1	0	1
Taxi concession	12	12	10
Personal alarm	2	3	2

5.6.11 Nutrition (ANSI)

ANSI scores are usually rated as Low (0-3), Moderate (4-5) and High (6+) nutrition risk. As described in the literature review 'high risk' is equivalent to <75% of RDI for 3 nutrients or low self rated health. Differences between groups were analysed as a dichotomous variable comparing 'high risk' with total of either 'low' or 'moderate risk'. These data have been presented in that form in Table 5.29. The control and intervention 1999 groups were not significantly different, Odds ratio (95%CI) 1.33 (0.44 to 4.06) p=0.57. The difference between the Intervention group in 1998 and1999 indicated lower risk but was not significant; Relative risk (95% CI) 0.71 (0.48 to 1.04) p=0.098. The frequency of ANSI scores is tabulated in table 5.28

Table 5.28 ANSI scores by group and year.

	Intervention group 1998	Intervention group 1999	Control Group 1999	Risk category
0	5	5	6	Low risk (0-3)
1	0	1	0	
2	6	4	10	
3	9	15	7	
Total 0-3	20	25	23	
4	3	2	1	Moderate risk (4-5)
5	8	9	9	
Total 4-5	11	11	10	
6	1	1	4	High risk (6+)
7	4	2	2	
8	4	3	2	
9	3	1	2	
10	0	0	0	
11	2	0	1	
12	1	0	0	
13	1	1	0	
14	1	1	0	
Total 6+	17	9	11	
Total	48	45	44	

Table 5.29. Nutrition risk by group and year

	Intervention group 1998	Intervention group 1999	Control group 1999
Low (0-3) or Moderate (4-5) nutrition risk	31 (65)	36 (80)	33 (75)
High nutrition risk (6+)	17 (35)	9 (20)	11 (25)
Total	48	45	44

Analysis of individual question in ANSI

Data on 137 completions of the ANSI checklist by 93 elderly people were pooled.

(Completions: control group 44, Intervention group 44 completed twice, 5 completed once)

The answers to individual questions indicating nutritional risk were totalled.

Table 5.30 Number of answers indicating poor nutrition to each question

	Total indicating nutritional risk	% of 137 completions
Change in diet	11	8.0
Three meals	16	11.6
Fruit & vegetables	4	2.9
Dairy product	6	4.3
Daily alcohol	5	3.6
Fluid intake	21	15.3
Teeth / swallowing	10	7.2
Money	2	1.4
Eat alone	65	47.4
>3 medications	90	65.6
Weight change	12	8.7
Shop, cook & feed	6	4.3

Five questions produced poor nutrition answers 6 or less times in 137 completions (4.3-1.4%).

These questions were:

Do you eat dairy foods most days?

Are you always able to shop cook and/or feed yourself?

Do you have 3 or more glasses of beer, wine or spirits most days?

Do you eat fruit and vegetables most days?

Do you have enough money to buy food?

These 5 questions contributed very little to the nutrition screen in this population.

By comparison the 4 questions that frequently were answered to indicate poor nutrition were:

Do you take 3 or more prescribed or over-the-counter medication per day?

Do you eat alone most of the time?

Do you drink 6-8 cups of fluid most days?

Do you eat at least 3 meals most days?

The frequency with which individual questions have contributed to the nutrition assessment could enable modification of the ANSI to a smaller number of questions.

5.6.12 Social contacts

Extent of social situation did not vary greatly between the two groups and did not change much in the intervention group in the 12 month interval between their 75+ HAs. This result was not unexpected. Living alone is common, representing nearly half of this sample, the predominant reason being death of partner. The 2 intervention participants with no one to call for assistance in 1998 were still living alone but claimed to have someone to call in 1999. Social isolation existed as demonstrated by 19-31% of the groups wishing they had more social outings.

Table 5.31 Social contacts by group and year

	Intervention group 1998	Intervention group 1999	Control group 1999
Live alone	22	19	21
Widowed	20	16	20
No one to call for assistance	2	1	1
Like to go out more (%)	9 (19)	12 (26)	14 (31)
Total	48	45	44

5.6.13 Housing

The denominator in the intervention group 1999 is 43 and in the control group is 42. If the participant was living in hostel or nursing homes bathroom hazards were not assessed. The housing and bathroom facilities were presumed to be adequate and professional carers were in attendance. Environmental risks for falls around the home were summarized in table 5.32.

Number of participants admitted to an institution had been chosen as a secondary outcome measure. In both the control and intervention groups, 2 people had moved form their own home into an hostel or nursing home in the intervening year. The intervention group were no more likely to remain in their own home; Odds ratio (95% CI) 0.98 (0.07 to 1.75) p= 1.0

Table 5.32 Environmental risks for falls

	Intervention group 1998	Intervention group 1999	Control group 1999
Inadequate housing	4	13	9
One problem	2	11	9
Multiple problems	2	1	0
Bathroom aids	19	29	32
Rails	19	26	24
Toilet risk			
Outside toilet	2	2	1
Toilet rails	14	18	15
Floor hazards	14	22	18
Scatter mats	6	17	15
Steps /stairs	7	10	6
Other	5	6	2
Total living in own home	48	43	42
In Hostel, Nursing Home or about to move in Nursing Home	-	2	2
Total	48	45	44

5.7 Results of Short Form 36

5.7.1 SF-36 completions

The SF-36 was administered to all study participants (control and intervention group) at enrolment (initial visit, 1998) and at second annual visit (1999). Data entry and analysis were as described in Chapter 4, Methodology. The number of study participants who completed a 75+ HA has been reported in Table 5.4. The number of participants who completed SF-36 questions is described in Table 5.33. One participant only partially completed the SF-36 enabling calculation of scores for some of the scales. The number of complete paired results,

(i.e. same individual, two annual SF-36s) is given at the bottom of table 5.33.

Table 5.33. Number of participants completing SF-36.

	Completion	Control	Intervention
Enrolled in 1998		50	50
SF-36 in 1998	Complete	49	49
	Partial	1	0
	No data	0	1
Remaining in RCT in 1999		44	45
SF-36 in 1999	Complete	43	45
	Partial	0	0
	No data	1	0
Complete (partial) paired SF-36 data.		42 (1)	44

5.7.2 SF-36 data and population norms

Results for both groups completing the SF-36 on 2 occasions are presented in table 5.34. All completions in each round have been included. The number of results presented in later figures of paired data are smaller due to the few participants for whom it was not possible to collect SF-36 data twice. (E.g. withdrew consent, too unwell or deceased).

These data are compared to the South Australian population norms in this age group, for both sexes combined. (125) These SF-36 data were not analysed separately for each sex. The South Australian population data are derived from interviewer-administered questionnaires, in the same way as these data. Other methods of administration (e.g. self-administered following mail out or telephone survey) may yield different scores. (129) Thus the South Australian population norm data represent the most valid comparative data for this RCT.

In all SF-36 tables, the results of scales are presented in the same order. Scales are arranged from the most valid measures of physical health (physical functioning) to the most valid measures of mental status (mental health). Scales in the middle have moderate validity for measuring both physical and mental components of health status. The summary scales (physical health and mental health) are not available in the SA population norms.

The large standard deviations of the mean (SD) reflect the variability of SF-36 scores in this age group. Comparing the SD in each age band in the SA population normative data the SD increases with age. The largest change is in the increase from 65-74-age band to the 75+ age band. All the means scored fall within one SD of the population norms. These data are presented in table 5.34 including the full name and abbreviation for each scale.

Outlying scores were sought, looking for patterns that might represent significant differences. The control group had 2 relatively outlying scores but still within one SD of the mean. These were PF low in 1998 and RP high in 1999. The intervention group had 3 relatively low scores (BP, SF and RE in 1998) and 2 relatively high scores (PF and RP in 1999). These scores also were less than one SD away from the mean. These differences are analysed further in the following sections comparing groups at baseline and change within each group.

The SF-36 data reported here demonstrates that, by this measure, the participants are similar to age specific population in South Australia.

Table 5.34. SF-36 transformed scores & SA population Norms.

SF-36 Scales	Abbreviations	Control 1998	Control 1999	Intervention 1998	Intervention 1999	SA population norms	
						Mean	SD
Complete data, (partial)		49 (1)	43 (0)	49 (0)	45 (0)		
Physical functioning	PF	41.94	55.35	53.91	61.67	52.4	30.5
Role physical	RP	66.33	69.77	51.53	71.67	57.5	43.0
Bodily pain	BP	66.48	68.81	57.16	67.51	67.0	29.4
General health	GH	61.48	62.25	62.08	65.75	58.4	24.4
Vitality	VT	55.53	56.86	55.61	56.22	54.1	25.0
Social functioning	SF	85.50	85.46	78.31	85.55	83.4	26.7
Role emotional	RE	85.33	89.92	64.62	89.62	84.5	32.8
Mental health	MH	77.84	79.35	76.73	80.53	80.4	17.6
Summary Physical Health		37.10	40.25	37.87	41.71		
Summary Mental Health		54.50	54.24	51.07	53.89		

5.7.3 Comparison of groups

Baseline data 1998

There was a significant difference between the control and intervention group in 1998 in two of the scales. In the other scales the two groups are not significantly different. See table 5.35.

Table 5.35. SF-36 scale scores, Control vs. Intervention, 1998

	Abbreviations	Control 1998	Intervention 1998	P-value
Physical functioning	PF	**41.94**	53.91	**0.0276**
Role physical	RP	66.33	51.53	0.0882
Bodily pain	BP	66.48	57.16	0.1534
General health	GH	61.48	62.08	0.6315
Vitality	VT	55.53	55.61	0.8776
Social functioning	SF	85.50	78.31	0.4947
Role emotional	RE	85.33	**64.62**	**0.0157**
Mental health	MH	77.84	76.73	0.8139

The control group had a significantly lower PF score than the intervention group whose PF score was close to the mean for the age-specific population. In the other scales that contain valid physical function components the trend is reversed (RP and BP) or equivalent (GH). This is interpreted as meaning that both groups had comparable physical health status at enrolment.

The intervention group had a significantly lower RE score at baseline, while the control group's score was close to the age-specific population mean. Importantly MH and VT scores were very similar in control and intervention group. The control group's SF score was higher but this did not reach statistical significance. These data are interpreted as meaning the two groups are similar in mental health status.

5.7.4 Change from baseline to follow-up.

Both groups tended to score higher in scale scores in the second year. A t-test was used to compare means of the scales. RE and SF were not normally distributed, so a mean and SD are not available. P-values for these two scales were calculated by Wilcoxon ranksum test. There were no significant differences in the changes (increases) in the means of the scale scores between the two groups. Table 5.36 contains these data.

Table 5.36. Comparison of changes in means of scales between Control and Intervention groups.

Change in score	Control 1998 to 1999.		Intervention 1998-1999		P value
	Mean	SD	Mean	SD	
Physical functioning	9.6	16.2	7.2	15.4	0.4816
Role physical	3.0	45.9	18.2	50.1	0.1467
Bodily pain	3.3	24.0	8.3	27.8	0.3797
General health	1.9	16.2	3.7	17.5	0.6192
Vitality	0.8	20.2	0.0	20.7	0.8934
Social functioning					0.7772*
Role emotional					0.1064*
Mental health	1.7	14.8	3.5	18.8	0.8588

*Wilcoxon ranksum test.

