Prevention of Depression and Anxiety in Residential Homes for the Elderly

Els Dozeman
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VU University Medical Center
EMGO Institute for Health and Care Research
Van der Boechorststraat 7
1081 BT Amsterdam
The Netherlands
Prevention of Depression and Anxiety in Residential Homes for the Elderly

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door

Elsien Dozeman

geboren te Zaandam
promotoren:
prof.dr. A.T.F. Beekman
prof.dr. H.E. van der Horst

copromotoren:
dr. D.J.F. van Schaik
dr. H.W.J. van Marwijk
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Chapter 1

General introduction
The background to the study

Mrs. White is 85 years old, and lives in a residential home for three years.
(Interview by J. Eggink, 2010)

“I don’t care if I die now. I think life has become pretty meaningless for me. Who cares about me? Yes, I know that I am precious to my children, but they are very busy themselves. They live their own lives, and that is how it should be. I don’t have any purposes left. In the past, when my husband was still alive, I was very content with my life. I was active, and met a lot of other people to participate in social activities. But now, I don’t feel the need anymore.

Some days I speak to no one at all, except for the care workers, of course. I don’t like it when I don’t know what day it is. Especially when the weather is bad. That’s bothering me more than it did before...In the past I went out on my own by car. I went to the city, or paid a visit to friends. At this moment I am dependent on other people, whether they can give me a lift back and forth. I don’t want to ask other people for help, I don’t want to be troublesome. Not just because other people have their own lives, but also because sometimes I have to pay a visit to the toilet quickly.

I don’t participate in the day trips that are organised here. Sometimes they seem nice, but I look at the problems that may arise at the site. For instance, it is difficult for me to climb the stairs in a museum. Also, a journey together with the other residents bothers me. I am not as badly disabled as the others. My friend is really depressed, she is mentally ill and doesn’t want to do anything. She doesn’t initiate anything, I have to initiate contact with her all the time, and she never does anything in return.

Now and then I have contact with my neighbours, a nice couple. The woman is very anxious and dependent on her husband, and she needs a lot of help from him. I think it is very hard for him, but at least he has a purpose in life.

I will never become depressive. I was always a woman who took life in a positive way. The glass is half full and never half empty. But I can be bad-tempered, especially when the days are long and I don’t speak to anybody…”

Living in a residential home

In the Netherlands there are several types of sheltered accommodation for the elderly, the two most important being residential homes and nursing homes. Residential homes provide assisted living facilities, including daily care (e.g. meals and housecleaning) and, if needed, non complex medical care. Nursing homes provide more specialised care to people of all ages, who are dependent on daily medical care. The demand for residential care depends mainly on (the lack of) a social network and (in)ability to manage everyday activities (1).
In homes for the elderly, depressive and anxiety disorders are very common and have a large impact on the wellbeing and daily functioning of the residents. There is a need for effective interventions to prevent and treat these disorders. Therefore we have set up a research project to examine the effects of a stepped care protocol for prevention of depression and anxiety that has already proven to be very effective for elderly patients, living in the community. We expected that we could adapt and transfer this programme to the residential homes population. In the Netherlands, General Practitioners are responsible for the medical care in residential homes, in contrast to the medical care in the nursing homes where responsibility lies with geriatric specialists.

In 2002 over 90,000 of the nearly one million elderly persons in the Netherlands, aged 75 years or older, lived in a residential home (2). This number has declined in recent years, due to the policy in the Netherlands to keep elderly in their own homes for as long as possible. As the number of elderly persons aged 75 years or older has increased, the age level of persons in homes for the elderly has also been increasing rapidly. In addition to this the levels of psychological and physical frailty are also increasing. The distinction between residential homes and nursing homes is disappearing slowly. When we started our study, we found that the elderly people living in the residential homes were more disabled than we expected beforehand.

Mrs. White’s story is one that we have frequently heard when visiting older people living in a residential home in Amsterdam in the Netherlands. Most of the people we visited told us they were not suffering from depression, and were absolutely convinced they would never do. Most of them recognised other people who were suffering from depression, or where anxious or lonely. However, when they told us about their present life they did not seem very happy, to put it mildly. Also, when they were interviewed, a third of them were suffering from serious symptoms of depression or anxiety according to our validated instruments. Mrs. White’s story illustrates some of the complexities of becoming old while living in a residential home. First, many residents live alone, and feel lonely. Children, if any, are loved, but they are either busy living their own lives, or they are not living in the neighbourhood. Lots of residents do not want to bother them, and this is often one of the main reasons they agreed to live in a residential home. Elderly people living with a spouse often live in the residential home because one of them is suffering from cognitive or severe physical impairments, putting a heavy load on the healthier partner. All residents live in an environment with only very old, and frail neighbours. Secondly, most of them suffer from somatic illnesses, which limit their participation in (social) activities they used to enjoy in past times. Thirdly, they do not want to complain or be a burden to other people. They feel that they have to accept their fate, and that their feelings of gloom and sadness are inextricably linked to their
very old age and their situation. Even their surroundings, such as family, care workers and their doctor agree with this idea that it is a natural thing to feel sad in the given context of somatic illness, loss and disability. Indeed, most of these elderly residents only have mild symptoms and do not develop a depressive or anxiety disorder. Yet, a substantial group does (3-6), and it is important to recognise these disorders, which is difficult and complicated (7). Depression and anxiety disorders are often considered to be consequences of physical vulnerability, rather than problems that deserve attention in their own right. Therefore, the focus of treatment and care for elderly people living in a residential home is mainly restricted to physical disability and disease.

**Depression and anxiety in older persons**

Major depression is one of the most important diseases in developed countries today and is the leading cause of disability (World Health Organisation 2001). The majority of depressions in older people start late in life (8). Anxiety disorders are found to be even more prevalent in late life than depression (9), but are often disregarded. Depressive and anxiety disorders seem to have overlapping symptoms and they share many risk factors. These disorders are often associated with a poor prognosis and with excess mortality, disability, handicaps and service utilisation.

Symptoms of depression, anxiety or both are highly prevalent in older people. In the present study, 221 of 754 (29%) residents we visited had clinically relevant levels of depression or anxiety as measured with the CES-D, and another 238 (32%) scored above average (≥8 on the CES-D). These symptoms eventually develop into major depression and generalised anxiety disorder, but these subclinical manifestations may already have serious consequences for quality of life (10-12).

Major depression is characterised by an abnormal depressed mood (dysphoria) and loss of pleasure (anhedonia). For a diagnosis this affect has to be present most of the day, and nearly all days for at least two weeks. In addition, a person who is depressed is typically lacking in both mental and physical energy, suffers from poor concentration, insomnia, loss or gain of body weight, irrational feelings of guilt and/or worthlessness and thoughts about death or suicide. It has been suggested that elderly persons, especially the very old, are more susceptible to age-related biochemical changes, which increase their vulnerability to depression (8;13).

Anxiety disorders are categorised in several subtypes. In this study we focussed on generalised anxiety disorder, being the most prevalent anxiety disorder in late life, but we also assessed the incidence of panic disorder, social phobia, and agoraphobia. Late age onset of anxiety disorders is rare (14), but usually a dormant anxiety condition has existed for some time. Important risk factors for the exacerba-
tion of dormant complaints are medical conditions and being single (14). In terms of expression of anxiety disorders, the content of worry appears to be congruent with life stages. Common worries for older persons include health concerns or concerns about loss, while younger adults worry more about work, family and finances.

**Prevention**

Although treatment has improved (15), older people with depression or anxiety often remain untreated. Given the large number of people who are affected, it is unlikely that even the most resourceful health services will be able to provide adequate treatment for them all. This is an important reason why alternative strategies, such as prevention, are necessary to reduce the adverse impact of late-life depression and anxiety on the health of the population (16-18). An additional argument for applying preventive strategies is that treatment such as antidepressant medication has major limitations in this group, mainly because of somatic co-morbidity and medication interactions.

Mrazek and Hagerty (1994) suggest three types of prevention to prevent mental disorders (19). Universal preventive interventions are targeted to entire populations; selected preventive interventions are targeted at subgroups of the population considered at high risk due to shared characteristics (e.g., poverty, trauma, bereavement); and indicated interventions are focused on individuals who have early signs or symptoms of the targeted disorder but have not crossed the threshold into a clinical episode. In each case, the focus of the intervention is to reduce incidence, that is, the number of new cases of the disorder. In contrast, the goal of treatment is to reduce prevalence, that is, the number of total cases of the disorder. Given that prevention works to lower the onset of a disease, it is especially suited for high-influx disorders. In a high influx disorder, the ratio between recent incidence and prevalence is high, which means that a relatively large proportion of patients have only recently developed the disorder (20).

Recently, meta-analyses have indicated that preventive interventions are effective in reducing the incidence rate of anxiety and depressive disorders by as much as 25 - 50% in adults (20-22), and that this also holds for older people (23). Previous work has suggested that prevention is most likely to be effective when targeted at those with a high a priori risk of developing the disorder (11;12). This can be achieved by either focusing on people with established risk factors for a disorder (selective prevention) or by targeting people who manifest with early symptoms of the disorder, but have not yet developed the full-blown disorder (indicated prevention).

Focusing attention on high-risk groups is likely to be more productive than adopting universal preventive strategies, and epidemiological data can be used
to select those high-risk groups. Elderly people living in residential homes are an example of such a high-risk group for developing depressive and anxiety disorders. Chronic illnesses, disability, loneliness, older age, and female gender may all contribute to this risk, and in the residential home setting these risks accumulate (13;24).

The stepped care programme
The aim of stepped care models is to maximize the effectiveness of interventions available while making the best use of available resources. Patients are first offered the least intensive intervention. If necessary, the intensity of care is stepped up sequentially. In stepped care, more intensive treatments are generally reserved for people who do not benefit from simpler first-line treatments, or for those who can be accurately predicted not to benefit from such treatments (25). When carried out systematically, the (cost-)effectiveness of the treatment as a whole can be improved (26-28). Moreover, it is reasonable to assume that different people prefer different levels of preventive activities. Some may be helped with working through a self-help manual, others could benefit from minimal-contact psychotherapy, and still others may prefer and require a form of pharmacotherapy or more intensive individual psychological treatment. In this study we focus on residents with mild symptoms of depression and/or anxiety who do not meet the criteria of a full-blown disorder. A stepped care prevention programme may be particularly relevant for this group. Residents already suffering from disorders might be better managed through more complex and intensive collaborative-care models (27;29).

In a study carried out among people of 75 years and older living in the community in the Netherlands, the application of a stepped care prevention programme reduced the risk of developing a depressive or anxiety disorder by 57.9% (30) with effects that were retained over two years (31), and in a cost-effective way (32). These promising results suggest that preventive interventions might be very (cost-)effective when offered in a stepped care format. Also for other elderly populations, for example in residential homes.

Objectives and outline of the thesis
This study focuses on the feasibility and (cost-)effectiveness of a stepped care programme to prevent the onset of full-blown depressive and anxiety disorders among residents of homes for the elderly with mild anxiety or depressive symptoms. The primary aim of this trial was to investigate whether a stepped care programme based on monitoring and evidence-based interventions is able to prevent the onset of depressive and anxiety disorders in residents of homes for the elderly as compared to care as usual.

Based on the prospective data of the Longitudinal Ageing Study Amsterdam (LASA) we estimated the incidence rate of depressive and anxiety disorder of elderly
with symptoms of anxiety and depression within two years at 35% (33;34). Our aim was to reduce the incidence of full blown anxiety and depression disorders in the prevention group to 20%. Secondary aims included reducing costs of health care consumption and improving satisfaction with treatment. The feasibility of this protocol was judged on the basis of motivation and evaluation of residents and caring staff. Chapter 2 presents the protocol for the pragmatic randomised clinical trial. In this chapter the focus is on the design of the study.

Chapter 3 describes the results of our pilot study in one residential home in Amsterdam. The aim of the pilot study was to test our screening procedures. We found more problems than expected in screening and motivating the inhabitants for our stepped care programme. This chapter describes these problems, and the adaptations we had to make in our final procedures in the trial.

Chapter 4 concerns the characteristics of our screening instrument, the Center for Epidemiological Studies Depression Scale (CES-D) in a residential home population. The CES-D is an instrument that is commonly used to screen for depression in community-based studies of the elderly, but the characteristics of the CES-D in a residential home population have not previously been studied. The aim of this study was to investigate the criterion validity and the predictive power of the CES-D for both depressive and anxiety disorders in a vulnerable, very old population living in residential homes. The use of a single instrument to screen for both depression and anxiety disorders at the same time would have obvious advantages in this very old population.

Chapter 5 focuses on the incidence rates of clinically relevant depressive symptoms and their predictors in a vulnerable elderly population living in the community. For the estimation of incidence rates in the main study, we used existing data on the combined incidence of anxiety and depressive disorders derived from a community based longitudinal study, whereas our study is conducted in residential homes. Very old people with a vulnerable health status are under-represented in studies focussing on incidence and risk factors, while the risk of developing depressive symptoms is expected to be very high in this group. As we know that people living in a residential home often have a very vulnerable health status, the aim of this study was to fund our assumption of high incidence rates of depression and anxiety in people living in residential homes. We therefore studied incidence rates in a comparable, very old and vulnerable population, with data that were collected during a longitudinal cohort study of vulnerable elderly persons in primary care in the Netherlands.

Chapter 6 presents the results of the main objective of this thesis: the evaluation of the effectiveness of a stepped care programme to prevent the onset of depression and anxiety disorders in elderly people living in residential homes after one year.
Chapter 7 evaluates the feasibility and effectiveness of a guided self-help intervention for the prevention of depression and anxiety in elderly people living in residential homes. The guided self-help intervention was the first intervention in our more comprehensive stepped care programme. Although the study was not designed to test the effectiveness of the separate steps in the programme, we were able to evaluate the first step because no other interventions were offered before, other than a waiting period of one month. We wanted to know if the self-help intervention alone was effective in diminishing the symptoms of depression or anxiety and in increasing pleasurable activities. Also we assessed if it was feasible for residents to participate, and for care-providers to adequately implement a guided self-help intervention under the prevailing conditions in residential homes.

In Chapter 8, we reflect on the sustained effects of the stepped care programme after two years. We hypothesized that these effects might not hold, as is in line with most studies on longer term effects. However, the assessment of 2 year follow-up supplies rare information on longer term effects of prevention in a very old and vulnerable population.

Chapter 9 evaluates the cost-effectiveness of the stepped care programme to prevent the onset of depression and anxiety disorders in residents of elderly homes compared with usual care from a societal perspective.

In Chapter 10, the results of this thesis are critically reviewed. The consequences and considerations for people living in residential homes are discussed. Furthermore, recommendations for future research are given, and a reflection on the way forward for better mental health care in homes for the elderly. Finally this thesis ends with a summary in both English and Dutch.
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Chapter 2

Depression and anxiety, an Indicated Prevention (DIP) protocol in homes for the elderly: feasibility and (cost) effectiveness of a stepped care programme

Els Dozeman
Digna JF van Schaik
Aartjan TF Beekman
Wim AB Stalman
Judith E Bosmans
Harm WJ van Marwijk

Abstract:

Background
Depressive and anxiety disorders are a very common, serious and underdetected problem in homes for the elderly. Elderly persons in residential homes are at high risk for developing major depressive and anxiety disorders, and, therefore, deserve attention with regard to prevention.

Methods/Design
This protocol describes a randomised trial on the feasibility and (cost) effectiveness of a stepped care programme for prevention of depressive and anxiety disorders in homes for the elderly. The main outcome measure is the incidence of depressive and anxiety disorder in one year with a two years follow up. Secondary outcomes are symptoms of depression and anxiety, quality of life, direct health care costs and satisfaction with treatment.

Discussion
The number of studies examining the effects of preventive interventions on the incidence of mental disorders in the elderly population is very small. However, indicated prevention by means of a stepped care programme seems to be an important option for decreasing the burden of illness for residents and their caregivers. This study contributes to the body of knowledge in this field. Positive effects may contribute to further use and development of tailored, (cost-)effective and easy to use interventions in a preventive stepped care programme.

Trial Registration
The Dutch Cochrane Center, ISRCTN27540731
Background
In homes for the elderly, depressive and anxiety disorders are very common and have a large impact on the well-being and daily functioning of the residents. In 2002 over 90,000 of the nearly one million elderly persons in the Netherlands, aged 75 years or older, lived in a residential home (1). Up to 30 percent of these residents develop symptoms of depression and anxiety, such as apathy and feelings of loneliness and hopelessness (2). In about 30 to 35 percent of residents with symptoms of depression and anxiety, these symptoms eventually develop into major depression and generalised anxiety disorder (3;4). These disorders are often associated with a poor prognosis and with excess mortality, disability, handicap and service utilisation. (5-11). Treatment can reduce the illness burden in the population, but only to a moderate extent (12). Therefore, prevention may be an attractive option.

Indicated prevention, as opposed to universal prevention (aimed at the general population regardless of risk status) or selective prevention (aimed at high-risk groups), aims to counter the onset or development of a disorder in those who already have symptoms. Indicated prevention may be a successful approach since it targets high-risk persons who are identified as having minimal symptoms foreshadowing mental disorders. Risk factors for depression and anxiety disorders in the general population are known; a large naturalistic follow-up study among persons 55 years of age in the community showed that a set of six indicators explained 83% of the total prognostic variance. The prediction model include symptoms of depression and/or anxiety disorder, functional limitations, small network, female gender, low education or suffering from chronic diseases (13). These characteristics are very common among residents of homes for the elderly, which makes this a population at high risk for depressive and anxiety disorders. Indicated prevention studies, in different target populations, have shown that several interventions are capable of reducing the incidence of depression and anxiety disorder up to approximately 30% (14). From an ethical and societal point of view, indicated prevention is preferred to universal prevention and selective prevention. Prevention activities may increase fear or uneasiness in the target population; however, this is legitimated most for people who already suffer of symptoms and are known to have a high risk.

Although caregivers in the homes recognize the impact of the problem as described earlier, symptoms of depression and anxiety are rarely identified and labelled as such (15;16). A substantial part of residents of homes for the elderly suffers from physical co-morbidity. Symptoms of depression and anxiety disorder like apathy and weariness may also be ascribed to physical illnesses (17). This makes that symptoms of anxiety and depression are often interpreted only as consequences of decline rather than problems that require intervention. Physical illness in the elderly is most of the time progressive and hard to cure. Depressive
and anxiety disorders, however, have more optimistic possibilities for prevention and treatment (14;18;19). Moreover, as the population is ageing rapidly and the policy in the Netherlands is to facilitate independent living as much as possible, the level of psychological and physical frailty in homes for the elderly has been increasing rapidly. At the same time, medical care is also changing: General Practitioners (GPs), who are responsible for medical care in the residential homes in the Netherlands, have for instance halved the number of house visits since 1987 (20). In addition, most homes suffer from staff deficits, in which cases the quality of care is threatened (21). Therefore, efficient use of the available, scarce resources, as supplied by this stepped care protocol, is of great importance.

This study focuses on the feasibility and (cost-)effectiveness of a stepped care intervention to prevent the onset of full-blown depressive and anxiety disorders among residents of homes for the elderly with subthreshold anxiety and/or depressive symptoms. The stepped care protocol chosen in this study is at the moment already being used in a related study for vulnerable elderly persons in the community (22). This program is based on the assumption that stepping up from lower, less intensive to higher, more intensive levels of preventive activities, based on monitoring outcomes, may increase the (cost) effectiveness of the programme and maximize efficiency of resource allocation (23-25). Moreover, it is reasonable to assume that different people prefer and require different levels of preventive activities. Some may be helped with working through a self-help manual, others could benefit from a minimal-contact psychotherapy, and still others may require a form of pharmacotherapy or more intensive individual psychological treatment. In this study we focus on residents with subsyndromal symptoms of depression and/or anxiety who do not meet the criteria of a full-blown disorder. A stepped care protocol may be particularly relevant for this group. Residents that already suffer from disorders might be better managed through more complex and intensive collaborative-care models (24;26). The primary aim of the present trial is to investigate whether a stepped care protocol based on monitoring and evidence-based interventions is able to prevent the onset of depressive and anxiety disorders in residents of homes for the elderly as compared to care as usual. Secondary aims include reducing the level of symptoms of depression and anxiety, improving quality of life, reducing costs of health care consumption and improving satisfaction with treatment. The feasibility of this protocol is judged on the basis of motivation and evaluation of residents, caring staff and general practitioners. Organisational barriers are also assessed.
Methods
Design
To evaluate the effects of the stepped care protocol, a randomised, controlled trial in residential homes for the elderly will be carried out. Homes for the elderly in Amsterdam will be selected. Caring staff and GPs of the participating residents will be involved in the intervention protocol. Participants are asked to give informed consent referring to the stepped care interventions, the randomisation and informing their GP during the intervention programme. The medical Ethics Committee of the VU medical Center in Amsterdam approved the study design.

Participants
Participants will be recruited among residents of homes for the elderly by means of a screening procedure using the Center of Epidemiologic Studies Depression scale (CES-D 20) as a screening instrument (27-29). Residents with a score of 16 and more are invited for a follow-up diagnostic interview. This score is widely accepted as an indication for symptoms of depression and/or anxiety (30). Residents meeting criteria for major depression and/or clinical anxiety disorder according to the Mini International Neuropsychiatric Interview (MINI) (31;32) or suffering cognitive impairment according to the Mini Mental State Examination (MMSE <21) are excluded. Residents capable of informed consent and with sufficient understanding of the Dutch language, are eligible for the study.

Interventions
Stepped care protocol:
Our intervention protocol is based on the protocol of The Prevention of Anxiety and Depression in Late Life consortium (PADLL, in which several Dutch universities and the national mental health institute collaborate) (22). This consortium designed a generic stepped care intervention protocol to be tested across different health care settings, different groups of elderly persons and different forms of prevention (prevention of episodes vs. relapse prevention). For use in homes for the elderly, we selected the interventions that seemed to be most suitable for this frail and isolated population. In organizing this stepped care approach, evidence-based guidelines are used as far as possible. Staff in the homes for the elderly and mental health nurses will be contracted to cooperate in the stepped care protocol. One caregiver will coordinate the care. Necessary training will be provided. When residents show continuously elevated CES-D scores, GPs of the residents will be involved.

The protocol contains the following steps (see Figure 1):
Step 1: watchful waiting
The first step of the program consists of watchful waiting, since frequently (up to 50% of the cases) the complaints disappear without active intervention (33). Residents will be included in the intervention group in step 2 after a three months period of persisting symptoms.

Step 2: biblio-therapy and a signal to the GP
Participants, who still have symptoms of depression and anxiety after 3 months of watchful waiting, as measured with the CES-D, are informed about the possibility of learning to cope with these symptoms by a self-help course for coping with depression and anxiety with an accent on activity scheduling. Self administered treatments for depression and anxiety have proven to be successful in clinical practice and for older adults (19;34-39). Staff will be trained to accompany and stimulate the residents while working through the course in their own tempo. At the same time, GPs will be involved by informing them about the persisting symptoms. After a period of three months the third measurement will take place.

Step 3: Life review intervention and consult GP
When symptoms persist, residents are informed that they qualify for a more specific treatment: the life review with problem solving accents. Life review is a promising treatment for elderly with symptoms of depression (40). The effect for elderly with symptoms of anxiety is not explicitly studied, however support exists for a decrease in disempowerment themes, such as anxiety and despair (41). The intervention will be delivered by a mental health nurse trained and supervised in the intervention. This training will be given by experienced supervisors of the national mental health institute (Trimbos institute), who adapted this intervention for the use in homes for the elderly in the Netherlands. GP’s of participants in step 3 receive advise to check for possible somatic causes of depression and anxiety symptoms (thyroid disease, vitamin deficiencies, Parkinson disease) or intake of depressogene substances (medication, alcohol). After a period of three months the fourth measurement will take place.

Step 4: consultation mental health specialist
In case the residents still have CES-D scores > 15, they will receive advice to consult their GP to consider medication (antidepressants) and/or consultation by a mental health specialist.
Usual care:
In the Netherlands, residential homes provide daily care to the infirm elderly with significant limitations to daily living; if needed, they also provide basic medical care. Nurses and care workers supply generic care, while GPs are medically re-

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Figure 1. Stepped-care protocol
sponsible. Residents assigned to the control group receive care as usual by staff of the homes and their GPs. Residents are informed that every three months measurements with CES-D and additional interviews take place in order to keep track of the symptoms.

**Data collection**

*Primary outcome:*

Depressive/anxiety disorder:
Both the intervention and control participants will receive blinded independent assessment interviews of depression and anxiety status with the Mini-International Neuropsychiatric Interview (M.I.N.I.), at baseline, 3, 6, 9, 12 and 24 months (see

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<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Social support</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Personality (Mastery)</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>TIC-P</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Euroqol</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>x</td>
</tr>
<tr>
<td>Pt. satisfaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
</tr>
</tbody>
</table>

Table 1. Time table for data collection
The M.I.N.I. is a short structured diagnostic interview for DSM-IV and ICD-10 psychiatric disorders. With an administration time of approximately 15 minutes, it was designed to meet the need for a short but accurate structured psychiatric interview for multicenter clinical trials and epidemiology studies and to be used in outcome tracking in non research clinical settings (32).

**Secondary outcome:**

**Depressive symptoms:**
Depressive symptoms are monitored by means of the Center for Epidemiologic Studies Depression Scale CES-D. This instrument is designed specifically for the screening of depression but has also been found to be a satisfactory screener for anxiety disorders (42). It consists of 20 items and its total score has a range between 0 and 60. Scores > 15 indicate clinical significant levels of depressive and anxiety symptoms. The CES/D is also used for follow up purposes.

**Anxiety symptoms:**
For follow up measurements of symptoms of anxiety the seven anxiety items of the Hospital Anxiety and Depression scale (HADS-A) (43) will be used in addition to the CES-D. The aim is to optimise the sensitivity and specificity of the CES-D for subthreshold anxiety.

**Quality of life:**
Quality of life will be measured using the EuroQol. Using the British and the Dutch tariff (44;45), the 5 dimensions of the EuroQol will be valued to obtain utilities. Subsequently, Quality Adjusted Life Years (QALYs) will be calculated by multiplying the utilities with the amount of time a resident spent in this health state.

**Health care utilization:**
A cost-effectiveness analysis will be performed from a societal perspective. Direct health care costs (e.g. visit to GP, specialist and use of medicines) and direct non-healthcare costs (self medication) are assessed with an interview based on the Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness (TiC-P). This questionnaire is developed by the Trimbos Institute Utrecht in combination with the institute for Medical Technology Assessment Rotterdam. Since all patients were living in a home for the elderly lost productivity costs and costs of informal and formal care are not relevant in this study. Resource use was measured using an interview that was based on the TiC-P. All direct costs are considered because it is difficult to determine which costs are associated with the depression and which are not. Resource use is valued using Dutch standard costs (46). Medication costs will be valued using prices of the Royal Dutch Society for Pharmacy (47).
Patient satisfaction
To measure satisfaction with the treatment, the “GGZ thermometer, developed by the national mental health institute (Trimbos), is chosen. The instrument focuses on the appreciation of treatment explanation, the caring staff and the result of the interventions.

Effect modifiers:
We assess the following potential effect modifiers on the level of de residents: presence of chronic illnesses and handicaps (48), social support (49), loneliness (50), personality (mastery) (51) and socio demographic characteristics, such as age, gender, level of education and marital status.

Sample size
Based on the prospective data of the Longitudinal Ageing Study Amsterdam (LASA) we conservatively estimate the incidence rate of depressive and/or anxiety disorder of elderly with symptoms of anxiety and/or depression within two years at 35% (33;52). Our aim is to reduce incidence of full blown anxiety and depres-
sion disorders in the prevention group to 20%. To be able to detect this reduction (alpha=0.5 and power=0.80) 134 completers are needed, 67 in both conditions (53). In the population of elderly persons in residential homes, substantial drop out (attrition) is expected because of illness and mortality. This is estimated at 20%, so therefore we need 172 participants. We know from previous projects that two thirds of subjects complete the CES-D, and we assume 40% will score 16 or more (22). We estimate that 20% of these subjects already have a depressive and/or anxiety disorder and therefore will be excluded. With 80% consenting for randomisation, we conservatively need to screen 1200 residents to find 86 residents per arm.

**Randomisation**
At least 172 residents will be included; 86 will start in the intervention group who follow the stepped care protocol. The other 86 will receive care as usual. Subjects are randomized at the patient level per home in computer generated blocks of four by an independent statistician, simultaneously with the inclusion in the study. Blocking is used to ensure that comparison groups are of approximately the same size per home.

**Blinding**
Interviewers are kept blind from the randomisation status of participants. It is not possible to keep the residents blinded. Staff members in the homes for the elderly and GPs are not informed about allocation of the residents. However, as residents receive questionnaires, staff will be aware of participation of the residents in the project.

**Analysis**
To examine differences on the primary outcome, survival analysis will be used. The secondary outcome measures are analysed using random coefficient analyses. The analyses will be performed according to the “intention to treat” principle. Additionally, data will be analyzed according to the per protocol principle. Differences in total costs between both groups are assessed and confidence intervals are estimated using bias-corrected and accelerated bootstrapping with 2000 replications (54). Cost-effectiveness and cost-utility ratios will be calculated by dividing the difference in total costs between the intervention and usual care group by the difference in the clinical effect measures and QALYs between the treatment groups. Uncertainty around the cost-effectiveness and cost-utility ratios will calculated using the bias-corrected percentile bootstrapping method (5000 replications) (55). The bootstrapped cost-effect pairs were plotted on a cost-effectiveness plane.
Discussion

By presenting the design of this study before the results are available we aim to offer researchers the opportunity to consider the methodological quality of this study with a critical view. Caregivers can benefit by considering the information on the practical applications of the proposed protocol on a vulnerable group of residents of homes for the elderly.

The importance of psychiatric disorders to public health makes prevention a serious issue. Indicated prevention has proven to be a very promising field (56). Nevertheless, the number of studies examining the effects of preventive interventions on the incidence of mental disorders is very small, especially among elderly (14). With this study we aim to supply more scientific knowledge to base guidelines for this kind of interventions on.

This study evaluates the effectiveness of a stepped care protocol for prevention of depression and anxiety in homes for the elderly in the Netherlands, while a similar study is conducted in the community. This offers the possibility to compare the results in these different elderly populations. This comparison may supply further information about effectiveness and feasibility of this prevention strategy in different populations of the elderly.

Another strength of the chosen prevention strategy is the focus on the combination of symptoms of depression and anxiety. Risk factors for the onset of these disorders overlap (57;58). Focussing on the combination of symptoms of a target group with high risk, may therefore increase the effect of the intervention.

The randomisation is at the patient level. The risk of confounding is merely applied to the one step in the intervention protocol where staff members, all or not provide and stimulate the self-help manuals. Therefore extra efforts will be attended to instructing the staff. Moreover, research on training and education of caregivers in primary care (59-61) shows that the influence of short courses on attitude in the management of patients with mental illness as on patient outcomes is relatively small. Therefore, contamination with the usual care group is neglectable. Finally, the main disadvantage of cluster randomisation, either on ward or on home level, is lack in unity of wards and homes.

The use of a self-help course as a second step in the protocol has numerous advantages. In the first place, it can be an efficient and high quality form of therapy (35). Secondly, a self-help course may lower the threshold for those who don’t want or dare to ask for therapist treatment. Moreover, it may contribute to the effectiveness of the following step (if necessary) by preparing the client for therapeutic treatment. On the other hand, unsuccessfully treatment may cause less willingness to undergo further, more involved treatment. Therefore, a thorough explanation of the rationale and procedures of the stepped care model is important.
Activities in this prevention program are addressed to people who are at risk to develop a serious disorder, but have no explicit request for treatment. The interventions therefore need to be non-threatening and short time limited. Life review seems to be a very useful method as it is a non-stigmatising, easy to use and easily administered treatment method, suitable for elderly residents (40;62).

The results of this RCT will provide valuable information about the feasibility and (cost)effectiveness of a stepped care protocol for prevention of depression and anxiety disorders in residential homes for the elderly. Moreover, positive effects may stimulate the further development and use of guidelines by caregivers in homes for the elderly for psychiatric issues and thereby improve the quality of living in these environments. The start of the study is anticipated for October 2006 with results available in 2010.

Reference List


Chapter 3

Problems when screening for depressive and anxiety disorders in elderly persons in residential homes

Els Dozeman
Digna J.F. van Schaik
Harm W.J. van Marwijk
Anne E. de Wit
Aartjan T.F. Beekman

**Summary**

Screening for depression and anxiety in residential homes for the elderly

Elderly persons in residential homes in the Netherlands are at high risk of developing major depressive and anxiety disorders. A stepped care protocol – which has already been used in a study of vulnerable elderly in the community – may also be feasible and effective for this group. A pilot study in a residential home in Amsterdam showed more problems than expected in screening and motivating the residents in terms this intervention protocol. This article describes the problems in our screening procedure. A personal approach, performed by familiar persons, directed at the more independent inhabitants is most likely to succeed. The need for research on the effectiveness and feasibility of evidence-based methods in residential care remains evident. However, the more vulnerable residents, possibly already being considered for nursing homes, have other needs. For this group of residents we need to look more closely at their needs and opportunities by conducting research using a qualitative design.
Introduction
Depressive and anxiety disorders in elderly persons pose a serious health problem. In the LASA study (Longitudinal Aging Study Amsterdam), conducted with Dutch elderly persons (55+) from the general population, the prevalence of anxiety disorders was 10.2%, and that of depressive disorders 15.1% (1;2). In addition, comorbidity of both disorders was often observed (3). Depressive and anxiety disorders are associated with a high disease burden and a reduction in quality of life. Loneliness and general feelings of demotivation often play a central role. Persons in residential and nursing homes represent a specific elderly group in which a high prevalence of these disorders is generally found with a few exceptions (4;5). Effective treatments are available but do not adequately reach the elderly. As a result, the majority continue to experience symptoms a year later (6).

Given the high prevalence of depressive and anxiety disorders and the associated disease burden and care needs, it seems an obvious choice to conduct early screening and guidance of elderly persons in residential homes with mild symptoms of anxiety and depression. It is estimated that 30% of those in residential homes have these mild symptoms (4). This form of intervention is referred to as “indicated prevention” (7). Prevention in mental health care is currently still in development. Only 3% of the Dutch national budget for mental health care is spent on prevention. However, the different collaborating parties across the broad social field of preventative mental health care rarely apply evidence-based interventions according to professional standards. In his research on the prevention of depression, Smit (2006) showed that indicated prevention aimed at groups with a high risk can be effective (8).

This article outlines the first findings from a research project focused on indicated prevention in a high risk group, namely elderly persons in residential homes. Traditionally, residential homes in the Netherlands are intended for elderly persons still able to perform most activities of daily living independently, but who no longer wish or are no longer able to live independently. In recent years, these services have increasingly developed from housing services to care services. As of 2003, care indications are required for both nursing and residential homes, as laid down in the Exceptional Medical Expenses Act (Algemene wet bijzondere ziektekosten). The differences between nursing and residential homes have decreased and they now fall under a single heading: the “nursing and residential home sector”. However, a distinction is still being made between these care services in practice (9).

To reduce symptoms of depression, anxiety and loneliness, the department of General Practice Medicine and Psychiatry of the EMGO+ Institute for Health and Care Research/VU University Medical Center would like to conduct a randomised trial with a stepped care intervention protocol. Different residential homes in Amsterdam had stated they were prepared to test this intervention for feasibility and ef-
ficacy. Identification and motivation of the target group should, of course, precede the intervention. We commenced a pilot study in 2007 in one of the homes in order to test our proposed screening method. Screening and recruitment were more complicated than we expected, especially due to the high level of care we found the elderly to require. In this article we would therefore like to separately address the (im)possibility of screening and recruiting people with a high risk of depressive and/or anxiety disorders in this setting for participation in an intervention project. How can we better reach and motivate persons in residential homes for screening and intervention programmes, such as this?

**Method**

Before we describe our approach in relation to screening and recruitment in the pilot study, we would first like to provide a short description of the intended intervention.

**The intervention protocol**

The proposed prevention protocol has been developed for elderly persons who have a certain level of self-reliance, but who are part of an at-risk group in relation to the development of a depressive or anxiety disorder (see Figure 1). The protocol was developed analogously to a research protocol for elderly living at home (10). A detailed description of our research protocol has been previously published (11). It is known that elderly persons, particularly women, who suffer from chronic conditions, and who have many functional limitations and a small social network, are more likely to develop a depressive or anxiety disorder (8). Given many elderly persons in residential homes meet these characteristics, it is expected they will benefit from such a protocol. The protocol aligns with recent insights and contains a number of interventions offered on a step-by-step basis, based on the severity and duration of the symptoms.