5.7.5 Status at Follow-up, 1999

Scale scores of both groups were compared at follow-up in 1999. Differences here might reflect improvements in health status of the intervention group as a result of the intervention. The general nature of the SF-36 makes it unlikely that changes in individual aspects of health status will be reflected in SF-36 scores. However, a multifaceted intervention encompassing medical, functional, psychological and social/environmental components may produce changes that are detected in a broad instrument like the SF-36. Statistical analysis revealed no significant differences between scores for any of the scales comparing control and intervention group.

Table 5.37. SF-36 scale scores, Control vs. Intervention, 1999

	Control 1999	Intervention 1999	P-value
Physical functioning	55.3	61.7	0.2759
Role physical	69.8	71.7	0.8244
Bodily pain	68.8	67.5	0.8237
General health	62.3	65.8	0.4328
Vitality	56.9	56.2	0.8968
Social functioning	85.5	85.6	0.5913*
Role emotional	89.9	89.6	0.9698*
Mental health	79.3	80.5	0.7779

*Wilcoxon ranksum test.

5.7.6 Summary of SF-36 data

The analysis of the SF-36 data confirms that the control and intervention groups were:

- Able to complete a SF-36 questionnaire when visited as part of this study,
- Equivalent to the normative data set for the same age group in South Australia. Despite variability around the mean scale scores, all scores were within one standard deviation of the mean.
- Comparable at baseline with only minor differences in PF (lower in control group) and RE (lower in intervention group)

At the second annual visit in 1999, SF-36 scores comparing the groups were not significantly different:

- Both groups recorded scores that tended to be higher but the increase in means was not significantly different between the two groups
- No significant differences existed between the control and intervention groups at follow up in 1999, and
- No health status difference is demonstrated by the SF-36 between the groups in the one-year interval. Consequently no health status improvement can be attributed to the intervention by measuring SF-36.

These SF-36 data confirm that the sample was representative of the 75+ population of South Australia and that randomisation has produced two equivalent groups.

5.8 Analysis of number of problems

5.8.1 Comparison of Control and Intervention groups

The control group had 50 participants enrolled in 1998 but only 44 of these participants

completed 75+ HA in 1999. The intervention group consisted of 50 participants. Two of these did not complete the first 75+ HA despite consenting and completing a SF-36. One year later 5 participants did not complete the second assessment (one deceased, 3 declined, one unable due to CVA). One participant who did not complete the first 75+HA managed to complete it in the second year. This left 44 people with complete paired data of 2 annual 75+ HAs. (See tables 5.3, 5.4 and 5.5) The number of problems in these 2 groups was reported in table 5.6 and statistical comparison in presented in table 5.38.

Table 5.38 Problems in control and intervention group 1999

	Intervention 1999	Control 1999
Number of problems	137	147
Participants without problems (%)	1 (2.2)	5 (11.3)
Participants	45	44
Mean problems (standard deviation)	3.04 (1.86)	3.34 (2.19)

Primary outcome measures chosen for this RCT were number of problems and number of participants with problems. The number of problems in control and intervention group was compared by a *t*-test. This difference was not significant: difference in means (95% CI) 0.30, –0.56 to 1.15, p= 0.49. In the control group, 5 (11.3%) participants had no problems and in the intervention group, one (2.2%) participant had no problems. Although more control participants had no problems this difference was not significant: Odds ratio (95% CI) 5.64 (0.59 to 133) p = 0.11.

5.8.2 Analysis of change in number of problems in the intervention group

Throughout the design of the study, the research team has struggled to arrive at an assessment instrument that had the necessary quantitative rigour, but was flexible enough to describe the

life and living conditions of the elderly population. One example of this is in housing assessment. A typical suburban older house might have loose mats on the floor, no rails in the bathroom and a steep set of steps at the back door. This housing situation might be of no concern if the occupant was an active 75 year-old who played golf 3 times a week. Conversely if the inhabitant had suffered a CVA, was older or potentially had osteoporosis from an early menopause the risks would be increased. They would clearly be at great risk of falls, fractures and, if living alone, in need of a personal alarm system. While this clinical scenario was clear cut, there frequently were 75+ HA where the clinical situation was less definite.

The research nurse who conducted the second annual 75+ HA was blind to the randomisation of the participants visited. Similarly, during the second round of assessments, the principle investigator reporting the data to the participant's GP remained blind to randomisation. At this time, there was no review of the previous years 75+HA if one had occurred. (i.e. the intervention group) The data collected at the home had to be reported in clinically useful descriptions. This was done by the research nurse reporting answers, data in the form of scores (e.g. Folstein MMS) and personal observations. The principle investigator then checked if the data were consistent with the research nurse's clinical opinion. Consensus was reached on aspects of the 75+ HA that required reporting to the participant's own GP as an identified 'problem'. By this method, clinically relevant information could be reported that the research team believed would be useful for the participant's own GP.

In the calculation of 'numbers of problems', these two characteristics of the 75+ HA produced difficulties. The clinical interpretation by the research team of the same situation but with the

person now one-year-older, or having had other illnesses in the intervening year, did not necessarily result in problems being classified in the same manner. What was counted as one problem may, on a second occasion, have been counted as two different problems. Remaining blind to the previous assessment meant that problems might be assessed, described and reported in a different manner.

In the counting of problems in the intervention group for statistical analysis there was further interpretation of each 75+ HA problem list. Both annual 75+ HAs were compared to classify problems as resolved, persisting or new. Interpretation then allowed a decision to be made as to whether the same situation existed as one year previous, whether it had resolved or indeed whether a previously non threatening situation was now a problem because of intervening illness or frailty.

The problem lists for the 1st and 2nd visits were compared for each of the 44 individuals for whom we had two complete 75+ HAs. The problems present at the 2nd 75+ HA were categorised as:

Resolved problems that had been present at the 1st but were not present at the 2nd 75+ HA.

Persisting problems that were present at the 1st 75+ HA and still present at the 2nd 75+ HA. These were further subdivided into:

Resolvable problems that potentially could be resolved (E.g. high depression score on GDS15)

Un-resolvable problems that clinically could not be expected to resolve. (E.g. emphysema) and

New problems that have arisen since the 1st 75+ HA

Table 5.39 presents the data

Table 5.39 Individual problem analysis in intervention group 1999

Problems		Numbers	
Resolved			58
Persisting	Resolvable	55	
	Un-resolvable	23	
		78	78
New problems in 1999			59
Total problems 1999			137

The paired data of participant's problems in 1998 and 1999 were then analysed (n=44). These data are contained in table 5.40

Table 5.40 Total problems in intervention group 1998 and 1999

	Intervention 1998	Intervention 1999
Number of problems	136	137
Participants without problems (%)	5 (10.4)	1 (2.2)
Paired participants	44	44
Mean problems (standard deviation)	3.1 (1.8)	3.1 (1.7)

Primary outcome measures chosen were number of problems and number of participants with problems. The number of problems in intervention group 1998 mean (SD) 3.1 (1.8) and 1999 mean (SD) 3.1 (1.7) was compared by a *t*-test. This difference was not significant: difference in means (95% CI): 0.0, (–3.2 to 3.2), p= 0.93. In the intervention group 1998, 5 (10.4%) participants had no problems and in 1999, one (2.2%) participant had no problems. Although fewer participants had no problems one year after their only 75+ HA this difference was not significant; relative risk (95% CI) 1.69 (1.11 to 2.56) p = 0.20.

5.8.3 Resolution of problems in Intervention group

Problems were classified as **Resolved** when they did not appear in the 2nd 75+ HA for an

individual. The mechanism by which the problem was resolved was not always apparent from the assessment. The most frequent resolved problems are listed in table 5.41 together with a presumed mechanism by which they resolved.

Table 5.41. Resolution of problems and presumed cause/agency

Problem	Number	Cause / agency
Folstein MMS increase	8	Normal variation
Nocturia / incontinence resolved	8	Medical
Falls no longer a problem	7	Medical
Nutrition risk decreased	7	Diet
Vision improved		
Glasses	4	Optometry
Cataract surgery	3	Medical
House modifications	4	Occupational Therapy
Hearing improved		
Aid	2	Audiometry
Other	2	Audiometry
Sleep problem resolved	3	Spontaneous
Depression less	2	Medical
Tetanus immunised	2	Medical/nursing
Hostel care	1	Placement
Medical (BP, cough, post op., mouth ulcer)	4	Medical
Personal safety	1	Neighbours.
TOTAL	58	

Problems that were **Persisting** at the second 75+HA having been present at the first 75+ HA were grouped and listed in table 5.42. Additionally these persisting problems were assessed for whether they were **Resolvable** (n= 55) or **Unresolvable** (n= 23). This distinction is somewhat arbitrary. Although it is reasonably clear when a problem is unresolvable (e.g. emphysema, past alcohol excess, dementia) the converse is not always true. Lack of tetanus immunity is an easily resolvable problem. Ongoing tobacco smoking is a resolvable problem

dependent on patient acceptance of the need to quit and their ability to change.

Being at high nutrition risk is not necessarily a resolvable problem. If high risk is due to factors such as ‘eats alone’ or ‘3 or more medications’ it may be quite difficult to reduce risk. Factors such as ‘3 meals per day’, ‘fruit and vegetables’ and ‘dairy food most days’ are only resolvable problems with a high degree of patient compliance to dietary advice. Patients have trouble adhering to the clear cut dietary guidelines for diabetes, how much harder is it to expect good adherence to dietary guidelines for a less well defined risk.

Even **unresolvable** problems may warrant service provision that significantly nullifies the problem. Past alcohol excess may be unalterable but the balance problems may be caused by cerebellar degeneration from alcohol. Provision of bathroom rails, a Zimmer frame for walking and a Taxi voucher for travel may resolve the problems in the short term.

Decisions about whether persisting problems were resolvable or unresolvable were based on clinical decisions incorporating the entire person’s position such as it was known. The number of problems counted is limited by these constraints that are characteristic of care for the elderly.

Table 5.42 **Persisting** problems at 2nd 75+ HA, Resolvable/unresolvable.

Problems	Resolvable	Unresolvable
Tetanus due	13	
Nutrition	8	4
Hearing aid	6	
Depression	6	1
House modifications	5	
Mobility /falls	5	5
Tobacco	4	
Dentures	3	
Emphysema		3
Driving	2	
Past alcohol excess		2
Medication	2	
Folstein		2
Sleep problems	1	1
Urinary incontinence		1
Radiation exposure		1
Polio as a child		1
Weight loss		1
Vision		1
TOTAL	55	23

5.9 Summary of the outcome measures

Primary and secondary outcome measures are reported in a form comparable to van Haastregt et al's systematic review. (45) These data could be included in a future revision of their systematic review. Table 5.43 contains the data comparing the control and intervention groups at the 2nd visit; there are no statistical significant differences. Specifically in the primary outcome measures:

The mean number of problems was less in the intervention group but the control group had fewer people with no problems,

'Mortality' was not significantly less despite 5 deaths recorded in the control group and 1 in the intervention group. (OR 0.18 (0.0 to 1.76) p=0.20)

Similarly, the secondary outcome measures reveal:

No change in 'Physical function' with no difference in self-rated health nor Barthel ADL scores

No difference in 'Psychological function' with similar Folstein MMS and GDS 15 scores

No difference in the number of people self-reporting falls and

'Admission to institution' is the same with 2 admitted from each group.