**Screening**

We have prepared and conducted the screening as follows: after introducing the study to the client board and during the departmental meeting or coffee break for all departments, residents (n=177) were personally visited. The aim of the study and screening questionnaire were briefly outlined during this visit. A simple questionnaire, the Center for Epidemiology Studies Depression Scale (CES-D) (12), was used to screen for the presence of symptoms of depression and anxiety. The CES-D was originally developed as a “self-completion instrument” for research within the general population and also appears to be a suitable instrument for elderly persons in residential homes (13). The questionnaire contains 20 questions with 4 possible answers. A score of 16 is the generally accepted cut-off point for
clinically relevant symptoms of depression and/or anxiety (14). During screening in the residential home, all elderly persons were individually asked if they were willing to complete the list and whether they would like help doing so. They were able to choose between assistance from family, staff members of the home or the research assistant. If residents appeared to have symptoms, the guidance model

![Step 1: watchful waiting](image1)

**Step 1: watchful waiting**
Time: 3 months
Activities: No treatment. Measurement of levels of symptoms with self-report scale (CES-D20) after 3 months and MINI (T1)

Filter to next step: symptoms below threshold CES-D (<16)
Expected % filtered out: 50%, % remaining: 50%

![Step 2: bibliotherapy and a signal to the GP](image2)

**Step 2: bibliotherapy and a signal to the GP**
Time: 3 months
Activities: stimulation and accompaniment by staff at the self help course. Measurement of levels of symptoms with self-report scale (CES-D20) after 3 months and MINI (T2)

Filter to next step: symptoms below threshold CES-D (<16)
Expected % filtered out: 50%, % remaining: 25%

![Step 3: Life review intervention and consult GP](image3)

**Step 3: Life review intervention and consult GP**
Time: 3 months
Activities: Life review by trained mental health nurses and consult GP for medical consult and advice. Measurement of levels of symptoms with self-report scale (CES-D20) after 3 months and MINI (T3)

Filter to next step: symptoms below threshold CES-D (<16)
Expected % filtered out: 50%, % remaining: 13%

![Step 4: consult GP and/or mental health specialist for medication and advice](image4)

**Step 4: consult GP and/or mental health specialist for medication and advice**
Time: 3 months
Activities: consult GP to consider suitable medication (antidepressants) and/or consultation by a mental health specialist. Measurement of levels of symptoms with self-report scale (CES-D20) after 3 months and MINI (T4)

Filter to next step: symptoms below threshold CES-D (<16)
Expected % filtered out: 50%, % remaining: 7%

Figure 1. stepped care protocol
### Table 1. Overview of reasons for deciding not to participate.

<table>
<thead>
<tr>
<th>Category</th>
<th>Reason</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical:</strong></td>
<td>feels very sick</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>not able to talk or with great difficulty</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>too tired, study costs too much energy</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>too deaf/blind to understand</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>disabled and requiring help</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>in a lot of pain</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>21 (23%)</td>
</tr>
<tr>
<td><strong>Psychological:</strong></td>
<td>no contact possible</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>already receiving psychiatric treatment</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>problems with comprehension and concentration</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>anxious, suspicious</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>grieving; has just lost a family member</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>confused</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>19 (20%)</td>
</tr>
<tr>
<td><strong>Motivation:</strong></td>
<td>does not feel like it</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>refuses to receive the researcher</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>does not feel up to it</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>no issues at all</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>32 (35%)</td>
</tr>
<tr>
<td><strong>Remaining:</strong></td>
<td>moving very soon, back to independent living</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>does not speak and understand any or barely any Dutch</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>aggressive</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>temporarily elsewhere</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>unknown</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td>20 (22%)</td>
</tr>
</tbody>
</table>
was explained in more detail and they were asked if they would like to participate in the study. A pre-existing depressive and/or anxiety disorder was subsequently excluded using the MINI International Neuropsychiatric Interview (M.I.N.I) (15). The cognitive ability of the resident was also measured in order to assess if they would be able to benefit from the interventions offered. The “Mini-Mental State” (MMSE) (16) at a cut-off point of 21 was used for this.

Results
At the time of the screening period, 177 elderly persons lived in the relevant residential home, in eight different care departments. The average age was 83.6 years (SD=8.4), and 43% were male. There was no difference in age and both genders were evenly divided between participants and non-participants. The screening period took a total of four weeks. 56% of the residents did not fill in the CES-D: seven (4%) passed away during this period, 56 (32%) immediately indicated they were not willing to participate, or were not able to participate in the screening and 36 (20%) did not wish to participate after they had received and read the CES-D. The reasons for not filling in the CES-D are summarised in Table 1, both for those who immediately decided they would not participate and those who did so after reading it. In the event multiple reasons were provided, we decided which reason was decisive. 24 indicated they did not “feel like” being part of such a study. Residents mentioned different aspects in relation to this when asked further questions: some found themselves too old to change, some did not wish others to be interfering in their affairs, but some also found such a confrontation taxing or it made them nervous.

Of the 78 residents for which a CES-D score could be determined (44% of the total), 29 (37%) scored higher than or equal to the cut-off point of 16, indicating clinically relevant symptoms of depression and/or anxiety. On the basis of their symptom profile, these 29 residents were therefore eligible for participation, but six were younger than the lower age limit of 75 (21%) and 19 of the remaining 23 (83%) decided not to participate in the study. Residents were able to indicate multiple reasons for this on the consent form. Four residents were willing to participate in the study and underwent a diagnostic interview. All four satisfied the criteria for depression, one of them had an anxiety disorder. Given the presence of a depressive or anxiety disorder is an exclusion criterion for this preventative intervention, no one was in fact eligible to participate in the study. The findings have been summarised in a flow chart (see Figure 2).

Discussion
Our aim was to offer a prevention programme for elderly at high risk of developing depression and anxiety. A comparable protocol was found to be feasible with fragile elderly persons (75+) in the general population, and it therefore also seemed
to be a suitable method for elderly persons in residential homes. Of all residents approached, 44% were prepared and/or able to fill in the screening list, with help if required. This was lower than we had expected on the basis of the previously mentioned research in the general population, in which two thirds completed this list. Of the residents who filled in the questionnaire, 37% appeared to have symptoms...
of depression and/or anxiety. It can be derived from this that the prevalence of the symptoms of depression and anxiety in this residential home is certainly as high as expected. However, we were subsequently expecting, on the basis of comparable research in the general population, that 80% of these residents with symptoms were prepared to participate. This was not the case.

**Suggestions for effective screening and recruitment of elderly persons in residential homes**

An adjustment to the screening procedure on the basis of the results comprising a personal interview with more opportunities for residents to discuss any reluctance and other considerations, accompanied by more information. Discussion with a client participation council confirmed this thought. Residents also indicated that “a feeling of trust” in the interviewer was important in order to want to participate in such a procedure. Given that physical limitations in filling in the questionnaire played a role for 24% of residents, an interview in which answer cards are used will further increase the percentage of residents able to participate. Answer cards were also used in the earlier mentioned LASA study, which may have played a role in the higher response in this study. It should be noted here that it was initially the intention to have the screening (partially) conducted by the staff members of the residential homes themselves, using existing observation instruments. However, this was not found to be feasible in this residential home due to the home being understaffed and the care personnel being overloaded. Implementation of such instruments is currently at different stages in different homes. We believe this development deserves attention in all homes.

Aside from an adjustment in the implementation of the screening interview, the target group chosen also appears to be crucial for feasibility of interventions specifically focused on depression and anxiety. Physical and psychological limitations form a great obstacle to participation. Comparable problems were encountered in a study with a stepped care protocol for depressed persons in nursing homes. Over 30% of those nursing home residents could not be approached because they did not function sufficiently on a cognitive or communicative level or were too ill according to the physician. Residents who refused to participate in that study gave a poor physical condition and too heavy emotional burden as reasons for not participating (17). In our study, the majority of residents with depressive or anxiety symptoms also indicated their decision not to participate was related to their poor physical condition. As a result, the feasibility of this protocol for these residents seems doubtful. An important finding from this pilot study is that this fragile group cannot be reached by screening. The question is how this group of people, who are close to the care needs of nursing home residents or already have an indica-
tion for such a home, can be reached and which interventions would subsequently be feasible.

An interesting finding within this framework is that Smalbrugge (2006) has found that the number of new cases of depression (incidence) is relatively small in the nursing home setting. The prevalence even decreases by 30% in the first half year after admission. Smalbrugge (2006) therefore poses that it is plausible that living in a protected environment, with specifically trained nursing home practitioners in a multidisciplinary team contributes to the reduction in symptoms (18). It is possible elderly persons in residential homes, who have a care need level comparable to that of nursing home residents, but whose care needs are not being met, are missing out on this benefit. Within the context of general practice medicine, employing specialised elderly care nurses for this specific target group could be a consideration.
References


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Chapter 4

The Center for Epidemiological Studies Depression Scale (CES-D) is an adequate screening instrument for depressive and anxiety disorders in a very old population living in residential homes.

Els Dozeman
Digna J.F. van Schaik
Harm W.J. van Marwijk
Max L. Stek
Henriette E. van der Horst
Aartjan T.F. Beekman

Abstract:

Objective
The CES-D is an instrument that is commonly used to screen for depression in community-based studies of the elderly, but the characteristics of the CES-D in a residential home population have not yet been studied. The aim of this study was to investigate the criterion validity and the predictive power of the CES-D for both depressive and anxiety disorders in a vulnerable, very old population living in residential homes.

Methods
277 residents were screened with the CES-D, and subsequently interviewed with a diagnostic instrument, the Mini International Neuropsychiatric Instrument. The sensitivity, specificity, and positive and negative predictive value of the CES-D were calculated by cross-tabulation at different cut-off scores. Receiver Operating Characteristics curves were used to assess the optimal cut-off point for each disorder and to assess the predictive power of the instrument.

Results
In a residential home population the CES-D had satisfactory criterion validity for depressive disorders and for any combination of depressive and/or anxiety disorders. With a desired sensitivity of at least 80%, the optimal cut-off scores varied between 18 and 22. The predictive power of the CES-D in this population was best for major depression and dysthymia (Area Under the Curve, AUC 0.87), closely followed by the score for any combination of depressive and/or anxiety disorder (AUC 0.86).

Conclusion
The use of one single instrument to screen for both depression and anxiety disorders at the same time has obvious advantages in this very old population. The CES-D seems to be a suitable instrument for this purpose.
Introduction
Although depression and anxiety are common disorders among elderly people living in residential homes (1-4), recognition of these disorders is difficult and complicated (5). Depression and anxiety disorders are often considered to be consequences of physical vulnerability, rather than problems that deserve attention in their own right. Therefore, the focus of treatment and care for elderly people living in a residential home is mainly restricted to physical disability and disease. However, because depression and anxiety disorders are amenable to treatment, more attention should be paid to improving the recognition rates.

Routine screening of residents for symptoms of depression and anxiety with standardised instruments may be helpful in improving psychosocial care in homes for the elderly (6;7). Screening may detect those residents who are already suffering from disorders, and who need treatment according to the current guidelines. Moreover, a screening procedure may be important in selecting and monitoring elderly people with (mild) symptoms, in order to prevent the onset of disorders (8;9).

Although several screening instruments are available, there is, as yet, no depression and anxiety screening instrument that is systematically used in residential homes in the Netherlands. For such screening, there is a need for "psychometrically sound" and easy-to-use instruments that generate an acceptable workload. Sensitivity and specificity, also referred to as "criterion validity", are important criteria for a screening instrument, as are the positive predictive value (PPV) and the negative predictive value (NPV) which determine its feasibility. Both the PPV and the NPV depend on the prevalence of the measured disorder.

The Center for Epidemiological Studies Depression Scale (CES-D) has been used as a screening instrument for depression in a large number of community-based studies of the elderly (10-12), and its sensitivity and specificity for depression have been found to be very good in this population (13;14). Moreover, several studies have focussed on the characteristics of the CES-D in medical settings (15-18), no studies have yet focussed on the characteristics of the CES-D in the vulnerable, very old population living in residential homes. Characteristics of the CES-D in such a population might differ from those in the more healthy general population living in the community. Both psychiatric and medical comorbidity may lower the sensitivity of the CES-D in the residential home setting. Optimal cut-off scores reported for depression are usually higher in populations with a high rate of psychiatric disorders than in the general population (15;18;19). Therefore, the optimal cut-off point at which to identify depression in residential homes is also expected to be higher than the cut-off point used in the general population. Depression and anxiety disorders are highly interrelated, and the symptoms of the two disorders often overlap. Therefore, the CES-D is sometimes also used as an instrument to detect anxiety disorders as well as depressive disorders (20).
use of one single instrument to screen for both depressive and anxiety symptoms has obvious advantages, not only in relation to the workload for the professionals, but also in relation to the capacities of the residents. However, we know little of the characteristics of this instrument with regard to the detection of anxiety disorders, especially in this type of population, and the optimal cut-off point for depression may differ from the optimal cut-off point for anxiety.

The main aim of this study was to investigate the characteristics of the CES-D in a residential home population, in order to assess its adequacy as a screening instrument for depression and anxiety disorders in this particular setting, and to determine the appropriate cut-off points. The second aim was to investigate the accuracy of the CES-D as a single screening instrument for both disorders together in this population.

**Methods**

**Procedures and participants**

The assessments in this study took place within the context of a stepped care prevention trial among elderly people who were at high risk for developing depression and/or anxiety disorders, living in residential homes in the Netherlands (21).

It was assumed that these residents were at high risk because they have many known risk factors for depression and anxiety disorders. These have been studied in the general population in a large naturalistic follow-up study among persons, 55 years of age and over. A parsimonious set of six indicators explained 83% of the total prognostic variance. This prediction model included symptoms of depression and/or anxiety disorder, functional limitations, small network, female gender, low education, or suffering from chronic diseases (22). These characteristics are very common among residents of homes for the elderly, which makes this a population at high risk for depressive and anxiety disorders. In two other studies it was found that up to 30% of older people living in residential homes and institutions in the Netherlands and in England develop symptoms of depression and anxiety, such as apathy and feelings of loneliness and hopelessness (23;24). Finally it was found that about 30-35% of the residents in residential and nursing homes with symptoms of depression and anxiety, develop major depression and/or generalised anxiety disorder (24-26).

We approached five major organisations providing care for older people in and surrounding the city of Amsterdam, four of which were willing to participate in the trial. The fifth organisation did not wish to participate because it was already involved in another research project at that time. The four participating organisations contained 14 residential homes. In the Netherlands, there are various facilities providing support and accommodation for older people, the two most important being residential homes and nursing homes. Residential homes provide daily care,
and residents (over 65) can choose their own health care providers, whereas nursing homes provide more specialist medical care to people of all ages. The lack of a social network, as well as the inability to manage everyday activities, is highly associated with older people’s demand for residential care (27). Most of the people in the residential homes live alone, but some live together with their spouse. An introductory letter, explaining the purpose of the research, was sent to all residents households (elderly people living alone or together with a spouse), after which interviewers visited every household and asked for permission to interview the resident(s) about symptoms of depression and/or anxiety. A total of 1,478 residents were approached, 754 of whom (51%) were able and willing to participate, according to the screening interview. Reasons for not being able to participate were mostly physical complaints (illness, inability to talk, see or hear, or too much pain), as well as psychological complaints (too confused to answer, not possible to make contact, too much grief, or too suspicious). 459 residents scored above the chosen cut-off point for participation in the follow-up interview, and 277 (60% of the eligible residents) subsequently gave informed consent for a diagnostic interview. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

Measures
Symptoms of depression and anxiety were measured according to the CES-D, which is a self report scale (28). This instrument was designed specifically to screen for depressive symptoms in the general population, but it has also been used to screen for anxiety symptoms (20;29). It consists of 20 items, and the total score ranges between 0 and 60. Scores of ≥ 16 are regarded as clinically significant levels of depressive symptoms in the general population (10). We invited respondents with a score above the CES-D cut-off point of 8 for a follow-up interview based on a diagnostic instrument. Those who scored below this cut-off point were not invited for the follow-up interview, because the prevalence of depressive and anxiety disorders is expected to be zero below this cut-off point.

Age, gender and demographic variables were recorded. Major depression, dysthymia, panic disorder, social phobia, agoraphobia, and generalised anxiety disorder were assessed with the Mini International Neuropsychiatric Instrument (MINI) (30). The MINI is a short, structured diagnostic interview for DSM-IV and ICD-10 psychiatric disorders. With an administration time of approximately 15 minutes, it has been designed to meet the need for a short, but accurate structured psychiatric interview for multicenter clinical trials and epidemiological studies, and to be used for outcome tracking in non-research clinical settings.
Analysis
First, missing answers on the CES-D were imputed with the mean score for the total list. Missing scores on the MINI were counted as negative answers, and we also counted the total number of “don’t know” answers on the CES-D and the MINI. The characteristics of our study population (n=277) with regard to symptoms and diagnosis of depression and anxiety, were described, using SPSS 14.0. To describe the residential home population in our study we interviewed the participants about demographic and physical characteristics, only after they were founded to be eligible for participation in the trial. 185 of the 277 residents in the study population were finally included in the trial, and therefore these residents were described in more detail.

The sensitivity of the CES-D for depressive and anxiety disorders was calculated by cross-tabulation at different cut-off scores (CES-D ≥ 16, 18, 20, 22). Subsequently, the specificity of the CES-D for these disorders, and the PPV and NPV were analysed in the same way. The association between CES-D scores and diagnostic measurements were analysed by calculating Receiver Operating Characteristics (ROC) curves. The closer the Area Under the ROC Curve (AUC) is to 1, the better the predictive power of the CES-D (31). The AUC can be regarded as the probability of correct prediction. A sensitivity below 80% is incompatible with most screening purposes. Therefore, cut-off points were first evaluated by assuring a sensitivity score in this population of at least 80%. A predictive power ≥ 0.8 is then considered to be very satisfactory. Finally, we compared the mean scores for the 20 items of the CES-D for depression and for anxiety disorders, in order to investigate the possibility of a difference in pattern between the two diagnosis.

Results
The baseline characteristics of our study population are summarised in Table 1. According to the MINI, 15.2% of the residents had a depressive disorder and 10.8% had an anxiety disorder. Moreover, 4.3% of the residents suffered from both disorders at the same time. Finally, 21.7% of the residents were found to be suffering from a depressive and/or anxiety disorder. In the residential population that we subsequently interviewed for the trial, 76.2% lived alone, 77.2% had completed primary or secondary education, and 22.8% had completed higher or scientific education. Finally, 71.9% suffered from two or more chronic diseases, such as cardiovascular diseases or diabetes.

Refusal to answer certain items was negligible. Of the 22,160 possible answers to the CES-D items, the answer “don’t know” was given only 15 times; of the 27,700 possible answers to items on the MINI, this answer was given 28 times.

The sensitivity, specificity and PPV for different cut-off points are shown in Table 2, and the optimal cut-off points are hatched in grey. When the aim was to detect
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total (N=277)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>84.6 (7.2)</td>
</tr>
<tr>
<td>Age range</td>
<td>61.6 – 101.9</td>
</tr>
<tr>
<td>Female gender N (%)</td>
<td>204 (73.6)</td>
</tr>
<tr>
<td>CES-D score ≥ 16 (%)</td>
<td>137 (49.5)</td>
</tr>
<tr>
<td>CES-D score ≥ 18 (%)</td>
<td>113 (40.8)</td>
</tr>
<tr>
<td>CES-D score ≥ 20 (%)</td>
<td>86 (31.1)</td>
</tr>
<tr>
<td>CES-D score ≥ 22 (%)</td>
<td>61 (22)</td>
</tr>
<tr>
<td>Depression and/or anxiety (%)</td>
<td>60 (21.7)</td>
</tr>
<tr>
<td>Major Depressive Disorder (MDD) N (%)</td>
<td>35 (12.6)</td>
</tr>
<tr>
<td>Generalised anxiety N (%)</td>
<td>18 (6.5)</td>
</tr>
<tr>
<td>Dysthymia N (%)</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Panic disorder N (%)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Social phobia N (%)</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Agoraphobia N (%)</td>
<td>14 (5.1)</td>
</tr>
<tr>
<td>Depressive disorder* N (%)</td>
<td>42 (15.2)</td>
</tr>
<tr>
<td>Anxiety disorder** N (%)</td>
<td>30 (10.8)</td>
</tr>
<tr>
<td>Depressive disorder* and co-morbid anxiety disorder ** N (%)</td>
<td>12 (4.3)</td>
</tr>
</tbody>
</table>

* MDD and dysthymia
**one or more of the following disorders: Generalised Anxiety, Panic disorder, Social phobia, Agoraphobia

Table 1. Baseline characteristics of participants
major depressive disorder (MDD), 80.9% of the residents were identified correctly at a cut-off point of 22. Using this cut-off point, the chance of correctly identifying a person with a MDD is tripled, from 12.6% at baseline to 41.2% when using this screener. Moreover, 83.4% of the residents were correctly identified as not having any disorder at this cut-off point. Taking MDD and dysthymia together, the optimal cut-off point is 20. When screening for anxiety disorders, the sensitivity for a generalised anxiety disorder as well as for all anxiety disorders together is very satisfying at a cut-off point of 18 (resp. 88.9% and 86%). However, the probability of correctly identifying the absence of a disorder at this cut-off point is only 62.5% resp. 64.8%. The a-priori chance of correctly identifying the presence of anxiety disorders is doubled.

When the aim is to use the CES-D to screen for any depressive and/or anxiety disorder, 83.3% of the residents were identified correctly as having a disorder at a cut-off point of 18, and 70.9% of the residents were correctly identified as having no disorder. The PPV is 44.2% at this cut-off point, implying that the a-priori chance of correctly identifying the presence of a depressive and/or anxiety disorder (21.7% at baseline) is doubled to 44.2%. With a cut-off of 20, the PPV further increases to 51.2% for both disorders together, but at this cut-off point the sensitivity drops below 80%. The NPV remains far above 90% for all the various disorders at different cut-off points, except for depressive and/or anxiety disorder at a cut-off point of 22 (NPV=90.0%) (NPV not shown in table).

The predictive power of the CES-D in this population was best for MDD and for depressive disorders, being the sum of MDD and dysthymia. The AUC found with ROC analyses, was 0.88 for MDD (Standard Error [SE]=0.032; 95% confidence interval (CI) 0.81 – 0.94 ; p<0.001), as well as for depressive disorders (SE=0.030; 95% CI 0.81 – 0.93 ; p<0.001). The predictive power was second best when screening for any depressive and/or anxiety disorder, where the AUC was
0.86 (SE=0.025; 95% CI 0.81 – 0.91 ; p<0.001) (Figure 1). For generalised anxiety disorder the predictive power was also very satisfactory; 0.84 (SE=0.039; 95% CI 0.77 – 0.92 ; p<0.001).

Finally, the pattern of scores for the 20 CES-D items separately did not differ between depressive disorders and anxiety disorders. Only on the last item (I could not get “going”), a small significant difference was found between the depression and the anxiety score (see Table 3).

Conclusions and discussion
The major conclusion of this study is that the CES-D is suitable for the detection of both depressive and anxiety disorders in a vulnerable, very old population living in residential homes.

Using the CES-D with a cut-off at >18, the sensitivity for Generalised Anxiety Disorder (GAD) was 88.9% and the specificity was 62%, while the PPV was 14.2%.
<table>
<thead>
<tr>
<th>CES-D items (range 0: rarely or none – 3 most or all of the times)</th>
<th>Depressive disorder Mean (SD) (N=30)</th>
<th>Anxiety disorder Mean (SD) (N=18)</th>
<th>Difference (BI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I was bothered by things that don’t usually bother me</td>
<td>1.3 (1.1)</td>
<td>1.2 (0.9)</td>
<td>0.1 (-0.7 – 0.6)</td>
</tr>
<tr>
<td>I did not feel like eating</td>
<td>1.3 (1.2)</td>
<td>0.9 (1.0)</td>
<td>0.4 (-1.1 – 0.3)</td>
</tr>
<tr>
<td>I felt that I could not shake off the blues</td>
<td>1.3 (1.1)</td>
<td>1.4 (0.9)</td>
<td>0.1 (-0.5 – 0.7)</td>
</tr>
<tr>
<td>I felt that I was just as good as other people</td>
<td>0.8 (1.1)</td>
<td>0.7 (1.0)</td>
<td>0.1 (-0.8 – 0.6)</td>
</tr>
<tr>
<td>I had trouble keeping my mind on what I was doing</td>
<td>1.4 (1.0)</td>
<td>1.1 (1.1)</td>
<td>0.3 (-0.9 – 0.4)</td>
</tr>
<tr>
<td>I felt depressed</td>
<td>1.5 (1.1)</td>
<td>1.3 (0.9)</td>
<td>0.2 (-0.9– 0.4)</td>
</tr>
<tr>
<td>I felt everything I did was an effort</td>
<td>1.7 (1.2)</td>
<td>1.4 (0.8)</td>
<td>0.3 (-0.9– 0.4)</td>
</tr>
<tr>
<td>I felt hopeful about the future</td>
<td>2.1 (1.0)</td>
<td>2.0 (1.2)</td>
<td>0.1 (-0.8 – 0.6)</td>
</tr>
<tr>
<td>I thought my life had been a failure</td>
<td>0.6 (1.0)</td>
<td>0.5 (0.9)</td>
<td>0.1 (-0.8 – 0.4)</td>
</tr>
<tr>
<td>I felt fearless</td>
<td>0.7 (1.0)</td>
<td>0.5 (0.7)</td>
<td>0.2 (-0.7– 0.4)</td>
</tr>
<tr>
<td>My sleep was restless</td>
<td>1.4 (1.1)</td>
<td>1.3 (1.3)</td>
<td>0.1 (-0.8 – 0.6)</td>
</tr>
<tr>
<td>I was happy</td>
<td>2.0 (1.0)</td>
<td>1.6 (1.0)</td>
<td>0.6 (-1.0 – 0.3)</td>
</tr>
<tr>
<td>I talked less than usual</td>
<td>0.7 (0.9)</td>
<td>0.8 (1.0)</td>
<td>0.1 (-0.4 – 0.7)</td>
</tr>
<tr>
<td>I felt lonely</td>
<td>1.2 (1.0)</td>
<td>1.1 (1.1)</td>
<td>0.1 (-0.8 – 0.5)</td>
</tr>
<tr>
<td>People were unfriendly</td>
<td>0.6 (1.0)</td>
<td>0.1 (0.3)</td>
<td>0.5 (-1.0 – 0.1)</td>
</tr>
<tr>
<td>I enjoyed life</td>
<td>2.4 (0.8)</td>
<td>2.2 (0.8)</td>
<td>0.2 (-0.8 – 0.3)</td>
</tr>
<tr>
<td>I had crying spells</td>
<td>0.8 (1.0)</td>
<td>0.6 (0.7)</td>
<td>0.2 (-0.8 – 0.4)</td>
</tr>
<tr>
<td>I felt sad</td>
<td>1.3 (1.0)</td>
<td>1.3 (0.9)</td>
<td>0.04(-0.5 – 0.6)</td>
</tr>
<tr>
<td>I felt that people disliked me</td>
<td>0.5 (0.9)</td>
<td>0.3 (0.5)</td>
<td>0.2 (-0.6 – 0.3)</td>
</tr>
<tr>
<td>I could not get “going”</td>
<td>1.7 (1.0)</td>
<td>1.0 (1.1)</td>
<td>0.7 (-1.3 - -0.04)</td>
</tr>
</tbody>
</table>

Table 3. Mean scores of CES-D items concerning depressive and anxiety disorders
For all anxiety disorders, the sensitivity was 86.7%, the specificity was 64.8% and the PPV was 23%. The base rate of all anxiety disorders was 10.8%. These figures would suggest that the CES-D is highly sensitive for anxiety disorders and for GAD. With regard to sensitivity, the CES-D performs just as well for depressive disorders as for anxiety disorders. Looking at Table 2, the specificity for GAD and MDD are very similar, at similar CES-D cut-off points. However, at the optimal cut-off point (which is higher for MDD than for GAD), the specificity for MDD is better than the specificity for GAD. The PPVs are best for MDD, lower for GAD, and lower still for Dysthymia. The CES-D distinguished accurately between residents with and without depressive and/or anxiety disorders together at a cut-off point of 18. The predictive power of the instrument when screening for depressive and/or anxiety disorders together is also very satisfactory. Therefore, the criterion validity of the CES-D is most satisfactory for depressive disorders and for depressive disorders and/or anxiety disorders together, slightly but less satisfactory for anxiety disorders only. The items on the CES-D do not differentiate between depressive disorders and anxiety disorders in this population, in which apparently, the symptoms of these disorders greatly overlap.

In our study population the optimal cut-off scores differed for depressive disorders and for anxiety disorders. For MDD and/or dysthymia the cut-off score was 20, rising to 22 for MDD alone. These relatively high scores are consistent with the findings in other settings with a high prevalence of depression and/or anxiety (19). Based on the desired sensitivity of at least 80%, the optimal specific cut-off point for anxiety disorders, was 18. However, the rate of false positives at this cut-off point makes the instrument less appropriate, which is in line with the original development of the CES-D as a screening instrument for depression. Other instruments that are used to screen for depression, such as the Geriatric Depression Scale (GDS) (32) may also have good, or even better properties for screening for depression in a vulnerable, very old population. Blank (15), for instance, has reported a sensitivity of 86% and a specificity of 82% in nursing home residents in the USA. However the GDS has not been used to screen for anxiety disorders. The practical benefit of using only one instrument, and screening for depression as well as anxiety disorders at the same time, makes the use of the CES-D attractive in this population.

Several methodological issues might affect the interpretation of our data. For instance, the length of the interview and the “taboo” concerning psychiatric disorders in this older generation may have made some of the residents unwilling to participate, and this group may have included more depressive and/or anxious residents. However, the impact on the results of this study would remain small, because the prevalence rate for depressive and anxiety disorders is already relatively high in this older population. Furthermore, the CES-D was originally designed as a self-
report instrument, and because most of the residents in this study population were unable to fill in the questionnaires, they were interviewed by trained interviewers. This might have lowered the final CES-D scores to some extent because of socially desirable answers (a ‘mode effect’).

Selecting a cut-off point amounts to finding a balance between sensitivity and specificity. For practical purposes, such as annual screening in residential homes, maximal sensitivity is most convenient, because it prioritises depression case-finding and minimises missed cases. However, when medical and psychiatric resources are restricted, as in most residential homes in the Netherlands, a minimum of false positives is also important. Raising the cut-off point has the desired effect of reducing the number of false positives, but comes at the cost of a greater number of missed cases. At individual level, the use of the CES-D as a screening instrument doubles the probability of correct identification of the presence of a depressive and/or anxiety disorder in this setting. The probability of correctly identifying the absence of a disorder remains above 90% at different cut-off scores for all disorders, implying that the probability of correct identification of a person as not being ill is very satisfactory. The question that remains is whether doubling the a-priori chance to correctly identify the presence of disorders is sufficiently satisfactory in a setting with restricted resources. The instrument may well be used for ruling out depression and anxiety, but requires further diagnostic assessment for all subjects scoring ≥ 18. In particular, follow-up diagnostic assessment is not only necessary to confirm the diagnosis of a disorder, but also to differentiate between depressive disorders and anxiety disorders.

In conclusion, when using the CES-D as a screening instrument in a residential home setting, attention must be paid to the possibility that scores above 18 not only indicate a depressive disorder, but also an anxiety disorder. In residential care it is important that parsimonious use is made of screening tools. One can use the CES-D to screen for both groups of disorders, but the optimal cut-off point for different specific disorders varies, and its specificity for anxiety disorders is somewhat lower than its specificity for depressive disorders (as were the base rates for these disorders).
**Key points:**

1. Recognition of depressive and anxiety disorders in a residential home population is complicated, and therefore there is a need for “psychometrically sound” screening instruments that are easy to use.

2. The criterion validity of the CES-D is higher for depressive disorders and for any combination of depressive disorders and/or anxiety disorders, and lower for anxiety disorders only.

3. The optimal cut-off points for depressive and/or anxiety disorders differ, and are higher in this population than in the general population.

4. The CES-D is an adequate single instrument with which to screen for any combination of depressive and/or anxiety disorders together in a residential home population.
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Chapter 5

High Incidence of Clinically Relevant Depressive Symptoms in Vulnerable Persons of 75 Years or Older Living in the Community

Els Dozeman
Harm W.J. van Marwijk
Digna J.F. van Schaik
Max L. Stek
Henriette E. van der Horst
Aartjan T.F. Beekman
Hein P. van Hout

Aging Ment Health. 2010 Sep;14(7):828-33
Abstract:

Objectives
Clinically relevant depressive symptoms are highly prevalent in people who are 75 years of age or older. However, very old people with a vulnerable health status are under-represented in studies focussing on incidence and risk factors, while the risk of developing depressive symptoms is expected to be very high in this group. The incidence rates of clinically relevant depressive symptoms and their predictors were investigated in a vulnerable elderly population.

Methods
In a community-based cohort, 651 vulnerable elderly (75+) people were identified by means of the COOP-WONCA charts. To study the incidence of clinically relevant symptoms of depression and their predictors, 266 people with no symptoms (CES-D score < 16 at baseline) were selected and measured again at 6 and 18 months. The incidence of clinically relevant symptoms of depression was defined as a CES-D score ≥ 16, in combination with at least a 5-point change between measurements. Logistic regression analyses were applied to determine risk indicators.

Results
After 18 months, the incidence rate of all clinically relevant symptoms of depression was 48% (95% CI 44.2-51.8). A vulnerable health status in elderly people, as measured with these charts, is associated with a high risk of depressive symptoms. No specific risk factors were identified within this population.

Conclusion
Our estimates of the incidence of depressive symptoms were considerably higher than those previously found in elderly populations living in the community. A vulnerable health status is associated with a high risk of depressive symptoms.
Introduction
The population in Western societies is rapidly growing older, and this will result in a pronounced increase in the number of very old vulnerable people in future decades. Self-reported depressive symptoms are common, and have impact on both well-being and functioning at all ages, but this impact is even probably even greater in the oldest old (1). Depressive symptoms decrease the quality of life, and are associated with excess morbidity and mortality in older adults (2-4). The presence of depressive symptoms, that do not (yet) fulfil diagnostic criteria, indicates a high risk of developing a major depressive disorder and dysthymia (5-9).

In the older adult population (55+) (10) the incidence rate of depressive symptoms varies worldwide from 7% (11;12) to 24.5% (13). Meller et al. (14) reported an annual incidence rate of 14% in a longitudinal study with a very old study population (85-103 years). In the Netherlands, an annual 6.8% risk of developing self-reported depressive symptoms was found in a 85-89 year-old cohort living in the community (15). This variation in incidence rates between studies may be due not only to differences in measurement instruments, and definitions of the concept of depression, but also to differences in the time-period of the measurements, and therefore the results of these studies are difficult to compare.

The vulnerable elderly can be defined as older people who have functional impairments at the end of life, and who are suffering from the cumulative effects of disease-related, psychosocial and environmental concerns, leading to an increased risk of dependency, institutionalisation and mortality (16). There are, as yet, no studies that have specifically focused on the incidence of depressive symptoms among the more vulnerable oldest people, while the risk of developing depressive symptoms is expected to be very high in this group, due to exposure to known risk factors for depression (e.g. disability, chronic disease) (17). A recent review of risk factors for depressive symptoms (18) confirmed the importance of biological, sociological and psychological risk factors. However, inconsistency was found in the factor “being older”. Possibly, in the most vulnerable and oldest population the majority of people suffer from physical disabilities and chronic disease. Therefore, in this population, biological factors might not discriminate between those who are developing depressive symptoms and those who are not. It is possible that other determinants, such as psychosocial factors, have a greater impact on the incidence of depressive symptoms in this group.

In the vulnerable elderly population, treatment and care mainly focus on physical disability and disease. Symptoms of depression are often seen as consequences of vulnerability, rather than as a problem that requires intervention in its own right. As it is imaginable that curative approaches toward depressive disor-
ders have a limited impact in this vulnerable population (19), preventive activities deserve attention, particularly because we know that the prevention of depressive disorders can be very effective in an elderly population (20;21).

The aim of the present study was to describe the incidence of depressive symptoms in very old vulnerable people, and to identify factors predicting incidence that may be possible targets for future preventive interventions.

The following research questions were addressed:
1. What is the incidence rate of clinically significant symptoms of depression after 6 and 18 months in a very old vulnerable population?
2. Which risk factors are associated with depressive symptoms in a very old vulnerable population?