By the measures reported, the intervention group is not significantly different one year after a 75+ HA compared to the control group who were left to 'usual care'.

Table 5.43 Comparison of Control and Intervention group

Category	Variable	Control 99	Intervention 99	Significance Odds ratio (95% CI) or Wilcoxon rank sums
Problems	No of problems, Mean (SD)	3.34 (2.19)	3.04 (1.86)	0.30 (-0.56, 1.15) p=0.49
	Participants with no problems N (%)	5 (11.3)	1 (2.2)	OR 5.64 (0.59, 133) p= 0.11
Physical function	Self-rated health, N (%) good, very good	26(59.1)	30 (66.7)	OR 0.72 (0.28, 1.87) p= 0.51
	Barthel ADL, Median (range)	95 (50-100)	100 (80-100)	p= 0.16*
Psychological function	Folstein MMS, N (%) normal	34 (77)	40 (89)	OR 0.43 (0.1, 1.54) p= 0.17
	GDS 15, Median (range)	2 (0-9)	2 (0-10)	p= 0.10*
Falls	Self-reported falls, N (%)	17 (38.6)	12 (26.7)	OR 0.58 (.21, 1.55) p= 0.32
Institutionalisation	Number living in institution	2	2	OR 0.98 (0.07, 1.75) p=1.0
Mortality	Number deceased	5	1	OR 0.18 (0.0, 1.76) p=0.20

* Wilcoxon rank sums

Analysis of change in the intervention group revealed no improvement in the primary outcome measures; (see table 5.44)

Mean number of problems was not decreased (p=0.93) nor did fewer participants report problems (p= 0.20)

However, significant improvements were observed in some of the secondary outcome measures:

'Physical functioning', self rated health is significantly better (p= 0.032) but mean Barthel ADL scores are no different (p=0.36)

'Psychological functioning', the difference in mean GDS 15 scores just reaches statistical significance (p=0.050) but the number of participants with normal Folstein MMS scores is no different. (p=0.13)

The number of participants who self-reported 'Falls' was significantly less frequently (p=0.033).

These results will be considered further in the next chapter, Chapter 6 Discussion.

Table 5.44 Comparison of 75+ HA of intervention group 1998 versus 1999

Category	Variable	Intervention 1998	Intervention 1999	Significance, Mean change or relative risk (95% CI) or McNemars
Problems	No of problems, mean (SD)	3.1 (1.8)	3.1 (1.7)	0 (-3.2, 3.2) p=0.93
	Participants with no problems N (%)	5 (10.4)	1 (2.2)	RR 1.69 (1.11, 2.56) p=0.20
Physical function	Self-rated health, N (%) very good, good	22 (50)	30 (68)	p=0.032*
	Barthel ADL mean (SD)	96.7 (6.0)	96.3 (4.9)	-0.8 (-9.4, 7.8) p=0.36
Psychological function	Folstein MMS N (%) normal	34 (77.3)	39 (88.6)	p= 0.13*
	GDS 15, mean (SD)	3.0 (2.5)	2.5 (2.8)	-0.5 (-3.95, 2.95) p= 0.050
Falls	Self-reported, N (%) falls	20 (45)	12 (27)	p= 0.033*

* McNemars test

Chapter Six Discussion

6.1 Introduction

The results of the RCT have been summarized in section 5.9, 'Summary of the outcome measures'. No significant differences were demonstrated between the control group and the intervention group 12 months after a 75+ HA, but significant improvements occurred in the some of the secondary outcome measures in the intervention group. The results of the RCT will be discussed in this chapter together with an interpretation of this study in comparison to the international literature and the Australian health care system. Specifically, the Aims, as delineated in chapter 1, will be discussed in section 6.2 and the limitations of the study in section 6.3. A generic classification of problems uncovered at 75+ HA based on pragmatic considerations for evaluative research is presented in section 6.4. The Hypotheses are reviewed in section 6.5. The overall evidence regarding this model of health care will be discussed in section 6.6 in considering the implications of this RCT, the evidence in the literature and recommendations that can be made.

6.2 Aims

6.2.1 Compare 75+ HA (intervention) with usual care (control) in a RCT in the elderly living independently in their own home.

The internal validity of the RCT needs to be considered to determine if this aim was achieved. This includes consideration of the sample frame, the achievement of randomisation and conformity to intention to treat.

The sample of patients was drawn from 6 general practices in the AWDGP. Practices were of varying size, computerised to a variable extent and drawn from all parts of the Division. The GPs were not told which patients were sampled and randomised to be controls, only being told about intervention subjects through provision of a 75+ HA report. Sampling only every 20th patient minimised the "cross over effect" of the GPs learning about 75+ HA and implementing a similar model of care inadvertently in all their patients including the control patients. (130) This sampling method avoided selection bias by recruiting a representative sample of Australian general practice patients.

Research nurses in the field adhered to the randomisation protocol, and participants did receive the control or intervention protocol to which they were randomised. Concealment was adhered to and sealed randomisation envelopes were opened only after written informed consent had been obtained. Checking revealed the correct sequence of 50 participants had been randomised to each group.

All participants were successfully traced. The only participants who did not receive the protocol to which they were randomised were those too ill to complete the 75+ HA in 1998, or who died, withdrew consent or were too ill in 1999. Losses to follow up were less than had been allowed for in sample size calculation (6 died, 4 withdrew consent and 1 too ill). All other participants completed second round SF-36 and 75+ HA. Analysis was completed on the intention to treat basis and incorporated all data collected, hence the total denominator of 89 composed of intervention (n=45) and control (n=44) subjects in 1999. Mortality data were available on all participants as all had been traced, so the denominator was 50 in each group for this outcome. SF-36 analysis confirmed two comparable groups had been produced.

The pilot study had produced a practical 75+ HA instrument that again proved straightforward to implement and assessments were complete. This adherence to methodological rigour has resulted in a RCT, which has effectively tested a model of 75+ HA in a representative sample of Australian urban general practice patients.

6.2.2 Use nurses to perform the data collection phase of the 75+ HA

Research nurses who had an appropriate background in age care and /or research were recruited to conduct the 75+ HA. All nurse training was conducted by the author to achieve consistency of implementation of the 75+ HA instrument. Bernabei, (3) Byles (46) and Stuck (40) have advocated that well trained nurses /home visitors were essential requirements for 75+ HA to successfully improve the health status of the elderly.

The first research nurse completed recruitment, randomisation and SF-36 for all patients and 75 + HA for the intervention group only in 1998. Both control and intervention groups had a SF-36 and a 75+ HA conducted by a second research nurse in 1999. Recall bias would be possible if the research nurse remembered the content of the previous visit. This necessitated having a different research nurse to complete the second 75+ HA (1999). Bias is possible in the comparison of the intervention group if the two nurses had inconsistently applied the assessment instruments. SF-36 results appeared higher in both groups in 1999 but were not significant different from the population norms, which had been derived from a relatively small sample size in this oldest age bracket (N=205) and consequently had a large standard deviation.

The second research nurse remained blind to the randomisation of the individuals she was visiting throughout the second year of data collection. This prevented measurement bias occurring between the control and intervention groups in 1999.

The research nurses were previously unknown to the participants. This situation is similar to what will frequently exist in current clinical practice. A range of nurses and allied health professionals is performing 75+ HAs. Variously they are employed by general practices, state based Community Services / District nurses, Aged Care Assessment Teams, Divisions of GP and the Royal Australian College of General Practitioners. They mostly will be unknown to the patients and, initially, performing a function of which the patients have no knowledge. The method of this RCT closely parallels the current service delivery process and has successfully tested the ability of nurses to complete 75+ HA in Australia.

6.2.3 Conduct 75+ HA in the aged person's home.

All 75+ HA were conducted in the participant's home as specified in the 'Letter of Invitation'. Forty-five people (of 145 eligible) declined to enter the study. Reluctance to have an unknown research nurse enter their home may have been a factor for these people. No data on reasons for not joining the study were collected from these people who did not give their consent. The consenting participants displayed no reluctance to allow the research nurses into their home at visits.

The international literature on primary care / general practice providing preventive care of the independent elderly has been reviewed in chapter 2. Home visits are the predominant model reported in the literature. Comparison with hospital in-patient or rehabilitation ward programs

has not been included in this analysis. Outcomes of primary care physicians conducting 'health checks' in their consulting rooms have not separately been tested in a RCT in the international literature. By comparison nurses /allied health professional performing 'health checks' in the home is the pre-eminent model studied and supported by the literature. (See section 2.2.3)

6.2.4 Evaluate whether there are measurable differences, in defined primary and secondary outcome measures, between control and intervention groups.

The analyses did not demonstrate any difference between control and intervention groups in the primary or secondary outcome measures. The total number of problems, and number of participants with problems, was not decreased by the intervention as had been hypothesized. The sample size calculation had been based on the assumption that the intervention would resolve problems and the intervention group would have fewer problems, or fewer people with problems, than the control group. By this measure, the intervention did not improve the health status of the intervention participants.

The other primary outcome measure was mortality which was lower in the intervention group (n=1) than the control group (n=5). This difference was not significant using Fischer's exact two-tailed test as is appropriate with low frequencies. The odds ratio and confidence intervals 0.18 (0.0 to 1.76) confirm the statistical non-significance of this difference.

Secondary outcome measures also did not reveal any improvement in health outcomes that could be attributed to the intervention. The number of participants admitted to a long term care institution during the course of the 12 month observation period was the same in control

and intervention group (n=2). 75+ HA was not shown to decrease institutionalization, an outcome that, when analysed by van Haastregt (45), was significantly decreased in only 2 of the 7 trials that included this outcome measure. The other secondary outcomes will be discussed in dealing with the individual components of the 75+ HA instrument in section 6.2.5.2.

6.2.5 In both Control and Intervention group:

6.2.5.1 Measure the acceptability to the elderly of this model of care

The acceptability of the intervention is measured by the number of participants who agreed to be enrolled in the RCT expressed as a percentage of the number of eligible people approached to enter the study. Letters of invitation were sent to people whose names appeared on GPs age-sex registers and enrolment proceeded until 100 participants had consented to enter the RCT. Eventually 200 letters were sent. Thirty-six people were un-contactable and contact was made with 164 to assess their eligibility. Of these 164 people, 19 were ineligible to enter the study and 45 declined to enter the study before 100 had agreed, given informed consent and been enrolled. Acceptability of the first 75+ HA was 68.9% (100/145). (See participant flow figure 5.1)

Participants were offered a second visit 12 months after their first visit. All 100 participants were successfully traced. Six participants had died during the intervening 12 months. Four of the 94 participants still alive declined a second visit. Therefore, of the eligible people approached to enter the study and who were still alive 12 months later (145-6 = 139), 90 accepted the offer of a second visit. Acceptability of a first and second visit as part of the RCT of 75+ HA was 64.7% (90/139) of the initial sample. However only the intervention group

had had a 75+ HA in the first year. Analysis of patient loss in the intervention group may be a more accurate measure of acceptability to the patients of the 75+ HA, as this group only had experienced a 75+ HA. Of the 50 enrolled only 48 had a complete 75+ HA in 1998. (Table 5.4) All 48 were alive and able to be traced in 1999. Only 3 of these 48 declined to have a second 75+ HA. Acceptability of a 75+ HA, in this group who had already experienced a 75+ HA, is 93.7% (45/48)

The YHAEPS pilot study had been conducted in a small country town. (117) The author had been a local GP for the preceding 11 years and most of the participants were recruited from the author's group practice. Additionally a small number of people from outside the practice, were included. The acceptability in this pilot study was 92.5% (37/40). The pilot study in Yarrawonga had included a telephone evaluation after the 75+ HA. This revealed high acceptability of the 75+ HA but was limited by poor memory of the visit. Telephone evaluation was not repeated in this RCT.

The high acceptability in the pilot study was expected given the reputation and credibility that long serving GPs acquire. By comparison, the RCT was conducted by a GP and research nurses initially unknown to the participants. Recruitment occurred from local GPs and practice records and participants were encouraged to return to their GP for management following a 75+ HA. This larger, urban, more anonymous study had a lower acceptability.

These high acceptability figures (64.7 – 93.7%) have important implications for service delivery and workload in practice. This issue may be more important in rural Australia where significant GP shortages exist and where GPs may be reluctant to add new services to their

workload.

Cost implications of high acceptability

Implications for Health Insurance Commission (HIC) are considerable. 75+ HA have been made available to all community dwelling elderly people from 1st November 1999. The rebate fee (85% of the scheduled fee) is $142. (1) This fee represents the cost to the HIC for each 75+ HA charged. Australian Bureau of Statistics (ABS) data, 1996 census, records 892,700 Australian residents aged 75 years and over. (4)

The original budget for the entire EPC package was $91,000,000 over 4 years. This included costs for other EPC items (Care Plans, Case Conferencing and Public Health). Sixty nine percent of elderly patients accepted the offer of 75+ HA from a research nurse and GP unknown to them. Greater acceptability has been measured when 75+ HA is offered by their usual GP (92.5%). Assuming that 75% of the elderly may take up the offer of a 75+ HA from their own GP, the potential annual cost to the HIC is calculated at $112,500,000.

6.2.5.2 Categorize the problems uncovered at each 75+ HA

Interpretation of the research nurse's observations into a problem list remains problematic. This clinical interpretation function has been performed by their usual GP in this RCT. Interpretation of each assessment depends on a broader understanding of the person's situation than is revealed by the "snap shot" nature of a 75+ HA as part of a research project. Although this represents a limitation of this RCT, it is similar to the clinical situation now current in Australia.

The American CGA model of preventive home assessments seems to exist largely independent of the elderly person's usual provider of primary care. (37) It would seem to be further removed from the Australian model than this RCT. The complexity of bio-medical illness increases with the multiple co-morbidities common with increasing age. In the same way the complexity of functional, psychosocial and social / environmental problems increases and defies reduction into quantifiable data. This difficulty has not entirely been resolved by this study.

Within these imprecise limits, the results of the RCT have been interpreted with caution. Use of the established 75+ HA instrument resulted in problems being described in 13 predefined categories: Hearing, Vision, Physical condition, Compliance, Medication Miscellaneous, Cognition, ADL, Mood, Mobility, Nutrition, Social & Housing. Summarized findings, within these categories, are discussed.

1. Hearing

About half of each group assessed reported inadequate hearing, yet 60-70% of them did not have an effective hearing aid. Reporting this problem to GPs did not result in change at 12-month follow-up in the intervention group.

2. Vision

The intervention group reported improved vision at their 2nd 75+ HA. Those self-reporting 'Good' or 'Very good', compared to those self-reporting 'Fair' 'Poor' or 'Blind', increased from 24/48 to 31/44 (RR (95% CI) 1.45 (0.98 to 2.13) p= 0.06). This result approached statistical significance. Analysis of problem resolution revealed this was due to glasses

prescribed and cataract surgery /IOL implantation. The intervention seems to have had the effect of precipitating referral for visual problems to opticians or ophthalmologists and at review fewer of the intervention group were self-reporting visual impairment.

In the intervention group, of those participants who reported impaired vision, fewer were driving in 1999 and fewer reported recent falls, but no statistically significant differences existed in these data. The intervention group's burden of impaired vision seems to have decreased.

3. Physical condition

Self-rated health was used as a secondary outcome measure because of its predictive value in older people. Analysing this measure there was no significant difference between control and intervention group but there was a significant improvement within the intervention group. ($p= 0.032$) This may be explained by the increased sensitivity of the analysis of paired data in the intervention group compared to the analysis comparing control and intervention groups.

Medical conditions reported were classified by ICPC. The expected commonest conditions were seen in similar numbers across all groups (Arthritis, Hypertension, Heart disease and NIDDM.)

Access to GP was good with 90-96% of participants in each group having seen their GP within the previous 13 weeks. The RCT did not encounter elderly people who did not regularly attend a GP. This would have been unlikely with our sampling method (GP practices), but not impossible. Participants were recruited with an initial letter of invitation on

practice stationery. They were clearly told that consulting their usual GP would be part of the management following the home visit. In some practices, patients remained on practice registers despite no longer attending the practices. Long term non-attenders were unlikely to be sampled by our approach and, if sampled, would be unlikely to consent to join a study that required them to visit a GP after an assessment at home. The regular attendance observed does not exclude non-attendance at a GP as an issue, for this age group.

4 & 5 Medication and Compliance

The number of prescription medications taken per person varied little across the 3 groups, (see table 5.17 for means and ranges) The average did not change significantly in the intervention group following the 1998 assessment. Opposing effects on number of medication may have been in operation. Reporting of medication unknown to the GP may have led to drugs being discontinued, as good aged care requires minimisation of drug usage. (83) However new conditions revealed may have led to new drug therapy being initiated. Not enough data were collected on changes to medication regimens to interpret the observed changes in raw numbers. A study to explore this issue could be constructed as part of 75+ HA evaluation. It would require extensive tracking of 'reasons for change' by the participating GP. This tracking was outside the scope of this study.

The expected prescription medications were observed most frequently and were broadly consistent with the frequency of self-reported medical conditions. Interesting observations include:

- Over half of all groups were taking warfarin or anti-platelet agents (aspirin)
- Antihypertensive medications were more common in the intervention group as was the

self reported diagnosis of hypertension.

- ACE inhibitors were the predominant antihypertensive in the intervention group but calcium channel blockers predominated in the control group. These data were collected before the recent uncertainty about calcium channel blockers could be expected to have translated into changed prescribing practice. (131)
- Relatively small numbers of participants reporting arthritis were taking NSAIDs (Intervention 7/28, control 4/18). Paracetamol usage was not reliably reported, as some participants do not perceive it as a prescription medication.
- Among antidepressants, tricyclics predominated over newer medications but overall small numbers make interpretation difficult. Total number of participants taking each class were tricyclics 10, SSRI one, RIMA 0. This may represent tricyclics being used for:

  Hypnotic effect: preoccupation with sleep being common in this age group.

  Control of Bladder symptoms; the data collected did not include specific reasons for individual medications consumed. It was not considered necessary to seek this information when the 75+ HA was being reported to the usual prescriber, and

  Long term continuation of medication, that has proved satisfactory /well tolerated. The elderly could be very resistant to change in medication despite sound logic in favour of change.

The majority of participants with impaired cognition did not have regular supervision of their medication consumption. (See table 5.15) Presumably, this was due to the insidious onset of memory impairment. Health care providers and carers may be unaware of the extent of memory impairment or the consequent risk of poor compliance. The intervention group had a smaller percentage of participants who had impaired cognition and were unsupervised in

taking their medication in the second year. This decrease was not statistically significant but may have been due to reporting it to their GP one year previous.

6 Miscellaneous

Tetanus

Relatively large numbers of participants reported that they were overdue for, or could not recall, their last tetanus immunisation. Notification of tetanus non-immunity to GPs did not result in significant improvement. Only 2 of 15 intervention participants recalled that they had been immunised when asked 12 months later. This represented the numerically largest 'Persisting but Resolvable' problem in the intervention group.

Self-report is an unreliable method of ensuring immunity. Having inquired about immunisation status, it should be checked against practice, or other source, records and administered if due. The study GPs may have checked tetanus immunisation after the first 75+ HA and either provided immunisation or realised it was not due. This numerically large persisting but resolvable problem may not be as great as it appears due to inaccuracies of self reported non-immunity. Alternately it may represent no action having been taken despite an indication to immunise. No data of GP actions were recorded to answer this question.

Recommendations for tetanus immunisation in this age group changed between the time of data collection and the writing of this report. At data collection, tetanus immunisation was recommended every 10 years (30) but now it is recommended once only at the age of 50 if a full course has been completed. (31)

Recall systems provide a more reliable way of maintaining immunisation. Data can be inserted into the practice recall system so prompts appear when immunisation is due. This is becoming more common with increasing computerization of general practice. Current recommendation for this age group would be to set up recalls for:

Tetanus once only over age 50

Pneumococcal vaccination every 5 years

Influenza vaccination annually in the autumn (31)

Smoking.

Only 7 participants in the RCT were current smokers. The 4 smokers in the intervention group continued to smoke, despite their smoking being notified to their GP after their initial 75+ HA. The intervention had no effect on reducing the incidence of smoking, but the small numbers of smokers would make it difficult to demonstrate an effect. Quitting depends on personal choice to attempt smoking cessation. A more intense intervention would be required to make significant smoking reduction a likely outcome of 75+ HA. The control group contained 3 current smokers and all were female.

Alcohol

Large numbers of both groups admitted to regular consumption of small amounts of alcohol. None of the control group admitted to being a heavy drinker in the past. In the intervention group, 5 participants admitted to past heavy alcohol consumption at each annual 75+ HA. Interestingly it was not the same 5 participants on both occasions. Three participants admitted to past heavy alcohol consumption twice and an additional 2 said yes in 1998 and a different 2 said yes in 1999.

Sleep

Complaints of sleep difficulties were common in both groups and not influenced by the intervention. Nocturia was statistically a less common complaint among the males than the females in the whole sample. (Relative risk (95% CI), 0.53 (0.29 to 1.00), p=0.035 Mantel-Haenszel) Sleep complaints may represent mood /depression symptoms or urological disorders in male (prostate) or females (prolapse) or the desire to spend more time asleep.