**Methods**

**Subjects and procedures**

Data for this study were collected during a longitudinal cohort study in primary care in the Netherlands (22). The participants in this cohort were recruited in 33 primary care practices (55 primary care physicians). The primary care physicians provided the names and addresses of all their patients who were 75 years of age or older and living at home. All community dwelling persons aged 75 or older received a postal health survey with a recommendation from their physician, containing questions about demographics, health, and psychosocial factors. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

**Vulnerability**

To assess vulnerability, we used the COOP-WONCA charts (Dartmouth Coop Functional Health Assessment Charts/ World Organisation of Family Doctors) which assess six domains of functional health: overall health, physical fitness, health changes, daily activities, emotional problems, and social activities (23). For our study, people with scores in the lowest quartile on at least two out of six charts were considered to be vulnerable (22;24). The quartile cut-offs were based on representative Dutch community-based supplemented data. Dutch COOP-WONCA scores are comparable to the scores in other countries (25;26).

**Depressive symptoms**

The primary outcome measure in this study was the incidence of clinically relevant depressive symptoms at 6 months or at 18 months. This was measured according to a validated self-report scale, the Center for Epidemiologic Studies Depression Scale (CES-D) (27). This self-report instrument was designed specifically for
screening depressive symptoms in the community. It consists of 20 items, and its total score ranges between 0 and 60, scores ≥ 16 indicating clinically significant levels of depressive symptoms. At this cut-off point the sensitivity was 100% and the specificity was 88% for major depressive disorder in an elderly population (55–85 years) in the Netherlands (28). In the elderly, milder forms of depressive symptoms are more prevalent than major depression, but they can cause just as much suffering (29). In this paper, a CES-D score of 16 and higher will be referred to as “clinically relevant depressive symptoms”. The incidence of depressive symptoms was defined as a CES-D score < 16 at baseline, in combination with a CES-D score ≥ 16 at 6 or 18 months and at least a 5-point change between measurements. This estimate for relevant change has also been used in other studies, and represents a medium to large change (12). We used this “relevant change criterion” to prevent false positive cases due to measurement inaccuracies in the CES-D.

**Possible determinants of the incidence of depressive symptoms**

Demographic variables included age, gender, partner status, and level of education. The physical health-related variables included the number of chronic illnesses, the presence of cardiovascular diseases, competence in performing instrumental activities of daily living, measured with the Groningen Activity Restriction Scale (GARS) (30), hearing and vision problems, measured according to Strawbridge (31), and bodily pain score, measured with the Short Form Health Survey (SF-36) (32). Scores above the median (score ≥38) on the GARS indicate major difficulties. The internal reliability of the GARS has been tested with Cronbach’s alpha, which was 0.91 (30). In the present study Cronbach’s alpha was 0.92, indicating good reliability. Hearing and vision problems were defined as “some difficulty” or “a great deal of difficulty” with at least one of the three vision/hearing problems that were assessed (31). Cognitive decline was measured with the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE), for which scores ≥ 3.6 indicate cognitive decline (33). The reliability of the self-report form of this instrument has been found to be good, with an Cronbach’s alpha of 0.94 (34). In the present study Cronbach’s alpha was 0.89, indicating good reliability. The psychosocial variables included measurements to assess fear of falling (yes/no), being alone for most of the day, and social support (yes/no). We also included the level of depressive symptoms at baseline (CES-D) as a risk indicator, because it is known that depressive symptoms can act as a precursor for depression (35).

**Analysis**

We first investigated potential selective attrition by comparing the baseline characteristics of the drop-outs and the completers. The incidence rates of depressive
symptoms, with their 95% confidence interval (CI), were calculated with SPSS-14, using a dichotomized CES-D score in combination with the predefined relevant change of 5 CES-D points between the baseline measurement and the follow-up measurement at 6 and 18 months. Odds Ratios (ORs) (and the 95% CI) of risk factors were calculated by performing univariate logistic regression analysis for the incidence at 6 and 18 months, as well as for the cumulative incidence in this period.

Subsequently, we assessed the predictive variables in a correlation matrix, because it was our intention to select only non-related predictive variables. We excluded a factor if the Pearson correlation coefficient was above threshold (r ≥ 0.5) (36). Finally, the remaining variables were analysed with multiple logistic regression analysis techniques, and backward selection procedures were used to select the best predictive model. We used a p-value of 0.2 to select variables for the model, as is common in prediction research (37).

Results
The postal health survey was mailed to 4,823 subjects. Among the 2,949 (61%) respondents, females were under-represented (41.3% versus 35.8%, X²=13.4 p < 0.0001), as were slightly older persons (83.5 versus 81.7 yrs, t=13.8 p < 0.0001). 651 vulnerable 75+ people were identified with the COOP/WONCA charts. As expected, the prevalence of clinically relevant depressive symptoms (CES-D ≥ 16) in this group was high (58%, N= 385), leaving only 266 vulnerable 75+ elderly people with no clinically relevant depressive symptoms available for participation in our study (mean CES-D score 11.2 [SD 3.3]).

Of the 266 non-depressed vulnerable elderly, 77 were lost to follow-up at 6 months (response rate of 71%), and 14 were lost to follow-up between 6 and 18 months (total response rate of 66%). Of those who were lost to follow-up, 25 (9%) had died during the 18 month period. There were no significant differences in gender, age or CES-D scores at baseline between the respondents and those lost to follow-up. The baseline characteristics of this group are presented in Table 1. As was expected in this vulnerable population, most people suffered from a chronic illness (86.8 %), but an impressive 61.6% suffered from more than one illness. Slightly more than half of these people (52.2%) were living alone, and the majority of them were alone for most of the day (62.8%). The mean CES-D score in our initial selection of 651 vulnerable elderly was 17.8 (SD 7.4), while the mean score in the selected population with no depressive symptoms was 11.3 (SD 3.3).

At 6 months, the incidence of (self-reported) clinically relevant depressive symptoms was 57/189=30.2% (95% CI 26.6-33.4%), and at 18 months it was 27/118=22.9% (95% CI 19.1-26.7%). Over the 18-month period a total of 84 of the 175 non-depressed participants at baseline developed clinically relevant depressive symptoms (48%, 95% CI 44.2-51.8%).
Pearson’s correlation coefficient showed a correlation of 0.64 between living alone and being alone for most of the day: we selected the factor living alone. The factors of two or more chronic illnesses and cardiovascular disease showed a correlation of 0.53: we therefore selected only the factor chronic illnesses. From the 6-month data, univariate analysis identified three candidate predictors for the incidence of symptoms of depression (p<0.2): level of depressive symptoms at baseline, high level of education, and fear of falling (see Table 2). We entered these candidate predictors in a multiple logistic regression analysis, but found no significant associations with the incidence of depressive symptoms (Nagelkerke R square=0.03). From using the 18-month data, univariate analysis also identified two candidate predictors for the incidence of symptoms of depression (p<0.2): fear of falling, and living alone. No significant associations were found in the logistic regression analysis.

Table1. Baseline characteristics of vulnerable but non-depressed elderly participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>N= 266</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (SD)</td>
<td>81.6 (4.0)</td>
</tr>
<tr>
<td>Female gender N (valid %)</td>
<td>164 (61.9)</td>
</tr>
<tr>
<td>Mean CES-D score (SD)</td>
<td>11.2 (3.3)</td>
</tr>
<tr>
<td>Level of education N (valid %)</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>169 (63.5)</td>
</tr>
<tr>
<td>Intermediate</td>
<td>49 (18.4)</td>
</tr>
<tr>
<td>High</td>
<td>48 (18.0)</td>
</tr>
<tr>
<td>Cognitive decline N (valid %)</td>
<td>24 (9.0)</td>
</tr>
<tr>
<td>Chronic illness N (valid %)</td>
<td>231 (86.8)</td>
</tr>
<tr>
<td>2 or more chronic illnesses N (valid %)</td>
<td>164 (61.7)</td>
</tr>
<tr>
<td>Cardiovascular diseases N (valid %)</td>
<td>162 (60.9)</td>
</tr>
<tr>
<td>Major ADL difficulties N (valid %)</td>
<td>113 (48.7)</td>
</tr>
<tr>
<td>Hearing difficulties N (valid %)</td>
<td>94 (39.8)</td>
</tr>
<tr>
<td>Visual difficulties N (valid %)</td>
<td>50 (21.5)</td>
</tr>
<tr>
<td>Bodily pain N (valid %)</td>
<td>118 (47.4)</td>
</tr>
<tr>
<td>Living alone N (valid %)</td>
<td>129 (52.2)</td>
</tr>
<tr>
<td>Alone most of the day N (valid %)</td>
<td>145 (62.8)</td>
</tr>
<tr>
<td>No social support N (valid %)</td>
<td>66 (27.4)</td>
</tr>
<tr>
<td>Fear of falling N (valid %)</td>
<td>124 (54.4)</td>
</tr>
</tbody>
</table>
We first studied the incidence of clinically significant depressive symptoms in an elderly population with a vulnerable health status, but with no symptoms of depression at baseline. In our baseline sample, 58% of the vulnerable elderly already suffered from depressive symptoms, and were therefore excluded from the study. Subsequently, we found an even higher risk than we expected for vulnerable elderly with no symptoms at baseline to develop clinically relevant depressive symptoms within 18 months, an astounding overall 48% (30.2% at 6 months and 22.9% over the following 12 months). The incidence rate we found at a cut-off score of 16 is very high, compared to previous findings in elderly populations (11-15;35). Apparently, the use of a multi-dimensional definition of vulnerability, according to the

<table>
<thead>
<tr>
<th>Candidate predictors</th>
<th>6 months</th>
<th>18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
<td>95% CI</td>
</tr>
<tr>
<td>Age</td>
<td>1.01</td>
<td>0.93 – 1.10</td>
</tr>
<tr>
<td>Female gender</td>
<td>1.32</td>
<td>0.69 – 2.53</td>
</tr>
<tr>
<td>CES-D score at baseline</td>
<td>0.94</td>
<td>0.86 – 1.03</td>
</tr>
<tr>
<td>Level of education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intermediate</td>
<td>0.90</td>
<td>0.81 – 3.93</td>
</tr>
<tr>
<td>High</td>
<td>1.78</td>
<td></td>
</tr>
<tr>
<td>Cognitive decline</td>
<td>0.96</td>
<td>0.32 – 2.87</td>
</tr>
<tr>
<td>2 or more chronic ill-nesses</td>
<td>1.04</td>
<td>0.55 – 1.96</td>
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<td>Major ADL difficulties</td>
<td>0.93</td>
<td>0.47 – 1.82</td>
</tr>
<tr>
<td>Hearing difficulties</td>
<td>1.04</td>
<td>0.52 – 2.07</td>
</tr>
<tr>
<td>Visual difficulties</td>
<td>1.50</td>
<td>0.64 – 3.58</td>
</tr>
<tr>
<td>Bodily pain</td>
<td>1.33</td>
<td>0.68 – 2.59</td>
</tr>
<tr>
<td>Living alone</td>
<td>1.25</td>
<td>0.65 – 2.41</td>
</tr>
<tr>
<td>No social support</td>
<td>1.05</td>
<td>0.50 – 2.18</td>
</tr>
<tr>
<td>Fear of falling</td>
<td>1.69</td>
<td>0.83 – 3.44</td>
</tr>
</tbody>
</table>

Table 2. Candidate predictors for incidence of depressive symptoms at 6 months and 18 months

Discussion
We first studied the incidence of clinically significant depressive symptoms in an elderly population with a vulnerable health status, but with no symptoms of depression at baseline. In our baseline sample, 58% of the vulnerable elderly already suffered from depressive symptoms, and were therefore excluded from the study. Subsequently, we found an even higher risk than we expected for vulnerable elderly with no symptoms at baseline to develop clinically relevant depressive symptoms within 18 months, an astounding overall 48% (30.2% at 6 months and 22.9% over the following 12 months). The incidence rate we found at a cut-off score of 16 is very high, compared to previous findings in elderly populations (11-15;35). Apparently, the use of a multi-dimensional definition of vulnerability, according to the
COOP-WONCA charts, selects a sub-group of elderly people who have a very high risk of developing depressive symptoms.

Subsequently, we studied the factors predicting clinically significant depressive symptoms in this very old vulnerable population. We expected to distinguish specific psychosocial risk factors in this population, because we assumed that biological factors might not discriminate in this group. Contrary to our expectations, we found no specific risk factors for the incidence of depressive symptoms. The ORs of most of the determinants were scattered round 1.0, indicating that this was not the result of lack of power in the statistical analyses, but that the absolute risk conferred by the risk factors that we studied was very small.

One could also argue that the, psychosocial risk factors did not discriminate because many of the participants had high scores for these known psychosocial risk factors for depression, as is shown in Table 2. For instance, 52% of the participants were living alone, and 55% were afraid of falling. However, a social factor such as 'living alone' tended to predict incident depressive symptoms at 18 months (OR 2.54), but the 95% CI was too wide to draw any conclusions. Overall, the number of participants in our study might have been too small to detect any specific risk factors for the incidence of depressive symptoms within this vulnerable population. However, as mentioned before, most of the absolute risks inferred were also very small, suggesting that a lack of statistical power was not the cause of the lack of associations that we found. Finally, our findings do confirm the high risk of developing symptoms of depression in people with high scores for known physical and psychosocial risk factors.

A limitation of our study is the absence of a formal diagnostic instrument. The CES-D was developed as a self-report instrument for the screening of depression in epidemiological studies, yet there is accumulating evidence to support the clinical validity of high scores (2;3;29). A score of 16 or higher on the CES-D correctly identifies most older people with minor and major depression, with a sensitivity of 100% and a specificity of 88% (28). Such a high self-report score is also the best predictor for the subsequent development of depression among elderly people (5;38). The impact on daily functioning of clinically relevant depressive symptoms in this oldest population may already be as serious as the impact of major depressive disorder (39). To correct for a possible over-estimation of depressive symptoms, we added a clinically relevant change criterion of 5 points on the CES-D (12). The study is further limited by an attrition of 34% (N=91), but because 28% of the participants were lost to follow-up due to death, this was to be expected in our study population. Drop-out was not related to CES-D score at baseline, but participants with incident depressive symptoms might have been less willing to participate at follow-up, resulting in an under-estimation of the incidence score.
We conclude that with the COOP WONCA charts we selected a vulnerable population with a high prevalence and a high risk of incident depressive symptoms. In other words, a vulnerable health status in elderly people, as measured with these charts, is associated with a high risk of depressive symptoms. No specific risk factors were distinguish within this population, but multicausal vulnerability in itself indicates a very high risk of developing depressive symptoms. The results of this study emphasize that it is important for professionals to be extra alert for mood symptoms in vulnerable elderly people.
Reference List


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Chapter 6

Contradictory effects for prevention of depression and anxiety in residents in homes for the elderly; a Pragmatic Randomised Controlled Trial

Els Dozeman
Harm W.J. van Marwijk
Digna J.F. van Schaik
Filip Smit
Max L. Stek
Henriëtte E. van der Horst
Ernst T. Bohlmeijer
Aartjan T.F. Beekman

Submitted
Abstract:

Background
To evaluate the effectiveness of a stepped care programme to prevent the onset of depression and anxiety disorders in elderly people living in residential homes.

Methods
A pragmatic randomised controlled trial was conducted to compare the intervention with usual care in 14 residential homes in the Netherlands. A total of 185 residents with a minimum score of 8 on the Center for Epidemiologic Studies Depression Scale (CES-D), who did not meet the diagnostic criteria for a depressive or anxiety disorder, and were not suffering from severe cognitive impairment, were recruited between April 2007 and December 2008. They were randomised to a stepped care programme (n=93) or to usual care (n=92). Stepped care participants sequentially underwent watchful waiting, a self-help intervention, life review, and a consultation with the general practitioner. The primary outcome measure was the combined incidence of a major depressive disorder (MDD) or anxiety disorder during a period of one year, according to the Mini International Neuropsychiatric Interview (MINI).

Results
The intervention was not effective in reducing the incidence of the combined outcome of depression or anxiety (IRR=0.50 and a 95% CI ranging from 0.23-1.12). However, the intervention was superior to usual care in reducing the risk of MDD incidence (IRR 0.26; 95% confidence interval [CI] 0.12-0.80), in contrast to anxiety incidence (IRR 1.32; 95% CI 0.48-3.62).

Conclusions
These results suggest that the stepped care programme is effective in reducing the incidence of depression, but is not effective in preventing the onset of anxiety disorders in elderly people living in residential homes.

Trial Registration
The Dutch Cochrane Center, ISRCTN27540731
Introduction
Depression and anxiety are common disorders among elderly people, and they are associated with excess mortality and reduced quality of life (1-4). Elderly people living in residential homes have an even higher risk of developing depressive and anxiety disorders than those living in the community: the rates of clinically relevant symptoms of depression and anxiety in people living in long-term care facilities have been estimated to be as high as 35% (5;6). Chronic illnesses, disability, loneliness, older age, and female gender may all contribute to this risk, and in the residential home setting these risks accumulate (7;8). Although treatment has improved (9), older people with depression or anxiety often remain untreated. Given the large number of people who are affected, it is unlikely that even the most resourceful health services will be able to provide adequate treatment for them all. This is an important reason why alternative strategies, such as prevention, are necessary to reduce the adverse impact of late-life depression and anxiety on the health of the population (10-12).

The results of recently performed meta-analyses indicate that preventive interventions are effective in reducing the incidence of anxiety and depressive disorders by as much as 25% in adults (13-15), and this also applies to older people (16). In a study in the Netherlands carried out among people of 75 years and older living in the community, the application of a stepped care prevention programme reduced the risk of developing a depressive or anxiety disorder by 57.9% (17) with effects that were retained over two years (18), in a cost-effective way (19). These promising results suggest that preventive interventions might be very effective when offered in a stepped care format.

The aim of stepped care models is to maximise the effectiveness of available effective interventions, while making the best use of available resources. Patients are first offered the least intensive intervention, and when necessary the intensity of the care is stepped up sequentially. When carried out systematically, the (cost-) effectiveness of the programme as a whole is improved (20-22). Previous research has suggested that prevention is most likely to be effective when targeted at those with a high a priori risk of developing the disorder (11;12). This can be achieved either by focusing on people with established risk factors for a disorder (selective prevention), or by targeting people with early symptoms of the disorder, but have not yet developed the full-blown disorder (indicated prevention).

In the present study we combined both strategies by focusing on a frail elderly population exposed to multiple risk factors, with above average levels of symptoms of depression and anxiety, but not yet meeting the diagnostic criteria for a disorder. We hypothesised that the stepped care prevention programme would be superior to usual care in preventing the onset of depressive and anxiety disorders in residents in homes for the elderly.
Methods
Design
We tested the stepped care programme in a pragmatic randomised controlled trial with two parallel groups. The design of this study has already been described in detail elsewhere (23). In brief, 14 residential homes in Amsterdam and surroundings were willing to participate in the trial. The 14 participating homes covered several areas in and surrounding the city, including both more affluent and deprived areas of Amsterdam. The randomisation of consenting residents, stratified according to residential home, took place after the baseline measurements in blocks of four with an equal allocation ratio, carried out by an independent statistician using random number tables.

The central clinical outcome was the cumulative incidence of DSM-IV depressive and anxiety disorders (panic disorder, agoraphobia, social phobia, or generalised anxiety) over a period of one year, with planned analyses for each of the distinct outcomes, as measured with the Mini International Neuropsychiatric Interview (MINI) (24). We measured both disorders at all points in follow up. Some respondents developed a depressive disorder, some an anxiety disorder, and others both. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Center.

Participants
In the Netherlands, several types of facilities for sheltered accommodation for the elderly are available, the two most important being residential homes and nursing homes. Residential homes provide assisted living facilities, including daily care (e.g. meals and housecleaning) and, if needed, uncomplicated demand-led medical care. Nursing homes provide more specialised medical care to dependent people of all ages. The demand for residential care mainly depends on (the lack of) a social network and (in)ability to manage everyday activities (25).

After a pilot study in one residential home (5) we found that many residents did not complete the screening questionnaires, mainly because they were not feeling fit enough. Furthermore, resources in the residential home were insufficient to screen all the residents. Therefore, we adapted the screening procedure: interviewers visited every address, and asked the resident(s) for permission to screen for depressive symptoms with the Center for Epidemiologic Studies Depression Scale (CES-D) (26). Respondents with a minimum score of 8, i.e. above average (27), were invited for a follow-up interview in which a diagnostic and cognitive assessment took place. Respondents who met the criteria for MINI/DSM-IV depressive or anxiety disorder were excluded, as were residents with evidence of substantial cognitive impairment, measured with a cut-off score of 21 for the Mini Mental State Examination (MMSE) (28). Residents who gave written informed consent, and who
had sufficient command of the Dutch language, were eligible for participation in the study.

**Stepped care programme**

*Step-up rules*

After one month of watchful waiting, assessments took place in cycles of three months. Participants were invited to step up to the next level of the intervention, if the level of their symptoms had not improved by at least 5 points on the CES-D. We used this definition of improvement because a 5-point change on the CES-D is both clinically relevant and statistically reliable, and has also been used in earlier studies (8;29;30). If at any measurement point a participant was found to have developed a DSM-IV depressive or anxiety disorder, the preventive intervention was considered to have failed, and this failure was recorded as a clinical end-point. These residents were referred to their general practitioner for possible psychological or pharmacological treatment. Participants with a decrease in symptoms of 5 points or more were not offered further intervention in the stepped care programme, but were monitored for the next three months.

The stepped care programme consisted of the following steps:

- **Step 1: Watchful waiting.** Participants were invited for the first follow-up interview after a period of one month, since frequently (in up to 50% of the cases) symptoms cease to exist without requiring active intervention (31).

- **Step 2: Activity-scheduling.** Participants who showed no improvement after one month, were invited for “activity-scheduling”, a module from a previously tested and effective self-help course “Coping With Depression” (32). Staff in the residential homes were trained to coach and encourage the residents to complete the course. Only staff members who coached a resident in the intervention group were trained in the self-help course. Also, they only received the self-help materials for their residents in the intervention group. All coaches were insistently instructed to deliver the materials only to the assigned residents, because this was important in order to avoid contamination between intervention group and care as usual. This method of treatment is attractive because it is relatively simple, and does not require any complex skills from the staff or the residents. During this second step of the protocol, general practitioners were informed about the participation of their patients in the stepped care programme.

- **Step 3: Life review and consultation with the general practitioner.** If symptoms remained unchanged after the activity-scheduling step, residents were invited to participate in a brief structured personal intervention: life review. The intervention is tailored for use with the very old because it is short, individual and positively focused (33). The adjusted life review protocol we used is effective for
residents in homes for the elderly (34). The intervention is relatively simple to implement by professionals with basic counselling skills, and was delivered by trained and supervised mental health nurses. At the same time, the participants were advised to consult their general practitioner to check for possible somatic causes of depression and anxiety symptoms (thyroid disease, vitamin deficiencies, Parkinson’s disease, or side-effects of medication).

- **Step 4:** Visit to the general practitioner for additional treatment. Residents who had a CES-D score $\geq 16$ (the level of clinically relevant symptoms of depression) after the third follow-up interview were advised to consult their general practitioner to consider the prescription of antidepressants or referral to a mental health specialist.

**Usual care**
Residents in the usual care group had unrestricted access to any form of health care that was considered to be appropriate. Their health care utilisation was recorded, including the prescription of medication.

**Measures**
Major depressive disorder and anxiety disorders were assessed with the MINI (24), which is a short, structured diagnostic interview to assess DSM-IV mental disorders. We measured both disorders at all points in follow up. Some respondents developed a depressive disorder, some an anxiety disorder, and others both.

Symptoms of depression and anxiety were measured with the CES-D, which consists of 20 items, with total scores ranging between 0 and 60. The CES-D not only detects depression, but has also been found to be a satisfactory instrument with which to screen for anxiety disorders, also in this specific setting (35).

Symptoms of anxiety were also measured with the Hospital Anxiety and Depression Scale (HADS-A) (36), which consists of 7 questions to which answers can be given on a 4-point rating scale. A minimum score of 8 on the HADS-A is a validated cut-off point for anxiety disorder (37).

Loneliness was measured with the 11-item loneliness scale (38), developed for older people. A cut-off score of 3 distinguishes between lonely and not lonely.

Health care utilisation was measured with the Trimbos/iMTA questionnaire for Costs Associated with Psychiatric Illness (Tic-P) (39).

**Blinding**
The interviewers were not informed about the randomisation status of the participants. However, in this type of intervention it is not possible to conceal randomisation status from the participants themselves.
Analysis

We first investigated possible baseline differences in demographic and clinical characteristics across the conditions (t-tests for continuous data, and Chi-square tests for categorical data). To check for possible selective attrition, we compared the prognostically relevant characteristics of drop-outs and completers in the intervention group and in the usual care group. We also compared the reasons for drop-out between the groups. To identify statistically significant predictors of incidence and selective drop-out, stepwise backward selection regression analysis was performed, so that in any subsequent analysis such confounders could be incorporated as covariates.

The main analyses were conducted on an intention-to-treat basis. This approach implies that the analyses are based on all randomised patients, and this requires the imputation of missing end-points. In a randomised trial of a curative intervention, the last observation carried forward (LOCF) is regarded as a conservative approach to data-analyses, because the baseline scores of the patients are unfavourable, and these unfavourable scores are analysed as outcomes if there is no observed outcome. Thus, in a curative trial, LOCF strengthens the null-hypothesis of no effect. However, in a prevention trial, LOCF might not be a conservative imputation technique, because the purpose of prevention is to reduce the risk of deterioration in health in people who are relatively healthy at baseline. Therefore, the use of LOCF in a prevention trial, might bias outcomes toward overly optimistic conclusions. To avoid this bias, it is better to replace missing end-points by their most likely values, such as those obtained with the Little and Rubin EM algorithm, as implemented in SPSS (15.0). By way of a sensitivity analysis, we also used another imputation strategy (regression imputation, as implemented in SPSS 15.0) and finally, we conducted a “completers-only analysis”, based on the data of the participants who completed the interviews.

To estimate the extent to which the intervention reduced the risk of depressive and anxiety disorders compared to usual care, we first performed an unadjusted Poisson regression analysis of the MINI/DSM-IV depressive and anxiety cumulative incidence both (1=developed a disorder and 0=remained disorder-free) on the treatment indicator (0=usual care, 1=intervention). In this way, we obtained a crude incidence rate ratio (IRR) which describes the difference between the incidence rate in the intervention group and in the usual care group. The superiority of the intervention would be supported if the IRR falls below 1, and would be significant at P< 0.05, 2-tailed.

As a second step we wanted to adjust for confounders and selection-bias, so we incorporated all significant confounders as covariates in the analysis, and then produced adjusted IRRs. We also obtained the number-needed-to-treat (NNT) as the inverse of the risk difference (RD). The NNT indicates how many people must receive the intervention in order to avoid one new case of depression or anxiety.
Finally, we assessed the IRR for both disorders separately, first with an unadjusted analysis, second the adjusted analysis for confounding.

All analyses were performed with SPSS (version 15.0) and Stata (version 8.2), while taking into account the clustering effect that the multi-site trial (with participants ‘nested’ within each of the 14 residential homes) introduced in the data. We therefore computed robust 95% CIs and test statistics by applying the first-order Taylor-series linearisation method. The IRR was obtained with Poisson regression (as estimated with GLM). The NNT was calculated as NNT=1/RD, rounded off to the nearest integer.

Results
Participants
Recruitment took place between April 2007 and December 2008. Of the 1784 residents who were invited for the screening interview, 754 (51%) were able and willing to participate. Of these, 459 (61%) scored higher than the predetermined threshold. A total of 270 (59%) gave informed consent, but 85 were excluded because they were already suffering from a mental disorder, cognitive impairment, or both. This resulted in the randomisation of 185 residents for the trial. They were either randomised to the stepped care programme (n=93) or to the usual care group (n=92) (Figure 1). Of the 185 participants, 55 (30 %) dropped out during the study.

Baseline characteristics
The participants were mainly women (73%), with a mean age of 84.3 (SD=6.5), and had chronic diseases and poor daily functioning. Most of the participants were living alone (83.2%), and felt lonely (70.8%). There were no significant differences between the intervention group and the usual care group at baseline, indicating that randomisation had resulted in a balanced distribution of these variables over the two groups (Table 1).

Analysis of drop-out
We assessed whether drop-out was associated with any characteristics of the participants at baseline, and found that it was associated with randomisation status ($\chi^2=6.310$, df=1, $P=0.012$), and poorer cognitive functioning ($t=3.135$, df=1, $P=0.002$). More participants in the intervention group were unwilling to continue their participation (14 out of 93) compared to participants in the usual care group (4 out of 92 ) ($\chi^2=6.035$, df=1, $P=0.014$). In the intervention group, 5 of the 93 participants died, compared with 6 of the 92 participants in the usual care group ($\chi^2=1.08$, df=1, $P=0.74$). One participant in the intervention group moved to another region. Furthermore, 17 of the 93 participants in the intervention group and
Figure 1. Flowchart of participants in the trial

Randomisation
N=185

Participants received the intervention (ITT)
N=93

Incidence of:
Depression N=3
Anxiety N=3
Both N=1

Drop-out N=4

Completed 1-month-follow-up after:
Watchful waiting N=89

Incidence of:
Depression N=2
Anxiety N=3
Both N=1

Drop-out N=18

Completed 4-month-follow-up after:
1. Activity scheduling N=51
2. Watchful waiting N=15

Incidence of:
Depression N=0
Anxiety N=2
Both N=0

Drop-out N=7

Completed 7-month-follow-up after:
1. Life-review N=30
2. Activity Scheduling N=11
3. Watchful waiting N=14

Incidence of:
Depression N=0
Anxiety N=0
Both N=0

Drop-out N=6

Completed 10-month-follow-up after:
1. Consult GP N=8
2. Life-review N=13
3. Activity Scheduling N=1
4. Watchful waiting N=25

Participants received usual care (ITT)
N=92

Incidence of:
Depression N=3
Anxiety N=2
Both N=1

Drop-out N=5

Completed 1-month-follow-up
N=87

Incidence of:
Depression N=3
Anxiety N=0
Both N=0

Drop-out N=9

Completed 4-month-follow-up
N=74

Incidence of:
Depression N=3
Anxiety N=1
Both N=1

Drop-out N=1

Completed 7-month-follow-up
N=70

Incidence of:
Depression N=3
Anxiety N=1
Both N=1

Drop-out N=5

Completed 10-month-follow-up
N=62
<table>
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<tr>
<th>Characteristics</th>
<th>Intervention Group (N=93)</th>
<th>Usual Care Group (N=92)</th>
<th>Total* (N=185)</th>
</tr>
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<tbody>
<tr>
<td>Female gender (%)</td>
<td>67 (72.0)</td>
<td>68 (73.9)</td>
<td>135 (73.0)</td>
</tr>
<tr>
<td>Age on entry in the trial (SD)</td>
<td>84.5 (6.7)</td>
<td>84.2 (6.4)</td>
<td>84.3 (6.5)</td>
</tr>
<tr>
<td>Age-range</td>
<td>61.8 – 100.3</td>
<td>62.1 – 94.9</td>
<td>61.8 – 100.3</td>
</tr>
<tr>
<td>MMSE (SD)</td>
<td>27.0 (2.1)</td>
<td>27.1 (2.0)</td>
<td>27.1 (2.1)</td>
</tr>
<tr>
<td>Married or living with a partner (%)</td>
<td>18 (19.4)</td>
<td>13 (14.1)</td>
<td>31 (16.8)</td>
</tr>
<tr>
<td>Education beyond secondary school (%)</td>
<td>20 (21.5)</td>
<td>17 (18.5)</td>
<td>37 (20.0)</td>
</tr>
<tr>
<td>Number of chronic diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (%)</td>
<td>4 (4.3)</td>
<td>5 (5.4)</td>
<td>9 (4.9)</td>
</tr>
<tr>
<td>1 (%)</td>
<td>13 (14.0)</td>
<td>22 (23.9)</td>
<td>35 (18.9)</td>
</tr>
<tr>
<td>2 (%)</td>
<td>34 (36.6)</td>
<td>29 (31.5)</td>
<td>63 (34.1)</td>
</tr>
<tr>
<td>&gt;2 (%)</td>
<td>42 (45.2)</td>
<td>36 (39.1)</td>
<td>78 (42.2)</td>
</tr>
<tr>
<td>CES-D score (SD)</td>
<td>14.9 (5.7)</td>
<td>14.4 (5.3)</td>
<td>14.7 (5.5)</td>
</tr>
<tr>
<td>HADS-A score (SD)</td>
<td>3.6 (2.8)</td>
<td>3.2 (2.6)</td>
<td>3.4 (2.7)</td>
</tr>
<tr>
<td>Loneliness score (SD)</td>
<td>3.4 (0.9)</td>
<td>3.4 (0.8)</td>
<td>3.4 (0.8)</td>
</tr>
<tr>
<td>Loneliness categorical (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not lonely</td>
<td>29 (31.2)</td>
<td>33 (35.9)</td>
<td>62 (33.5)</td>
</tr>
<tr>
<td>Lonely</td>
<td>64 (68.8)</td>
<td>59 (64.1)</td>
<td>123 (66.5)</td>
</tr>
<tr>
<td>ADL score (SD)</td>
<td>35.1 (5.7)</td>
<td>34.4 (6.3)</td>
<td>34.7 (6.0)</td>
</tr>
<tr>
<td>Major difficulties ADL (%)</td>
<td>50 (53.8)</td>
<td>45 (48.9)</td>
<td>95 (51.4)</td>
</tr>
<tr>
<td>Suffering from feelings of depression/anxiety in the past (%)</td>
<td>48 (51.6)</td>
<td>53 (57.6)</td>
<td>101 (54.6)</td>
</tr>
<tr>
<td>Length of stay in residential home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1 year (%)</td>
<td>29 (31.2)</td>
<td>24 (26.1)</td>
<td>53 (28.6)</td>
</tr>
<tr>
<td>&gt;1 year (%)</td>
<td>54 (58.1)</td>
<td>64 (69.6)</td>
<td>118 (63.8)</td>
</tr>
<tr>
<td>&gt;10 years (%)</td>
<td>10 (10.8)</td>
<td>4 (4.3)</td>
<td>14 (7.6)</td>
</tr>
<tr>
<td>Hearing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no problems</td>
<td>51 (54.8)</td>
<td>52 (56.5)</td>
<td>103 (55.7)</td>
</tr>
<tr>
<td>serious problems</td>
<td>43 (46.2)</td>
<td>40 (43.5)</td>
<td>82 (44.3)</td>
</tr>
<tr>
<td>Vision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no problems</td>
<td>47 (50.5)</td>
<td>55 (59.8)</td>
<td>102 (55.1)</td>
</tr>
<tr>
<td>serious problems</td>
<td>46 (49.5)</td>
<td>37 (40.2)</td>
<td>83 (44.9)</td>
</tr>
</tbody>
</table>

* There are no significant differences between groups (t-test/Chi-square test)

Table 1. Baseline demographic and clinical characteristics of the participants
9 of the 92 participants in the usual care group dropped out because of physical illness ($\chi^2=2.76$, df=1, P=0.10).

Loneliness (P=0.01), CES-D score at baseline (P<0.01), HADS-A score at baseline (P=0.01), and the number of chronic diseases were predictors (P=0.04) for the incidence of a major disorder, and MMSE score at baseline (P=0.01) was a predictor for drop-out. We used all five statistically significant predictors for incidence and drop-out as covariates in the Poisson regression analysis of the MINI/DSM-IV depressive and anxiety cumulative incidence evaluations, while also reporting on the crude (unadjusted) outcomes.

**Compliance**

To assess compliance with the stepped care intervention, we investigated the participation rates in each step of the intervention. After the first step, in which no active intervention was applied, the participants were offered a self-help course in the second step. 63 participants were eligible for this intervention, but only 45 participants (71%) reported starting with the intervention. Furthermore, only a minority (11 out of 45=24%) finished all exercises in the self-help intervention. In the third step 43 participants were eligible for the life review intervention. 31 (72%) of them accepted and completed the life review intervention. Finally, 7 out of 8 participants reported that they had contacted their general practitioner after being advised to do so.

**Usual care**

We found that 6 out of 92 participants in the usual care group received counselling from a psychiatrist or psychotherapist, compared to 8 out of 93 participants in the intervention group ($\chi^2=0.29$, df =1, P=0.59) during the study period; 10 out of 86 participants in the usual care group received antidepressant medication, compared to 16 out of 84 participants in the intervention group ($\chi^2=1.81$, df=1, P=0.18); 36 out of 86 participants in the usual care group received sedative medication, compared to 35 out of 84 participants in the intervention group ($\chi^2=0.17$, df =1, P=0.90).