7 Cognition

The Folstein MMS proved simple to administer and acceptable to the participants in the RCT. It was analysed as a secondary outcome measure. At the second visit more participants in the intervention group than in the control group recorded normal scores but this difference was not significant. More participants in the intervention group recorded normal scores at the 2nd than the 1st 75+ HA but this difference was also not significant. (See table 5.22)

Despite shorter validated cognition tests being available (91), the greater detail contained in the Folstein MMS supports its continued use in 75+ HA. Some variation of individual Folstein MMS scores occurred in the intervention group. The intervention participant with the lowest score in 1998 (MMS = 20) increased his score to the normal range in 1999 (MMS = 26). His low score in 1998 may have been due to intercurrent illness (e.g. fever, hyperglycaemia) causing an acute confusional state. Alternatively, variation could have been due to inter-observer variability in the interpretation of answers between the two research nurses. Training of both had been similar and conducted by the author. Some increase in scores occurs with learning of the test, but this would have been minimal with the test used

only twice, 12 months apart. Participants may have been exposed to the Folstein MMS in other clinical situations. The Folstein MMS proved useful in alerting GPs to the likelihood of unrecognised dementia in their patients but no measurable improvement in the intervention group was apparent.

8 ADL

Barthel ADL scores were used as a secondary outcome measure. ADL scores were high in this population, in each group 70-82% of participants scored 95 or 100, and scores were analysed as a non-parametric continuous variable. Tests of significance did not reveal any difference between the control and intervention group, nor any improvement in the intervention group from 1st to 2nd 75+ HA. The 75+ HA did not have the effect of improving the measurable ADL skills of the intervention participants.

Most scores of 95 were due only to occasional urinary incontinence and do not represent severe disability. However almost all participants scoring <95 reported needing help or being unable to ascend /descend stairs. Lower scores included additional significant disabilities. Thus scores of <95 can be taken to represent significant disability. In this sample, the elderly living independently either had no Basic ADL disability or were already in receipt of support services. These support services were either provided by their own family or by community services. The few with severe impairment of Basic ADL were obvious. The Barthel ADL index successfully discriminated between levels of functional ability among this independent living population of 75 years and over. Scores of 95 or 100 did not indicate significant disability but scores of 90 or less indicated at least one significant functional disability.

This RCT of 75+ HA did not include an Instrumental ADL assessment. This may have usefully distinguished some participants as being at a different level of health care need. Bula et al found 93 of 414 participants (22%) had Instrumental ADL impairment alone in their secondary analysis of Stuck's RCT in California. (38) Only 5 of 414 participants (1.3%) were in the paradoxical position of having Basic ADL impairment but not Instrumental ADL impairment. In terms of classifying the functional ability of the elderly, it would be appropriate to use the Barthel Basic ADL and Lawton's Instrumental ADL instrument. The need to evaluate this possible avenue for preferentially providing 75+ HA for a vulnerable cohort is discussed further in section 6.6.9 and 6.6.10.

9 Mood

Screening for depression used the GDS 15 and this was analysed as a secondary outcome measure. Discrimination at scores of 3 or greater had been shown to have 100% sensitivity of detecting depression. (94) The intervention group did not have significantly lower GDS 15 scores than the control group (Section 5.6.9), so are no less likely to be depressed as a result of a 75+ HA. GDS 15 scores in the intervention group were lower at their second 75+ HA and this result just reached statistical significance. (T-test (95% CI), –0.5 (-3.95 to 2.95) p= 0.050) Individual high GDS15 scores in 1998 were not associated with antidepressant medication 12 months later. No data were collected after the 75+ HA in 1999 to evaluate whether high GDS 15 scores had resulted in the diagnosis of depression. Other studies have reported some data supporting mood improvement in the elderly after 75+ HA. McEwan refers to a positive influence on morale due to the attention and education provided by the intervention. (11) Byles speculated in her literature review that the interaction with the elderly person, not the content of the health assessment, might have been responsible for the observed beneficial

effects. (46) This may have been responsible for the lower GDS 15 scores in the absence of evidence of treated, clinically diagnosed, depression.

As discussed in the Literature Review (Chapter 2) various alternate depression screening instruments (GDS 1, 4, 5, and 10) have been proposed, also derived from the original 30 item GDS. Validation of these alternate instruments is not possible with this dataset in the absence of a validated clinical diagnosis against which to test them.

10 Mobility

The number of participants reporting falls was used as a secondary outcome measure. No significant difference was apparent between control and intervention group: OR (95% CI) 0.58 (0.21 to 1.55). However, the number of participants reporting falls was significantly decreased in the intervention group in the second year. (McNemars test of paired data $p = 0.033$) No data of injuries resulting from falls were collected but further refinement of this outcome measure could include additional questions about injuries and hospitalisation.

The profile of community services used was similar in all groups, with Podiatry and Taxi concession vouchers being the most prevalent. Usefulness of a Taxi concession voucher is limited to urban dwellers who have access to a Taxi service. This result would be expected to be different in rural Australia.

11 Nutrition

The intervention group seemed to have improved their nutrition by the second 75+ HA although this difference was not significant nor were they significantly different from the

control group. The 5 questions that rarely contributed a positive answer could be deleted from the ANSI for use in this 75+ HA. (See table 5.30) This is not to deny the importance of dairy food, fruit nor vegetables in the diet. It is a reflection that this is an infrequent issue in the Australian elderly population sampled. Alcohol is specifically inquired about elsewhere in the 75+ HA.

12 Social

The social situation did not vary greatly between the two groups and did not change much in the intervention group. Living alone is common, representing nearly half of this sample, the predominant reason being death of partner. The 2 intervention participants with no one to call for assistance in 1998 were still living alone but claimed to have someone to call in 1999. Social isolation existed as demonstrated by 19-31% of each group wishing they had more social outings.

13 Housing

Two participants from each group were not living in their own home at the second 75+ HA and were in a nursing home or hostel. The intervention group was no more likely to have remained independent. (OR 0.98)

6.2.5.3 Measure Quality of Life using the SF-36 at each annual visit

The SF-36 is a well-established measure of overall quality of life. (69, 124) It was used to compare the control and intervention groups, without diluting the effect of the intervention. The scale scores for each group were compared to the South Australian normative data for the 75 years and over age group. (125) No significant differences existed between scores for any

of the groups and the normative data. There is considerable variation in SF-36 scores, as reflected in the large standard deviations in the normative data. None of the group means were more than one standard deviation away from the population mean.

The intervention and control groups had 2 significant differences at enrolment. PF scores were lower in the control group and RE scores lower in the intervention group. There were no significant differences in the other scale scores that measure, to a varying extent, physical and mental health. These isolated scale differences, in the absence of differences in the other scales, do not mean the two groups are not comparable.

The data of change of means were used to compare initial and second SF-36 scale scores for the two groups individually. All changes were in a positive direction (increase) or no change but none of these changes in mean were statistically significant. Neither group was demonstrated to have improved quality of life one year after enrolment in this RCT. This was confirmed by comparison of scale scores between control and intervention group in 1999, as no significant differences existed in these 8 scale scores.

This non-significant increase in scores from 1998 to 1999 may have been due to differences in the technique of the two research nurses. If so, differences were not great enough to produce significant differences in scale scores. The benefit of using different nurses, so the second nurse could remain blind to randomisation, outweighs this minor inconsistency in SF-36 data. Alternatively, the second scores may be higher because of the effect of the visit alone. This 'Hawthorne' effect was also proposed by Byles in her literature review (46) when she was unable to discriminate which components of the assessment were statistically associated with

a positive effect.

The two groups were thus comparable to the South Australian population norms for the SF-36 for this age group. The SF-36 has performed a useful function in this RCT in ensuring that comparable groups were created by randomisation. It did not measure a positive, nor negative, intervention effect of 75+ HA. The SF-36 will remain useful for research in 75+ HA but has not been demonstrated to be useful as part of the 75+ HA instrument.

6.2.6 In the intervention group:

6.2.6.1 Follow sequentially the problems uncovered at the first 75+HA

The two assessments, 12 months apart, of the same individual often produced different reports despite their situation being basically unchanged. No reference was made to the first 75+ HA report in producing the second 75+ HA report. Analysis of data was not commenced until after the last visit was completed (February 2000). The second 75+HA in the intervention group consequently produced a different interpretation of the situation of the participant. This caused difficulty in interpretation of problems as new / persisting / resolved.

6.2.6.2 Categorize problems at the second visit

The problem lists for the 1st (1998) and 2nd (1999) visits were compared for each individual in the intervention group. At the 2nd 75+ HA the problems were categorised as:

Resolved, present in 1998 but not 1999,

Persisting problems, further subdivided into,

Resolvable problems and

Un-resolvable problems and

New

Tracing of problems from the first to the second 75+ HA necessitated adjustment of the numbers counted at one of these two visits. It was decided to correct the interpretation of the first visit and leave the second visit unchanged. This had the advantage of consistency across the two groups in 1999 when one research nurse conducted all assessments. Thus the control and intervention groups are comparable in 1999 and the problems can be realistically traced from 1998 to 1999. This interpretation of the data explains the difficulty of analysing the raw data presented in table 5.7 and described in the adjacent text. Table 5.38 is reproduced here showing the numbers of problems in each category.

Table 5.38 Individual problem analysis

Total problems 1998			136
Resolved			58
Persisting	Resolvable	55	
	Un-resolvable	23	
		78	78
New problems in 1999			59
Total problems 1999			137

6.2.6.3 Evaluate whether there is a measurable difference in primary and secondary outcomes in the intervention group 12 months after their first 75+ HA

The primary outcome measures of change in the intervention group were number of problems and number of participants with problems. There was a decrease in mean number of problems but also a decrease in number of people with no problems. Both of these differences were not significant 12 months after the first 75+ HA.

These two similar outcome measures were chosen at the start of the RCT for pragmatic reasons. It was hypothesized that a clinically useful result would be if the number of functional problems was decreased by 75+ HA. Problems revealed could be dealt with by provision of services, accepting that with time new ones would arise. Additionally some problems would not have a readily apparent solution or would be too dependent on the individual elderly person's desire to change. This simplistic notion of resolution of problems identified is not supported by the demonstrated inability of the 75+ HA to significantly reduce the number of problems in the intervention group to the point where they had fewer problems than the control group.

6.3 Limitations of this study

6.3.1 Generalizability (external validity)

The practices

The study was based in the Adelaide Western Division of General Practice and participants were recruited from a convenience sample of practices. Six of 9 practices approached agreed to participate in the RCT. Recent evidence confirms that a random general practice sampling frame provides a valid sample of the general population. (132) The small sample limits confidence that the results are generalisable to the Australian 75+ population. Patient losses were less than allowed for in the sample size calculation.

Practice age-sex registers

The level of computerization in the practices ranged from none to largely computerized. An age-sex register was created in each practice. The ease of creating an age-sex register was

dependent on whether the practice had computerised records and the level of knowledge of the software by the staff. Even in non-computerised practices with a card index, it was possible to create an age-sex register, although this took considerably longer.

The accuracy of the practice databases was variable. Computerised systems facilitated creating age-sex registers but the accuracy of data extracted is dependent on how consistently it has been maintained. The two practices where the most accurate age-sex registers could be created were very different. They were the:

- Smallest, most computerised practice incorporating electronic medical records and
- Longest established practice, with no patient register, and medical records on manilla cards. The cards in the 'current' file were sifted to create an age-sex register. The stable nature of the patient base at this practice must have contributed to their ability to maintain an accurate record of 'their' patients.

The methods of sampling and randomisation were chosen to ensure a representative cross section of the urban elderly was enrolled in the trial. The range of practices enrolled supports the generalisability of the results into contemporary Australian general practice.

The RCT of 75+ HA was designed (in 1997) to reflect the likely service delivery of this model of aged care. The chief difference between the RCT design and normal service delivery is that the GP reading the nurse's assessment data and creating the problem list was not the patient's usual GP. The GP did not know, and was not known by, the patients. More than that it was not the GP that they had chosen to provide their primary health care. Interpretation of the assessment data was, however, by the patient's own GP. General practice, particularly the

care of the aged, depends on an understanding of the patient's medical, social and psychological situation. (133) This knowledge is gained slowly with caring for a person over a period of time. It is only glimpsed briefly in reviewing data collected by a relatively rigid assessment instrument. Interpretation of data and creation of a problem list together with deciding whether they are resolvable or unresolvable becomes somewhat arbitrary. Conversely having all the 75+ HA data reported by one GP did create consistency of reporting to the patient's own GP.

Other aspects of the RCT are consistent with the model by which 75+ HA are already being delivered to the elderly Australian population. (134, 135) Specifically:

- Letters inviting participation were mailed from the practice at which the patients sought their general practice health care. Patients who had changed practice mostly did not agree to enrol. Unlike the GPs in the practices whose age-sex register were used to sample patients, these GPs did not know about the study prior to their patients being invited to join. The few patients who agreed were enrolled to comply with the sampling method and their new GP was fully informed about the study.
- The patient's own GP is left with the interpretation of the data and the implementation of therapeutic initiatives after the 75+ HA. This role is crucial to the success of 75+ HA as it is to other aspects of health care (e.g. diabetes). This study did not collect data on the method by which problems were resolved, merely on whether they had resolved or were persisting at 12 months. Further evaluation of 75+ HA is required to determine what level of active intervention is required to resolve problems and what additional costs are incurred.

A RCT of 75+ HA was successfully completed that has direct relevance to the Australian model of care. (Medicare item number 702)

6.3.2 Non resolution of resolvable problems

The intervention group had 78 persisting problems at the second 75+ HA, of which 55 were classified as resolvable. The arbitrary nature of this distinction between resolvable and unresolvable is acknowledged. The number of persisting resolvable problems (n=55) is similar to the number of resolved problems (n=58). The 75+ HA protocol tested in this RCT has been able to find a range of problems in the elderly but has not been sufficient to resolve more than half of the resolvable problems. A possible explanation of this shortcoming is that the GPs may not have perceived this RCT as a useful part of clinical practice. They may have largely ignored the 75+ HA report because it was a research project and not part of the care they were providing. Although consenting to research occurring in their practice and their patient list being sampled, they may have not acted on the problems itemised for them, even if solutions were available.

6.3.3 No net reduction in the problem burden

The number of problems identified in the Control group at their 2nd visit was similar to the number of problems identified in the intervention group at their 1st and 2nd 75+ HA. The intervention did not lead to a significant reduction in the burden of problems in the intervention group compared to the control group. This equivalence is produced by the number of resolved problems (n=58) being similar to the number of new problems (n=59) that arose. (See table 5.38)

This limitation may be explained by the acknowledged differences between this RCT and normal general practice care. The GP researcher initially reporting the data collected was not the usual provider the care. Data interpretation in the absence of clinical knowledge of the patient is inconsistent with normal general practice. This process was necessary for the study design chosen, as it provided the consistency of one GP researcher reporting all data to the participant's GPs and satisfies the methodological rigour required of a RCT. This limitation does not exist in clinical practice (since the introduction of the EPC item numbers) where the individual GP is the interpreter of the data, the provider of medical care and the coordinator of services indicated.

6.3.4 Did the control group start with fewer problems?

It would have been useful to know, in the control group, the number of the problems that were new since their consent /enrolment in the study. This would have required the control group to have a 75+ HA at entry. Ethically it was unacceptable to assess the control group at entry and not report their problems to their GP /other health care provider. The number of problems in the control group at entry is unknown. The random construction of both groups and their similarity, as measured by their demographics and SF-36, implies that their number of problems would be equivalent at entry. It is expected that the rate of development of new problem is the same in both groups.

6.3.5 Did problem resolution occur with the provision of usual care?

If the intervention had no effect on problem resolution then the number of problems in both groups would be equivalent at each 75+HA. This is the observed result. Insufficient data were

collected to be sure how each problem was resolved. Thus, is a 75+ HA equivalent to usual care and is usual care good enough? If this RCT has demonstrated that 75+ HA in this format is no better than usual care, and then the persisting-resolvable problems exist in the control group. The intervention group data demonstrate the inadequacy of usual care in the control group. Implementation of 75+ HA will not have this artificial distinction between control and intervention group. There will not be a control group agreeing to a home visit but not receiving any intervention.

The problems recorded in the intervention group as 'resolved' may have come to notice in clinical practice and been dealt with in the course of providing usual care. This process would have occurred in both control and intervention group. If so, it would have occurred in the other 19 of every 20 patients who weren't sampled for this study. The resolution of 58 problems (42% i.e. 58/136) reported initially in the intervention group, may be a measure of what usual care is providing and may be independent of the 75+ HA reported to the GP. The 75+ HA report may have been ignored by the participating GPs if they perceived it as a piece of academic research in which they had no interest. The result may have been no action arising from the report: it neither augmented nor impeded the provision of usual care.

Data collected in an evaluation study would need to be more extensive to resolve these issues and could include reporting of services provided for each problem recognized.

6.3.6 Has the RCT devised an assessment instrument that produces numeric data?

Initial planning of the study considered the difficulty of producing an instrument that would reduce clinical assessment of the elderly into valid statistical data. Has the pilot study

produced the instrument, and the RCT demonstrated that the 75+ HA instrument achieved the sophistication necessary to reduce the clinical encounter into numeric form?

The elderly are a vulnerable group and a range of comorbidities complicates their medical problems. The content of the 75+ HA is not confined to the biomedical aspects of health but includes functional, psychological, and social / environmental components. Structured instruments are used as part of this 75+ HA protocol that incompletely cover the biomedical aspects and are even more inadequate in their coverage of the complexities of functional, psychological and social / environmental aspects of this assessment. The 75+ HA protocol produces a mix of qualitative and quantitative data. Predefining criteria that would generate a 'notification to the GP' within each component of the 75+ HA could enhance consistency. Other factors will influence achieving this level of sophistication.

There has been extensive uptake of 75+ HA under Medicare item number 702. A phase of evaluation of a newly established model of health care now needs to occur. Evaluation of 75+HA will require data collection from a representative sample of Australian general practices. These will be 75+ HA conducted by nurses (mostly) and the person's usual provider of GP care. Interpretation of the assessment data will be by GPs familiar with their patient's situation and responsible for their ongoing care. The proliferation of advice on the conduct of 75+ HA means that a heterogeneous range of assessment protocols will be in use. Evaluation will have to cope with disparate forms of data and it would be naïve to expect that consistency of interpretation would be achieved. A generic classification as an Australian standard would facilitate this evaluation. (See section 6.4)

This inability to reduce the complex lives of people aged 75 years and over to a measured assessment has been the chief difficulty faced in the design of this 75+ HA instrument. Nor should the life of the elderly be reduced to an assessment score, at the expense of the richness and diversity of old age.

6.3.7 Reviewed sample size

The sample size necessary to identify if 75+ HA would produce significant results has been re-calculated. This was based on 2 outcome measures: change in self-rated health (in the intervention group) and the difference in mortality (control versus intervention) seen in this study. The same values for alpha (0.05) and beta (0.10) were used as in the original sample size calculation. Both calculations produced a necessary sample size of 420 (210 in both control and intervention group). If these two outcomes were similar in a future study, it would need to be more than four times the size of the study reported here to produce statistically significant results.

These outcome measures had both produced reasonably favourable results that were not apparent across all the outcome measures. Other outcome measures revealed no difference between control and intervention (e.g. institutionalization, N=2 both groups) and suggest no sample size would be large enough to demonstrate a significant difference.

The clinical relevance of these results is not immediately apparent. The statistically significant improvements in the intervention group suggest that the intervention had a useful effect despite this not being measurable in the difference between control and intervention groups. These findings are consistent with the variable results analysed by van Haastregt and Byles in

their reviews of the literature. Clinical relevance may only be determined by evaluations of routine practice of 75+ HA and the measurement of health outcomes. As described previously the target population in Australia is 872,000 people. If the measurable effect is small, but consistently positive, then the intervention may be justifiable given the large population.

6.3.8 Multiplicity

Multiplicity is the problem when multiple measures, or multiple occasions of measurement, are undertaken and significant results occur by chance. With increasing numbers of outcomes measured there is increasing likelihood of type one errors occurring; the difference in some measures will reach statistical significance by chance alone. (136) Multiplicity is unlikely to explain the significant differences found in the intervention group. Measurement occurred at the minimum number of times to measure change. The control group only had one 75+ HA and completed the SF-36 on only two occasions. Consistent results were obtained in all 9 primary and secondary measures comparing control and intervention group in 1999. An initial and final measure was required to measure change in the intervention group. Significant differences were recorded in 3 of the 7 measures that could be applied to measure change in the intervention group. All significant changes were in the direction of improved health in the 2nd 75+ HA but were in the secondary, not the primary, outcome measures. The observed significant changes were therefore assumed to be real differences apparent because of the ability to analyse paired data.

6.3.9 Information Technology / Information Management in General Practice

Practice management systems can be set up with data obtained from 75+ HAs, and other

sources. There is potential to be more efficient for some components of care of the elderly than annually repeating the same questions.

The chief weakness of the data collection phase is the reliance it places on memory, particularly when dealing with a population some of whom will be memory impaired. It will always be crucial to ask the patient some components of the 75+ HA. Examples of this include; the self-rated health questions, adequacy of hearing and vision, services received, medication actually consumed, tests of cognition etc. Other components that rely on 'hard data' include immunisation status and recall / test results for physical illness (e.g. diabetes)

The efficient implementation of 75+ HA will be considerably easier in computerised practices. Functions that will be facilitated include:

- Generation of an age-sex register. The RCT demonstrated that this could occur in 10 minutes in a practice with computerised accounts, even in the absence of computerised medical records. (Practices 1, 2 and 6). The age-sex register becomes the basis for offering 75+ HA to the practice patients.
- The annual workload can be spread by the 'birthday card' reminder system. Each month throughout the year patients who had a 75+ HA 12 months previously, or have just entered the age range, or who have not participated previously are sent a 'invitation' to have a nurse visit at home. Individual form letters for a manageable quantum of 75+ HA can be generated. This function is then repeated monthly. This process can be further refined to allow for staff absences, differences in monthly workload etc.
- Implementing a recall system for parameters that are managed by recall at defined intervals rather than annual questionnaire. The 3 immunizations particularly relevant to

the elderly could be managed by constructing a recall for influenza (annually in autumn), pneumococcal (every 5 years) and tetanus (once only over age 50 if fully immunised). (31) Similar automated reminders can be created for diabetes monitoring, patients on antihypertensive medication and patients on warfarin.