**Outcomes**

Based on the intention-to-treat analysis with EM imputation, the crude incidence of both disorders together was 12 out of 93 (12.9%) participants in the intervention group, and 15 out of 92 (16.3%) in the usual care group, resulting in an IRR of 0.79 and a 95% CI ranging from 0.38 to 1.65. As a second step, we adjusted for five covariates, not only because of the confounding effect introduced by differential drop-out rates, but also because the incidence rates over a period of one year were lower than anticipated, resulting in a lack of power. The adjusted analysis resulted in an IRR=0.50 and a 95% CI ranging from 0.23 to1.12. which suggested
that the incidence rate may have been halved by the intervention, but this effect was not statistically significant (SE=0.21, z=-1.68, P=0.09).

With regard to the incidence of depressive disorders, 6 out of 93 (6.5%) participants in the intervention group, and 13 out of 92 (14.1%) in the usual care group developed a major depressive disorder, resulting in an IRR of 0.46 and a 95% CI ranging from 0.17 to 1.21. The adjusted analysis resulted in an IRR=0.26 and a 95% CI ranging from 0.12 to 0.80. Therefore, the adjusted risk of developing a depressive disorder during the stepped care programme was reduced by 74% in the intervention group as compared to usual care. This effect was statistically significant (SE=0.11, z=-3.13, P<0.01). With an adjusted RD of 0.09, the NNT was 11, implying that the onset of major depression was prevented in 1 out of every 11 participants who received the intervention instead of usual care.

With regard to the incidence of anxiety disorders, 8 out of 93 (8.6%) participants in the intervention group, and 4 out of 92 (4.4%) participants in the usual care group developed an anxiety disorder, mainly generalised anxiety (crude IRR 1.98; 95% CI 0.74-5.28, with an adjusted IRR 1.32; 95% CI 0.48-3.62), suggesting that

<table>
<thead>
<tr>
<th></th>
<th>IRR (I v C)</th>
<th>SE</th>
<th>z</th>
<th>P</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EM imputation</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>MINI depression</td>
<td>0.26</td>
<td>0.11</td>
<td>-3.13</td>
<td>&lt;0.01</td>
<td>0.12 – 0.80</td>
</tr>
<tr>
<td>MINI anxiety</td>
<td>1.32</td>
<td>0.68</td>
<td>0.53</td>
<td>0.60</td>
<td>0.48 – 3.62</td>
</tr>
<tr>
<td>MINI major disorder</td>
<td>0.50</td>
<td>0.21</td>
<td>-1.68</td>
<td>0.09</td>
<td>0.23 – 1.12</td>
</tr>
<tr>
<td>MINI depression</td>
<td>0.39</td>
<td>0.12</td>
<td>-2.97</td>
<td>&lt;0.01</td>
<td>0.21 – 0.73</td>
</tr>
<tr>
<td><strong>Regression imputation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MINI anxiety</td>
<td>1.48</td>
<td>0.77</td>
<td>0.77</td>
<td>0.45</td>
<td>0.54 – 4.09</td>
</tr>
<tr>
<td>MINI major disorder</td>
<td>0.71</td>
<td>0.18</td>
<td>-1.38</td>
<td>0.17</td>
<td>0.43 – 1.16</td>
</tr>
<tr>
<td>MINI depression</td>
<td>0.33</td>
<td>0.14</td>
<td>-2.62</td>
<td>&lt;0.01</td>
<td>0.14 – 0.75</td>
</tr>
<tr>
<td><strong>Completers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MINI anxiety</td>
<td>1.66</td>
<td>0.77</td>
<td>1.10</td>
<td>0.27</td>
<td>0.67 – 4.10</td>
</tr>
<tr>
<td>MINI major disorder</td>
<td>0.69</td>
<td>0.24</td>
<td>-1.08</td>
<td>0.28</td>
<td>0.35 – 1.35</td>
</tr>
</tbody>
</table>

IRR=Incidence Rate Ratio,
SE= Robust Standard Error adjusted for 14 clusters in the residential homes

Table 2. Adjusted Incidence Rate Ratio for depression, anxiety and both per imputation strategy and completers
the adjusted risk of developing an anxiety disorder may have been increased by 32% in the intervention group, compared to the usual care group. However, this effect was not statistically significant (SE=0.68, z=0.53, P=0.60).

To assess the robustness of the outcomes, we performed a sensitivity analysis, and repeated the first intention-to-treat analysis, basing it this time on regression imputation. This resulted in an adjusted IRR for depression of 0.39 (95% CI 0.21-0.72), which again was significant (SE=0.12, z=-3.01, P<0.01). Finally, in the analysis of the completers the adjusted IRR for depression was 0.33 (95% CI 0.14-0.75), which was significant (SE=0.14, z=-2.62, P<0.01), thus replicating the previous results. Our former findings with regard to anxiety disorders, and to both disorders together were also replicated in the sensitivity analysis (see Table 2). In summary, our sensitivity analysis indicates a risk reduction of depressive disorder in the range of 61-74%, but the intervention was not associated with a favourable impact on the onset of anxiety disorder.

**Discussion**

**Main findings**

We hypothesised that the stepped care programme, based on monitoring and evidence-based interventions, would be more successful in preventing the onset of depressive and anxiety disorders in residents in homes for the elderly, compared to usual care. The stepped care programme did not prove to be effective in reducing the incidence of major depression and anxiety disorders together. However, the programme did reduce the incidence of depressive disorders, in contrast to the effect on anxiety disorders.

**Strengths and limitations**

As might be expected in this frail elderly population, there was considerable attrition in various phases of the study, and the self-help part of the intervention in particular was not received well by many of the participants. An important limitation of the study is therefore potential bias due to selective loss of participants. To overcome this problem, we performed a sensitivity analysis, including (i) intention-to-treat analyses based on two different imputation techniques, and (ii) a comparison of the results with a completers-only analysis. In addition, we adjusted the analyses for covariates associated with selective drop-out. All our sensitivity analyses produced results that were almost identical, which underscores the robustness of the findings. Another limitation to the study concerns the low proportion of residents that were finally randomised (185 of 1784 [10%]), possibly leading to selection bias. However, there is no obligation to participate in the intervention and people should be willing to participate. This involves of necessity some amount of self-selection which is likely to
reflect the same sort of selection in clinical (prevention) practice. If this were the case then the studied sample would be representative of the type of residents that is likely to make use of the intervention. Finally, a limitation of the study is the possibility of unobserved predictors of dropout. These unobserved covariates may give rise to a violation of the missing at random assumption used in the imputation procedures.

Strengths of the study include the fact that the study design was a pragmatic trial, with very few a priori exclusion criteria, which enhances generalisation to usual care in residential homes in the Netherlands. Other strong features include the use of structured psychiatric diagnoses to measure outcome and the use of a stepped care format, including evidence-based interventions.

Methodological considerations
In the data-analysis phase of the study it turned out that our study was under-powered. Therefore, some caution is needed with regard to accepting the effects of the intervention on anxiety disorders and on both disorders together, because the effects were non-significant. The intervention was clearly favourable for depression (both clinically and statistically significant). The effect on anxiety, although not significant, was in the opposite direction, those participating in the intervention reporting about 30% more anxiety disorders than those in the control group. When we designed the study, preventative interventions for depression were more developed and tested than for anxiety disorders. This is especially true when considering older people. Given similar effects of both medication and psychotherapy on both depression and anxiety and given similar results on anxiety and depression in the earlier trial among older patients in the community (17), we hypothesised that the intervention would be beneficial for both depression and anxiety. Nevertheless, one might hypothesise that the intervention programme induces anxiety in this vulnerable population, and therefore this issue needs careful further study, both in epidemiological studies and in future trials.

The object of our trial was to test whether adding our stepped care intervention to care as it is currently is both feasible and effective. In a pragmatic trial, such as ours, one aims to exclude as few people as possible and other treatments going on are monitored, but interfered with. Given a quite well developed health service for older people in the Netherlands, this amounts to quite a tough test, as (i) the intervention is not tested against a placebo condition and (ii) because in both conditions other interventions are allowed. The effect of these two is to blur distinctions between the two conditions.

Public Health significance
The considerable burden of common mental disorders on residents in homes for the elderly, in combination with a lack of resources for treatment, combine to make
prevention an interesting option for health promotion in this setting. To our knowledge, this is the first study that provides evidence of the effectiveness of a stepped care preventive programme in a residential home setting. However, our programme was effective for the prevention of depression, but not for anxiety. For the prevention of anxiety the programme would need to be improved, for example by including components that focus more specifically on anxiety disorders. Nevertheless, the preventive effect on depression is encouraging, and suggests that prevention may be a viable option, even in very old frail residents of residential homes.

“What this paper adds” box

Earlier evidence has demonstrated the effectiveness of a stepped care programme for the prevention of depression and anxiety in elderly individuals in the community, but evidence for the residential home setting has been lacking. Our stepped care intervention is effective in reducing the incidence of depression in residential home residents. The (selective) attrition in the study posed a data-analytical problem, and poor compliance rates indicated that the intervention is only acceptable for a minority of the residents. The programme therefore needs to be further improved.
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Chapter 7

Feasibility and effectiveness of activity-scheduling as a guided self-help intervention for the prevention of depression and anxiety in residents in homes for the elderly; a pragmatic Randomised Controlled Trial

Els Dozeman
Digna J.F. van Schaik
Harm W.J. van Marwijk
Max L. Stek
Aartjan T.F. Beekman
Henriëtte E. van der Horst

Abstract:

Background
Elderly people living in residential homes are at high risk for developing major depressive and anxiety disorders, and therefore deserve attention in terms of preventive interventions. We evaluated the feasibility and effectiveness of a guided self-help intervention for the prevention of depression and anxiety in these residents.

Methods
We conducted a pragmatic randomized controlled trial in two parallel groups comparing the intervention with usual care, in 14 residential homes in and surrounding the city of Amsterdam in the Netherlands. A total of 129 residents with a score of 8 or more on the screening instrument, the Centre for Epidemiologic Studies Depression Scale (CES-D), who did not meet the full diagnostic criteria for disorders, and were not suffering from cognitive impairment were recruited between April 2007 and December 2008. Participants were randomized to a guided self-help intervention (n=67) or to usual care (n=62). The main outcome measures were improvement in the level of symptoms of depression and anxiety. The secondary outcome was improvement in participation in organized activities in the residential homes. The study is registered in de Dutch Cochrane Centre, under number ISRCTN27540731.

Results
Only 21% of the participants (mean age 84.0 years [SD 6.7], 72.1% suffering from two or more chronic illnesses) completed the intervention. Although we found some large positive effect sizes on the CES-D, none of these effects were statistically significant.

Conclusion
Although guided self-help may be promising in the prevention of depression and anxiety, it proved to be difficult to apply in this very old and vulnerable group of people living in residential homes.
Introduction

Elderly people living in an institution have a higher risk of developing depression and anxiety disorders than elderly people living in the community, and therefore they deserve more attention in terms of preventive interventions (1). Chronic illnesses, disability, loneliness, older age, and female gender (2;3) may all increase this risk, and for many, if not most residents in homes for the elderly, all these risks add up. An important argument for the application of preventive strategies is that antidepressant medication has limitations in this group, mainly because of somatic co-morbidity, and potential interactions with other drugs (4).

Not surprisingly, the rates of clinically relevant symptoms of depression and anxiety in people living in long-term care facilities have been estimated to be as high as 35%(1;5). The prevalence of anxiety disorders alone has been estimated at 6.7% by Smalbrugge et al. (2003) in a review focusing on institutionalised elderly people. Moreover, 30-35% of the residents in residential and nursing homes with symptoms of depression and anxiety develop a full-blown major depressive disorder and generalised anxiety disorder (6;7). The risk of an increase in the level of symptoms is also very high; in a study of frail elderly people with scores below 16 on the Centre for Epidemiologic Studies Depression Scale (CES-D), it was found that 48% developed clinically relevant levels of depression within 18 months (8).

Several studies have shown that the prevention of depression and anxiety in high risk populations can be very effective (9), and the use of a guided self-help intervention has several advantages. It has also already been found to be an efficient and effective form of therapy in other settings (10), and it may lower the threshold of requesting help for those who are reluctant to acknowledge distress, or unwilling to participate in formal methods of treatment. Furthermore, it is an easy-to-use and cheap type of intervention. In a recent meta-analysis, Gellatly et al. found a large effect size (pooled standardised mean difference 0.80, 95% Confidence Interval [CI] 0.58-1.01) for self-help interventions in various populations (11). Providing some guidance in the use of self-help interventions was a significant positive moderator of the treatment effect, although the effect had no clear relationship with the therapist’s background, the content or mode of the guidance (monitoring/ supportive), or the number of sessions. In a recent systematic review of meta-analyses on the efficacy of self-help interventions for depression and anxiety disorders these large effect sizes were confirmed (12), also for older people (13).

However no studies have yet assessed the feasibility and effectiveness of this type of intervention in a residential care setting. The reading ability of older people is important if they are to understand self-help type of information. Moreover, the educational format of the course may be unfamiliar to those with only a few years of formal schooling (14). For residents, most of whom have a lower educational
status and are frequently suffering from vision impairments, these factors may be barriers to completing a self-help course. Furthermore, it is likely that the residents who have the highest risk for depression and anxiety may be the most difficult to reach with preventive interventions, due to the very same reasons that constitute their vulnerability for depression and anxiety. The aim of the present study was to determine the feasibility and the effectiveness of a self-help course for elderly residents with a high risk of developing a depression or an anxiety disorder.

We addressed the following research questions:
1. Is it feasible for residents to participate, and for care-providers to adequately implement a guided self-help intervention under the prevailing conditions in residential homes?
2. What is the effectiveness of a guided self-help course in activity-scheduling, compared to usual care, on the reduction of symptoms of depression and anxiety, and on participation in organized activities in a residential home population?

With regard to aspects of the feasibility of the intervention our hypotheses were:
   a. Uptake of the intervention is probably difficult for this old and vulnerable population.

With regard to the effectiveness of the intervention our hypotheses were:
   a. Guided self-help is more effective than usual care in reducing the symptoms of depression and anxiety in residents.
   b. Residents with more severe symptoms of depression at baseline will benefit most from the guided self-help intervention.
   c. The intervention is more effective in reducing symptoms of depression than symptoms of anxiety.
   d. The effect of the intervention is related to an increase in participation in organized activities.

**Methods**

**Design**

We tested our guided self-help intervention in a pragmatic randomized controlled trial with two parallel groups of participants. The word “pragmatic” refers to the fact that we performed this trial under regular care conditions, with very few exclusion criteria, in order to assess the feasibility of the intervention in “real life” conditions. The guided self-help intervention was part of a more comprehensive stepped-care program for elderly people with a high risk for developing depression and anxiety, living in residential homes. The design of this study has been described in detail elsewhere (15). In the present paper we focus on the effectiveness of this first step in the intervention protocol: guided self-help, which may lower the threshold for the
following steps for those who are reluctant to acknowledge distress. Four major health services providing care for the elderly in and surrounding the city of Amsterdam were willing to participate in the trial. These organisations covered a total of 14 residential homes. After informing the staff and the client council of these organisations, an introductory letter was sent to all residents in the homes (elderly people living alone or together with a spouse).

Interviewers visited every address, and asked the resident(s) for permission to assess their symptoms of depression and anxiety with the CES-D (16). Respondents with a score of 8 or more were invited for a follow-up interview, during which a diagnostic and cognitive assessment took place. The chosen cut-off point on the CES-D reflects symptom levels which are higher than the average levels found in the general population of elderly people (17). Respondents were excluded if they met the criteria for DSM IV depressive and anxiety disorders, according to the Mini International Neuropsychiatric Interview (MINI) (18), or were suffering from cognitive impairment, defined as a cut-off score of 21 for the Mini Mental State Examination (MMSE) (19). Residents who gave informed consent and who had sufficient command of the Dutch language were eligible for participation in the study. The study is registered in the Dutch Cochrane Centre, under number ISRCTN27540731. The study protocol was approved by the Medical Ethics Committee of the VU University Medical Centre.

Participants
In the Netherlands, several types of facilities for sheltered accommodation for the elderly are available, the two most important being residential homes and nursing homes. Residential homes provide assisted living facilities, including daily care (e.g. meals and house-cleaning) and, if needed, uncomplicated demand-led medical care. Nursing homes provide more specialised medical care to dependent people of all ages. The demand for residential care mainly depends on the lack of a social network and (in)ability to perform everyday activities (20).

Of the residents who were approached for the screening interview (n=1478), 51% (n=754) were able and willing to participate. Furthermore, of the 754 residents 459 (61%) scored higher than the predetermined threshold, 277 (60%) gave informed consent, and 85 were excluded. Seven residents were unwilling to participate before randomisation, for various reasons, resulting in the randomisation of 185 residents for the stepped care trial. However, in our trial we offered the guided self-help course after one month of watchful waiting, because it is well known that symptoms frequently disappear without any active intervention (21). We considered participants eligible for participation if the level of their symptoms had not improved by at least 5 points on the CES-D, and they had not developed a DSM IV depressive and anxiety disorder after one month. We used this definition
for improvement because a 5-point change on the CES-D is clinically relevant and statistically reliable, and has also been used in earlier studies (3;22;23). After the period of watchful waiting, residents in both groups either improved according to the 5-point criterion, or developed a MINI depressive and/or anxiety disorder, and therefore dropped out of the study. A total of 129 residents were finally eligible for inclusion in the guided self-help intervention. Assessments took place at the start, and directly after the end of the intervention. The flow-chart of participants is presented in Figure 1.

**Intervention**

We selected the module on “activity-scheduling” from a previously tested and effective self-help course “Coping With Depression” (CWD) (14). This course has been found to be effective in reducing depressive symptoms in several randomized clinical trials, both in group and individual format, and also in self-help format. The selected module on activity-scheduling consisted of four steps, in which participants monitored their mood and designed a pleasurable activity plan. We adjusted the lay-out for our specific study population (font and format of the characters were enlarged).
There are clear indications that activity-scheduling is effective, also as a preventive intervention (24). Activity scheduling is relatively simple, and does not require complex skills from coaches or patients. It is a behavioural treatment for depression in which patients learn to monitor their mood and daily activities. So far, the evidence with regard to its effectiveness is limited to depression, but because depression and anxiety overlap to a large degree, and because similar interventions are often found to be effective for both, we also wanted to determine whether activity-scheduling would have effects not only on depression, but also on anxiety.