- Interaction with other EPC items. The Eyre Peninsula Division of General Practice has developed software to facilitate the clinical process of EPC item numbers. (113) This has been sponsored by Pfizer and is to be distributed free throughout Australia. The Eyre Care software extracts data from Medical Director files (demographics, medication, medical conditions etc) and generates 75+ HA, Care Plans or Case Conferencing forms. If duplication can be kept to a minimum this will encourage GPs to increase their use of multiple new models of care.
- Medication review. Increasingly Australian GPs are prescribing electronically. Electronic templates for 75+ HA can extract medication labelled as regular from prescribing packages (E.g. 'Eyre Care' EPC software and 'Medical Director' prescribing). Data reported from the home visit could be used to update the practice medication records. Integrated with an annual home visit that reviews stocks of medication on hand, this could lead to reduction in drug interactions, decreased wastage and potential cost savings.

6.4 Generic classification

No consistent method of conducting a 75+ HA had been found in the literature reviewed. Recurrent themes have been identified and the evidence supporting each component has been discussed. A generic classification would make it possible to interpret data from a variety of sources. Ideally it would collect data from routine clinical practice, allow evaluative data analysis and be comparable to other international models of care. Such a generic classification

is proposed to address all these issue within the limits of current knowledge.

The 75+ HA instrument described in this thesis, defined problems within 13 categories. Subsequently the Medicare Benefit Schedule guidelines suggested a similar content, described as 5 components. (1)

Medical,

Physical function, (including ADL and Falls)

Psychological function, (including Mood and Cognition)

Social function and

Other

The weakness of this classification is the large number of items in the 'Other' component. Most of these are medical problems and should rightly be in the Medical component. Exceptions being 'fitness to drive' and 'footcare', both of which could be included in Physical function, and 'sleep'. Sleep complaints may represent mood / depression symptoms or urological disorders. In the absence of a diagnosed problem, it is considered most useful to include sleep complaints in the 'Psychological' component of the assessment.

The RACGP template (114) interpreted the Medicare guidelines into 27 question that also strongly overlap with this study's 75+ HA instrument. The Eyre Care book /CD-ROM package uses a structure closely copied from the Medicare schedule. (113) Stuck, Alessi, Bula and others working collaboratively in California and Switzerland have evolved a structure they defined for their assessments. (37) Their structure has 4 components:

Medical (including cognition),

Functional (physical),

Mental health (including mood, anxiety, substance abuse etc) and

Social /environmental.

Their structure is inherently ordered and logical but does place greater emphasis on universal medical screening (blood testing, faeces for occult blood etc) that is not supported by Medicare item number 700 and 702. They also include cognition assessment as part of Medical (Neurological) not with depression in Mental Health. Cognition testing should remain in the Psychological (or the synonym Mental Health) not the Medical classification. Clinical difficulties can exist in distinguishing depression and dementia (e.g. depression presenting as pseudo-dementia) but this is not a common problem. New medications are being released for early dementia based on neurotransmitter deficits. (137) Consequently, dementia will increasingly be seen as a neurological disorder requiring pharmacological therapy. Its predominant symptoms are more usually described as psychological and to remain consistent with the Medicare schedule, Cognition should remain in the 'Psychological' category.

Thus the proposed Australian standard classification of 75+ HA problems for research and evaluation is

Medical

Physical function

Psychological

Social / Environmental

Adoption of this structure allows analysis in a consistent form, is consistent with DHAC and Medicare, allows input of data from RACGP and 'Eyre Care' structures and facilitates international comparison. These concepts are presented in Table 6.1, which is an extension of table 2.5 in the literature review (chapter 2). Each column representing one of the protocols

for health assessment and each row comparing like concepts.

Table 6.1 Comparison of structure of 75+ HAs

Newbury 75+ HA		RACGP Q n	Topic	Health Insurance Commission also 'Eyre Care'	Process of Care in CGA Alessi et al	Domains (predictors) Stuck 'functional status decline'	Proposed Australian Standard
1	Hearing	15	Hearing	Other	Medical	Hearing	Medical
2	Vision	14	Vision	Other	Medical	Vision (poor self-rated)	Medical
3	Physical Condition	1	Self report		Medical	Self rated health (poor)	Medical
	List problems	2	Current problems, FMH	Other	Medical	Comorbidity (chronic conditions)	Medical
	GP contact						Medical
4	Compliance	25	Medication		Medical		Medical
	Supervision						Medical
	Pre-packaged						Medical
	Over the counter			Medical			Medical
5	Medication	25	Medication	Medical	Medical	Medication	Medical
6	Miscellaneous	4	Smoking	Other	Mental health	Smoking (current)	Medical
	Alcohol	5	Alcohol	Other	Mental health	Alcohol (none vs. moderate)	Medical
	Dentures	12	Oral health	Other			Medical
	Sleep	21b	Sleep	Other	Medical		Medical
	Tetanus	26	Vaccinations	Medical			Medical
7	Cognition (Folstein)	18	Mental status	Psychological	Medical	Cognition (impairment)	Psychological
8	Barthel Basic ADL			Physical function	Functional	Functional limitation (lower limb)	Physical Function
	(Q10 in Barthel ADL)	22	Continence	Medical	Medical		Medical

Newbury 75+ HA		RACGP Q n	Topic	Health Insurance Commission also 'Eyre Care'	Process of Care in CGA Alessi et al	Domains (predictors) Stuck 'functional status decline'	Proposed Australian Standard
9	Mood, GDS 15	21a	Mood, consider GDS 15	Psychological	Mental health	Affect (depression)	Psychological
10	Mobility	3	Community / Allied Health	Other	Functional		Physical Function
	Driving	16	Fit to drive	Other			Physical Function
	Falls	24	Mobility (incl. falls)	Physical function	Functional	Falls	Physical Function
	Podiatry	13	Feet	Other			Physical Function
11	Nutrition (ANSI)	17	Nutrition (ANSI)	Other		Nutrition (BMI high or low)	Medical
		7-9	Wt, Ht, BMI	Other			Medical
12	Social	19	Living alone	Social function	Social / environmental	Social (few contacts)	Social / environmental
	Contacts, family	20	Social support	Social function			Social / environmental
13	Housing	23	Home safety	Other	Social / environmental		Social / environmental
		6	Exercise		Functional	Physical activity (low level)	Physical Function
		10	BP / pulse	Medical	Medical		Medical

6.5 Hypotheses

That in comparison with usual care:

The offer of a 75+ HA is acceptable to aged persons and their established health care providers.

The 75+ HA proved acceptable to the elderly and to the GPs involved in this study. General availability of 75+ HA since November 1999 has significant implications for GP workload and cost to Medicare.

A significant number of problems will be uncovered at each 75+ HA.

Problems were uncovered across a broad spectrum of need. New problems continued to be discovered in the repeated annual 75+ HA in the intervention group.

Problems uncovered will be either amenable to resolution by existing local facilities or unresolvable due to their irreversible nature.

Some problems were resolved but a large number of resolvable problems were still present after 12 months in the intervention group. Unresolvable problems persisted as expected. The mechanism of problem resolution or non-resolution was unclear. The results of the study were achieved without interval reminders to the GP and tested a model of care where 75+ HA is an annual adjunct to usual care.

The intervention group will have significantly better health outcomes than the control group as measured by primary and secondary outcome measures

The RCT did not demonstrate statistically significant differences in primary nor secondary outcomes comparing control and intervention groups. There were

significant differences in some of the secondary outcomes that measured change in the intervention group.

6.6 Implications of this Study and Recommendations

6.6.1 Inability to conduct another RCT of the intervention.

Medicare item numbers for 75+ HA were introduced on the 1st November 1999 in Australia. Large numbers of 75+ HA item numbers have been claimed. (73, 138) Further RCTs comparing 75+ HA with usual care would require creation of a valid control group of the elderly not receiving 75+ HA. This would be impossible given the widespread implementation of 75+ HA. Additionally, study design would need to consider the likely confounding effect of GP education about 75+ HA influencing their 'usual care' of the control group. The 2 RCTs of 75+ HA described (this study (139) and Byles PCT of 70+ Veterans for DVA) both largely collected data before implementation of Medicare item numbers. These 2 studies are the only Australian RCTs of 75+ HA. The evidence presented is not conclusive in all aspects of 75+ HA but it has been derived from a methodologically sound RCT. The Australian situation today is similar to Great Britain in 1990 when 'health checks' were introduced without conclusive evidence having been produced of their effectiveness. Consequently, we need to develop evaluation studies of 75+HA, as occurred in Great Britain, after the initiation of this model of care.

Recommendation 1 Evaluation studies of the 75+ HA initiative should occur now that Medicare funding is in place and widespread adoption has occurred.

6.6.2 Definition of health should be broad, not exclusively bio-medical

Studies from age 75+ have emphasized the need for an holistic notion of health that is consistent with the Alma Ata declaration of the World Health Organisation. At a younger age, health should have more emphasis on the bio-medical model as exemplified by the Dubbo study of cardiovascular risks in the elderly (65+). This broad functional focus creates the difficulty of reducing the complexity of old age into quantifiable data. This depends on interpreting a number of observed factors that may represent a real problem for an individual. The same observations may not represent a problem for another elderly person. A realistic notion must be maintained of which problems might be amenable to solution. This difficulty has not been resolved in the international literature nor resolved by this RCT. Further evaluation could proceed along the lines proposed with greater refinement of process expected.

Recommendation 2 Health services for the 75+ people should concentrate on a functional model of health not exclusively on a bio-medical model of illness.

6.6.3 Nurse or Allied Health professional staff only

Nursing and allied health professional staff are ideally suited to conducting 75+ HA home visits. Nurses /allied health professionals have conducted almost all the preventive home care reported in the international literature. None of the investigators have advocated that medical practitioners need to do the data collecting home visits. The studies have all depended on a medical practitioner interpreting the data generated and supervising, but not delivering, the ongoing services indicated.

Medicare funding adequately remunerates GPs in Australia for conducting the home visit themselves, but alternatively allows them to delegate this component to nurses or allied health professionals. (119) One Australian study has reported GPs conducting home visits for 75+ HA, (73) but no studies have evaluated the necessity for GPs to perform this function. Chew in Great Britain found that GPs concentrated on bio-medical illness which is not the primary focus of 'health checks' / 75+ HA. (20)

The data collection at home by nurses and allied health professional, on behalf of the GP, should be preserved and promoted as the optimum method of 75+ HA.

6.6.4 Home assessments only

Assessment of the independent elderly needs to include a visit to the elderly person's home. The literature reviewed does not test this model of care in the absence of home based assessments and the aspects of the 75+ HA that can only be achieved at a home visit have been detailed. The more mobile elderly are able to get to the GP's practice. They are likely to be best functioning group with no Instrumental ADL impairment and less likely to benefit from a 75+ HA. Given the marginal benefits demonstrated from 75+ HA, there is no justification for strategies that decrease the likely net return by conducting entirely practice based 75+HA. The Medicare item number for 'at consulting rooms' 75+ HA (Item 700) should be discontinued.

Recommendation 3 Nurses or allied health professionals should conduct the data collection phase of 75+ HA in the elderly person home.

Recommendation 4 ***Medicare item number 700 should be discontinued.***

6.6.5 Development of practice record systems and age-sex registers

An electronic age-sex register is required to reliably offer functional status screening or 75+ HA to the entire age specific practice population. Individual practices could create a system so they can:

Initially offer a 75+ HA to all their regular patients once in the course of a year,

Repeat the invitation annually to all patients whether they accepted or declined the offer in the previous year,

Include patients who have recently turned 75,

Categorize patients as current, casual, no longer attending the practice or deceased and

Offer other health care initiatives as they are developed.

6.6.6 Implementation of recall systems

A recall system can be used to prompt practices to offer annual 75+HA when due. Individual patient preference for participating in this model of care can be recorded; so as to not repeatedly offer a 75+ HA visit that is unwanted. This more personalized style may be more acceptable with a stable patient population than the screening process based on an age-sex register. It would need to be integrated with an age-sex register to include new patients or those recently turned 75.

Recall systems provide a more reliable way of maintaining immunisation as recommended. Data can be inserted into a practice recall system so prompts appear when immunisation is

due. This is becoming more common with increasing computerization of general practice. Current recommendation for this age group would be to set up recalls for:

Tetanus once only over age 50

Pneumococcal vaccination every 5 years

Influenza immunisation annually in the autumn (31)

Recommendation 5 Information technology systems need to be customized to facilitate components of the 75+ HA.

6.6.7 Need for Consistency of Framework for Evaluation Studies.

The evidence in the international literature is confusing with different populations sampled, different interventions, different methods of monitoring the control group, different ages of initiating this model of care and consequently inconclusive results of RCTs. These disparate data prevented Byles (46) and van Haastregt (45) from completing meta-analyses of RCT results. Consequently, this uncertainty led to van Haastregt advocating that 75+ HA be discontinued if they could not be made more effective. (45) This uncertainty could be minimised by consistency of implementation and reporting of the necessary evaluation studies.

6.6.8 Proposed Australian standard framework for reporting of 75+ HA

The proposed standard framework is offered out of a desire to be able to evaluate and compare a range of different styles of 75+ HA already in use in Australia. The difficulty of reducing the complex problems of the elderly to numerical data is acknowledged and should

not be trivialized. The need for sound evaluation is now paramount, particularly for health economic evaluation. The detail of the framework has been described and referenced and the 4 main components are:

Medical

Physical function (falls, ADL etc)

Psychological (cognition and mood)

Social /environmental

Recommendation 6 Consistency of reporting of 75+ HA will facilitate evaluation of outcomes. An Australian standard composed of 4 components is proposed:

Medical

Physical function

Psychological

Social /environmental

6.6.9 Proposed model of care for the elderly based on their functional state

Review of the recent international literature and the interpretation of this RCT suggest an appropriate risk management strategy. The independent living population aged 75 years and over, can be conceived to occupy one of 3 functional states as described by Bula. (38) Delimiting each functional state is their abilities at Instrumental and Basic ADL. The evidence quoted supports the idea that these levels of functional impairment determine health outcomes for the elderly. Provision of health care could be rationalized based on their functional state as described below.

Not functionally impaired

The studies of 'health checks' examined have not consistently demonstrated improvement in health outcome for the independent healthy aged. In the absence of good evidence, they should be left to access the "general stream" of health facilities as described in the CCT assessment of health care needs. (66, 140)

Impaired Instrumental ADL functions only

Those with one, or more, impairment of Instrumental ADL but not impairment of Basic ADL functions have been demonstrated to benefit from preventive health assessment at home.

Van Rossum selected a healthy elderly population and achieved disappointingly negative results in his RCT of 'health checks'. (13) He did however notice some positive trends in an initially "un-healthier" group whose self-rated health was poor. (0-5 out of 10.) Van Rossum had not used ADL instruments to define his "un-healthier" group. Pathy used a postal questionnaire to find the elderly who warranted a visit. (14) He achieved good results (decreased mortality) despite only intervening with a home visit in 60 % of his sample. He was in effect seeking out this middle and lowest level of functional health status. Secondary analysis of the Santa Monica study, (38) and Stuck's recent study in Bern, Switzerland, (40) support the notion that preventive in-home visits are most useful for the poorer functioning independent elderly, but without Basic ADL impairment. Bula et al conclude "in-home preventive visits delays onset of disability in people without initial Basic ADL impairment. Further studies in larger samples are needed to determine optimal intervention strategies and effectiveness among (these) well functioning older people." (38)

Thus, the elderly with only Instrumental ADL impairment are most likely to benefit from an annual 75+ HA. Emphasis should be placed on functional, psychological, social and environmental problems. A 75+ HA is likely to find problems not revealed in accessing the "general stream" of health care (66). Problem resolution will often need community and allied health professional services. GPs will benefit from the teamwork that providing this level of care will engender. The cost of this level of care will be less than the more intense care required with greater disability.

Impaired Basic ADL functions.

Those with impairment of Basic ADL functions need a more intense level of health care provision. 75+ HAs have not been demonstrated consistently to improve either their morbidity or mortality. Although initially this seemed paradoxical, it is now apparent that they need a greater intensity of care that can be provided by 'Care Plans' that provide 'coordinated care'.

Bernabei advocated Care Plans following his RCT of a more dependent group of community dwelling people aged 65+. (3) Hendriksen had conducted a RCT of "assessment and intervention" with a more intensive follow up process than most trials, including a nurse visit every 3 months. (12) He proposed that this care coordinator function in his RCT had been one of the reasons for its success. Similarly, Stuck's meta-analysis had found that "programmes with control over medical recommendations and extended ambulatory care were more likely to be effective." (32)

The elderly people with Basic ADL impairment may be recognized through the 75+ HA process, but once their first Care Plan has been created they should be maintained

at this level of care and do not need annual screening. They need more frequent than annual updating of their Care Plan.

An individual's functional state within these 3 categories of need has to be established and reviewed. Progression through levels of increasing need is to be expected. Movements between functional states will be discerned by some of the strategies reported in this thesis. Basic (41) and Instrumental (27, 28) ADL assessments will assess risk but require a formal screening process if used to categorize risk for the entire population.

Recommendation 7 75+ HA should be concentrated on the elderly with impairment of Instrumental ADL.

6.6.10 Evaluation of targeting cohorts within 75+

The independent living population aged 75 years and over, can be conceived to occupy one of 3 functional states as described by Bula. (38) Delimiting each functional state is their abilities at Instrumental or Basic ADL.

Not functionally impaired.

Impairment of neither Instrumental nor Basic ADL and in need of acute services only.

Impaired Instrumental ADL functions only.

Impairment of Instrumental ADL but not impairment of Basic ADL and demonstrated to benefit from 75+ HA.

Impaired Basic ADL functions.

Impairment of Basic ADL functions and in need of ongoing coordinated care through the provision of Care Plans.

The 75+ HA model of care may be usefully implemented by screening all of the 75+ population for functional status, hence risk. Basic and Instrumental ADL assessment could be sought for the entire 75+ population. Results could be used to initiate a level of service provision, (General stream, 75+ HA or Coordinated Care). In the conduct of this RCT, it was unethical to assess an individual and not act. A screening process could continually assess this entire age group and generate a process of care for some. Those with no functional impairment would be left to the appropriate level of 'on demand' acute care services.

Recommendation 8 A trial of screening the 75+ elderly for Instrumental and Basic ADL impairment and delivering the appropriate model of health care for each cohort should occur.

6.6.11 The Australia Coordinated Care Trials

Consistent with this analysis, the cohort of the elderly with Basic ADL impairment is at high risk of nursing home admission. Coordination of care for the elderly identified as needing extensive care is subject to ongoing trials. If positive outcomes can be consistently demonstrated, then the importance of identifying all the elderly who fit within this cohort is increased.

6.6.12 Quality of Life measurement

The SF-36 quality of life measure has been used in the Australian CCTs and in this RCT of 75+ HA. Its sensitivity to discriminate impairment in single system disease has not been established. It remains the most widely used and best-understood quality of life instrument currently available. It is generally applicable and has 8 scales that range from the purely physical to the purely psychological. Normative data sets have been established for different populations, age groups (125), and disease conditions (124). Importantly it is applicable across the functional states of health needs for the aged described here. SF-36 data collected in a 75+ HA may form part of a Care Plan dataset.

The SF-36 should continue to have a place in measuring quality of life and its ubiquitous presence will remain one of its main assets. In itself, it is too general to be a useful part of 75+ HA for the elderly. It will remain a useful tool in research and evaluation studies for comparing groups independently from the 75+ HA instrument.

Recommendation 9 The SF-36 Quality of Life measure should remain a useful tool for evaluating 75+ HA outcomes.

6.6.13 Alternate strategies for identifying the ‘at risk' elderly

Some elderly people who may fall through the gap between services are the unrecognised high risk elderly. Most of these would eventually be detected by a thorough application of annual 75+ HA. (141) Alternatively, these high-risk elderly could be recognized by other opportunistic screening strategies.

Alternative strategies, such as proposed by Martin, (77) (requests for repeat, non-psychiatric, medications) could be developed to recognise the elderly who are likely to fit into a functional status for which service provision is indicated. Targeting strategies such as this would increase the likelihood of assessment being up to date.

Recommendation 10 Alternate strategies for seeking out the elderly who would benefit from 75+ HA have been suggested. These and other potential strategies need to be evaluated.

A clearer understanding of the potential of these models of aged care will provide greater benefits. The 75+ population would benefit from health care tailored by our best understanding of their needs. General practice will be enriched by greater teamwork with the allied health professions. The medical workforce implications of this shift of care may benefit the communities, particularly rural ones, lacking adequate access to GPs. The move of health care from hospital to community is in line with known cost effective trends. Most importantly, the elderly would appreciate a greater level of health care that is sensitive to their wishes towards the end of their life.

6.7 Summary

The richness and diversity of old age cannot be reduced merely to scores on assessment instruments. Respect for the elderly demands providing appropriate care, in the most sensitive manner possible, and this can include 75+ HA.

Models of care very similar to 75+ HA have been extensively studied internationally. Conclusive evidence of the effectiveness of these models of care has not been forthcoming. Some definite conclusions can be reached from this literature review and RCT. The appropriate age to commence this model of care is 75 years. The data collection phase of 75+ HA should occur in the elderly person's home and should be conducted by a nurse or allied health professional. The Medicare item number for 75+ HA entirely in the GP surgery should be discontinued. A practical framework for reporting 75+ HA has been developed and is proposed as an Australian standard.

More favourable outcomes of 75+ HA may occur among those elderly who have impairment of Instrumental ADL but not impairment of Basic ADL. A study of screening the age specific population for Instrumental and Basic ADL impairment to guide delivery of appropriate services is proposed. The elderly without any ADL impairment can be left to access the acute care stream of services as currently. The elderly with Basic ADL impairment should have Care Plans, renewed at least twice a year. Conclusive evidence in support of Care Plans is not yet apparent from the Australian CCTs. The elderly with Instrumental ADL impairment alone may be the appropriate group to receive 75+ HA annually.

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