We designed the intervention as a guided self-help course, which can be distinguished from other self-help interventions by the support that is given by a coach to the client in working through the standardised treatment schedule. The nature of this support should only be guidance or facilitation, and the staff and volunteers in the residential homes were instructed to guide and stimulate the residents to work through the course at their own pace. All the coaches were individually trained by one researcher (ED) in a 60-minute training session, in which they were given information about the rationale of the course. They received a process evaluation leaflet, containing instructions and questions about the coaching sessions. The focus in this training was on practising the tasks in the course together. All the coaches were specifically instructed to deliver the materials only to the assigned residents. They were instructed to visit the residents at least twice, but more often if needed, with a maximum of five visits. The management of the homes allowed the coaches no additional time to follow the training, and their visits to the residents also had to fit in with their regular shifts. During the course the coaches received feedback by telephone or, occasionally, during personal contacts. The instruction leaflets were collected by the researcher after the end of the sessions.

**Usual care**
Residents in the usual care group had unrestricted access to any form of health care that was deemed appropriate. In residential homes in the Netherlands, nurses and care-givers provide generic care, and general practitioners are responsible for medical care. Volunteers and occupational therapists also offer their help with (collective) social activities. All residential homes provide an activity program on a daily basis, and this can include group activities such as music performances, parlour games, gymnastics, and bus tours. The health care uptake of all participants was recorded, including their use of prescribed medication.

**Outcome measures**

*Aspects of feasibility*
To assess the participation of each resident in the intervention, the coaches filled in a process evaluation leaflet in which the number of visits, the steps of the interven-
tion that had been completed, and the time spent on coaching were recorded. At the end of the coaching sessions the leaflet was collected by the researcher, who evaluated the sessions with the coach.

Finally, we also measured the resident’s satisfaction with the intervention with a GGz Thermometer, developed by the Netherlands National Mental Health Institute (Trimbos). The participants were asked to score, on a scale ranging from 1-10, the usefulness of the intervention for themselves and for others, and also give an overall evaluation of the intervention.

Effectiveness
Depressive and anxiety symptoms after three months were the primary clinical outcomes. In the follow-up interview, symptoms of depression were measured with the CES-D, which consists of 20 items, with total scores ranging from 0-60. A minimum change of 5 points on the CES-D would indicate a medium to large effect size, which is deemed to be clinically relevant (22;23). Symptoms of anxiety were measured the Hospital Anxiety and Depression scale (HADS-A) (25). The HADS-A consists of 7 questions concerning anxiety, to which answers can be given on a 4-point scale (0-3). The total HADS-A score varies from 0 (no symptoms of anxiety) to 21 (many symptoms of anxiety).

The secondary outcome was the participation of residents in activities organized in the residential homes, measured with the Trimbos/iMTA questionnaire for Costs Associated with Psychiatric Illness (Tic-P) (26). The Tic-P generates quantitative data on use of the mental health services and other related services. The recall period for the questions is three months, and the questionnaire is constructed with modules that can be omitted if necessary. We used only the participation in activities module, to assess participation in the various different activities organized in the homes.

Sample size
In other studies focusing on self-help treatment with activity-scheduling for depression and anxiety, considerable effects have been found in the reduction of symptoms of depression ($d=0.8$) (11;27). To detect a difference in symptom means of Cohen’s $d =0.50$ (with an alpha=0.05 and 1-beta=0.80), 64 residents per group are needed (28).

Randomisation
Randomisation took place after the baseline measurements. The participants were randomised to the intervention group or to the usual care group, in blocks of four, by an independent research assistant using random number tables.
Blinding
The interviewers were blinded for the randomisation status of the respondents during all measurements. However, because residents in the intervention group received the self-help intervention and those in the control group did not, it was not possible to blind the participants. Care-providers were allocated to individual residents in the intervention group to help them with the intervention when needed.

Analyses
First we investigated possible differences in demographic and clinical characteristics at baseline (t-tests for continuous data, and Chi-square tests for categorical data). To check for possible selective attrition, we compared the characteristics of drop-outs and completers at baseline. For our primary outcome, the analyses were conducted on an intention-to-treat basis. This approach requires that the analyses are based on all randomized patients, therefore all missing observations need to be replaced by the most likely values. First, predictors of outcome and drop-out were identified. Prediction of outcome supplies the most precise value of the outcome variable, while prediction of drop-out helps to correct for the bias that may be caused by selective loss to follow-up. The statistically significant predictors for outcome and drop-out (age, CES-D score at baseline, HADS score at baseline, and number of activities at baseline) were used in a Maximum Likelihood Estimation (MLE), as implemented by the Estimated Maximum (EM) algorithm in SPSS, to obtain and impute the required predicted values. Because guided self-help has not yet been assessed among very old and vulnerable elderly people, and therefore we were unsure of the feasibility of the intervention, we also performed analyses for the completers.

To obtain an impression of the magnitude of the effect in the analysis of the completers, we calculated effect sizes: Cohen’s $d$, by subtracting the mean score difference in the usual care group from the mean score difference in the intervention group, and dividing the result by the pooled standard deviation of the difference scores. This frequently used measure enables comparison with the results of other studies. Effect sizes between 0 and 0.3 are considered to be small, between 0.3 and 0.5 they are considered to be moderate, and between 0.5 and 1.2 they are considered to be large (23). In order to test the hypothesis that the effect is modified by the severity of the symptoms at baseline, we calculated effect sizes for a sub-group of participants with more severe symptoms of depression at baseline (CES-D≥16). The effectiveness of the self-help intervention was further assessed by performing an analysis of covariance (ANCOVA) with the baseline score as a covariate, because this approach corrects for baseline status. It also allows us to investigate the possible interaction effects between participation in the trial and the characteristics of the residents, and between participation in the intervention
and outcome measurements. Pre-test data were available for all participants. All analyses were performed with SPSS (version 15.0), and statistical significance was considered as 2-tailed p<0.05.

Results
Participants
Recruitment took place between April 2007 and December 2008, and 129 residents were allocated to the intervention group (n=67) or to the usual care group (n=62) (Figure 1). Of the 129 participants, 22 (17 %) dropped out during the study period. The reasons for drop-out are shown in the flowchart (Figure 1). On average, drop-out in the intervention group was higher than in the usual care group; 23.9% versus 9.7%. This difference was significant ($\chi^2 = 4.59$, df=1, p=0.04).

Baseline characteristics
The baseline characteristics of the participants are summarized in Table 1. The majority of the participants were female (74%), and their mean age was 84.0 years (SD 6.7). Most of them (83.7%) were living alone, and most of them (72.1%) suffered from two or more chronic diseases, such as heart disease and arthritis. The mean CES-D score for depressive symptoms was 15.1 (SD 5.3), and the mean HADS-A score for anxiety symptoms was 3.4 (SD 2.5). No significant differences (p < 0.05) in these variables were found between the two groups. Most of the residents had visited their general practitioner in the past three months (72.9%), with a mean of 2.2 visits (SD 1.7). Only two residents reported that they had visited a mental health specialist (data not included in the table), both of whom were randomized to the usual care group.

Usual care
We found that in both the intervention group and the usual care group no participants had received counselling from a psychiatrist or psychotherapist during the study period. 6 participants in the usual care group received antidepressant medication vs. 11 participants in the intervention group ($\chi^2 = 1.28$, df=1, P=0.26). Finally, 24 participants in the usual care group received sedative medication vs. 30 participants in the intervention group ($\chi^2 = 0.44$, df=1, P=0.49).

Aspects of feasibility
A total of 51 residents were eligible for participation in the guided self-help intervention, 44 (86%) of whom finally attended the self-help course with guidance from a coach. Evaluation, by means of the process evaluation leaflets revealed that 2 residents were unwilling to participate in the self-help course, while 5 coaches failed
to contact the resident. When coaches were asked for the reasons for non-compliance of residents, they reported lack of time themselves or illness of the residents. The mean number of visits made by the coaches was 2, and the mean amount of time they spent on guiding the residents in the self-help course was 48 minutes for each resident (SD 44.6, range 5-180 minutes). A total of 14 residents completed all four steps in the self-help course, and 8 residents completed three steps, but failed to complete the last step, i.e. making an activity plan for the following week. 14 residents accepted the course but did not start performing the exercises, 4 completed 1 step, and 4 completed 2 steps. 34 out of 44 (77%) residents answered the questions about satisfaction with the intervention, 9 (27%) thought that the self-help intervention was a useful way to improve their mood, 19 (53%) thought it was not useful, and 6 (18%) answered “don’t know”. A positive response to the intervention was equally spread among completers and non-completers; a quarter of the participants in both groups thought that the intervention was helpful. The overall

Table 1. Baseline characteristics of participants (n=129)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention group (N=67)</th>
<th>Usual care group (N=62)</th>
<th>χ² or t-test</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>83.7 (6.7)</td>
<td>84.2 (6.8)</td>
<td>0.373</td>
<td>0.71</td>
</tr>
<tr>
<td>Female, N (%)</td>
<td>46 (68.7)</td>
<td>50 (80.6)</td>
<td>2.431</td>
<td>0.12</td>
</tr>
<tr>
<td>CES-D score, mean (SD)</td>
<td>15.6 (5.7)</td>
<td>14.5 (4.9)</td>
<td>-1.178</td>
<td>0.24</td>
</tr>
<tr>
<td>Level of anxiety symptoms, mean (SD)</td>
<td>3.8 (2.7)</td>
<td>3.1 (2.3)</td>
<td>-1.587</td>
<td>0.12</td>
</tr>
<tr>
<td>MMSE, mean (SD)</td>
<td>27.1 (2.0)</td>
<td>26.8 (2.0)</td>
<td>-0.760</td>
<td>0.45</td>
</tr>
<tr>
<td>Education beyond high school, N (%)</td>
<td>19 (28.4)</td>
<td>12 (19.4)</td>
<td>1.430</td>
<td>0.23</td>
</tr>
<tr>
<td>Married/living with a partner, N (%)</td>
<td>12 (17.9)</td>
<td>9 (14.5)</td>
<td>0.272</td>
<td>0.60</td>
</tr>
<tr>
<td>Two or more chronic illnesses, N (%)</td>
<td>50 (74.6)</td>
<td>43 (69.4)</td>
<td>0.445</td>
<td>0.51</td>
</tr>
<tr>
<td>Number of years of living in residential home, mean (SD)</td>
<td>4.4 (4.1)</td>
<td>3.7 (3.0)</td>
<td>-1.166</td>
<td>0.25</td>
</tr>
<tr>
<td>Numbers of residents visiting a GP, ** (N (%))</td>
<td>49 (73.1)</td>
<td>45 (72.6)</td>
<td>0.010</td>
<td>0.92</td>
</tr>
<tr>
<td>Number of visits to the GP, ** (N (%))</td>
<td>2.4 (1.9)</td>
<td>2.1 (1.4)</td>
<td>-0.994</td>
<td>0.32</td>
</tr>
</tbody>
</table>

*participated in one week
**in the past 3 months
GP= general practitioner
score for the self-help intervention varied from very bad (1-5 on a scale of 1-10) (6/35=17%), to moderate (6 or 7 on a scale of 1-10) (12/35=34%), and very good (8 or higher on a scale of 1-10) (8/35=23%). Again, 7 residents answered “don’t know”, and there was one missing score. The mean overall score for the self-help intervention was 6.3 (SD 2.2), 9 residents (25%) thought that the effect of the self-help intervention could be improved if the coaches were more attentive, and 4 residents (11%) thought that the intervention could be useful for other people, but not for themselves.

In this pragmatic trial we tried to involve the personal care-givers, or contact nurse for the individual residents. A total of 20 care-givers coached their own residents, and 11 of them had more than one resident in their case-load. When personal care-givers were not available, we trained occupational therapists (two) or volunteers (four).

No interaction effects were found between participation in the intervention group and sub-groups with specific characteristics (age, living alone, or number of chronic diseases). Moreover, no interaction effects were found between level of uptake of the intervention and symptoms of depression. Residents who completed the intervention received significantly more visits from their coaches than those who did not (3.2 [SD 1.2] vs. 1.8 [SD 1.0] t=4.12, df=42, p< 0.01), and the coaches spent more time visiting the completers than the non-completers (73 minutes [SD 47] vs. 35 minutes [SD 38] t=2.78, df=39, p < 0.01).

<table>
<thead>
<tr>
<th>Scale</th>
<th>Usual care (N=62) Mean (SD)</th>
<th>Intervention (N=67) Mean (SD)</th>
<th>Intervention completers (N=14) Mean (SD)</th>
<th>Effect size Cohen’s d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-test Post-test</td>
<td>Pre-test Post-test</td>
<td>Pre-test Post-test</td>
<td>All Completers</td>
</tr>
<tr>
<td>CES-D</td>
<td>14.5 (4.9) 13.8 (7.6)</td>
<td>15.6 (5.7) 13.5 (5.4)</td>
<td>16.6 (5.1) 12.2 (4.8)</td>
<td>0.24 0.60</td>
</tr>
<tr>
<td>HADS-A</td>
<td>3.1 (2.3) 2.6 (2.5)</td>
<td>3.8 (2.7) 2.7 (2.2)</td>
<td>4.1 (2.2) 2.6 (2.4)</td>
<td>0.18 0.48</td>
</tr>
<tr>
<td>Activities</td>
<td>2.4 (1.0) 2.5 (1.1)</td>
<td>2.4 (1.0) 2.6 (0.8)</td>
<td>2.4 (1.3) 2.7 (1.2)</td>
<td>-0.01 0.08</td>
</tr>
</tbody>
</table>

Effect size is presented as Cohen’s d; the difference between two means divided by a standard deviation for the data.

Table 2. Effects of guided self-help on symptoms of depression, symptoms of anxiety, and participation in organized activities
Effectiveness

Effect sizes were small ($d < 0.30$) for symptoms of depression, symptoms of anxiety, and participation in activities in the population as a whole (Table 2). In the sub-group of participants with more severe symptoms of depression at baseline (CES-D $\geq 16$), a large effect size on reducing symptoms of depression was found ($d=0.55$). The effect sizes with regard to symptoms of anxiety and level of activities were small in this sub-group (Table 3). In the group of completers ($n=14$), reduction in the symptoms of depression and anxiety was greater than in the usual care group (a large effect size on symptoms of depression $d=0.60$, and a medium effect size on symptoms of anxiety $d=0.48$) (Table 2). Finally, in the sub-group of completers with severe symptoms of depression at baseline (CES-D $\geq 16$, $n=7$), a large effect size was found on reduction of depressive symptoms ($d=0.80$) (Table 3). However, the effects of the guided self-help course on depressive symptoms found with ANCOVA, correcting for baseline severity, were not significant (Table 4).

Discussion

In the intention-to-treat analysis, no significant difference was found between guided self-help and usual care. We hypothesised that participation in the intervention would probably be difficult for these old and vulnerable residents. We did, indeed,
observe that only a minority of the residents were able to complete the intervention (14/67=21%); 7 (14%) did not accept the intervention at all, and 14 accepted the course, but did not start performing the exercises. The drop-out in the intervention group was significantly higher than in the usual care group. However, many residents (n=8, 50%) dropped out of the intervention group because of somatic illness, which does not seem to be related to the intervention, although a certain amount of energy is needed for the exercises. There was no significant difference between the mean baseline characteristics of the completers and the drop-outs. Only 27% of the residents thought that the intervention was useful. There may have been several reasons for this low assessment of feasibility, and lack of effect:

1. Because we actively screened all residents and invited those with an average or above average CES-D score for symptoms of depression to participate, we may have selected a group of residents with low acknowledgement of their symptoms of depression and anxiety. Many participants did not feel that they needed

<table>
<thead>
<tr>
<th></th>
<th>Intervention Mean (SD)</th>
<th>Usual Care Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CES-D Pre-test</td>
<td>15.6 (5.7)</td>
<td>14.5 (4.9)</td>
</tr>
<tr>
<td>CES-D Post-test</td>
<td>13.5 (5.4)</td>
<td>13.8 (7.6)</td>
</tr>
<tr>
<td></td>
<td>F (1,126)=1.27</td>
<td>P= 0.26</td>
</tr>
<tr>
<td>CES-D Pre-test ≥16</td>
<td>21.0 (4.3)</td>
<td>19.2 (2.4)</td>
</tr>
<tr>
<td>CES-D Post-test</td>
<td>16.8 (5.8)</td>
<td>18.3 (8.7)</td>
</tr>
<tr>
<td></td>
<td>F (1, 52)=1.61</td>
<td>P= 0.21</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Intervention Mean (SD)</th>
<th>Usual Care Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CES-D Pre-test</td>
<td>16.6 (5.1)</td>
<td>14.5 (4.9)</td>
</tr>
<tr>
<td>CES-D Post-test</td>
<td>12.2 (4.8)</td>
<td>13.8 (7.6)</td>
</tr>
<tr>
<td></td>
<td>F (1, 73)=3.00</td>
<td>P= 0.08</td>
</tr>
<tr>
<td>CES-D Pre-test ≥16</td>
<td>20.6 (3.9)</td>
<td>19.2 (2.4)</td>
</tr>
<tr>
<td>CES-D Post-test</td>
<td>13.0 (5.4)</td>
<td>18.3 (8.7)</td>
</tr>
<tr>
<td></td>
<td>F (1, 31)=2.76</td>
<td>P= 0.11</td>
</tr>
</tbody>
</table>

Table 4. ANCOVA for guided self-help effects with the pre-test CES-D score as covariate
help for their (mild) symptoms, and therefore might be less motivated to start and to complete the intervention, compared to participants in other comparable studies. This is in line with our finding that the effect sizes were greater in the sub-group of residents with more severe symptoms of depression at baseline. Some residents might even have been discouraged by being confronted with their symptoms during the self-help intervention. Therefore, self-help should only be offered to residents who are interested and motivated.

2. Minimal contact interventions, like this activity-scheduling self-help intervention, aim to empower high risk groups to improve their own functioning themselves. However, in an institutional environment, such as a residential home, the aim of the intervention (i.e. empowerment) might be in conflict with the attitudes and needs of residents for help and security in a caring environment. Other interventions may be more appropriate for residents for whom hospitalisation is a barrier to self-help.

3. We performed this trial under regular care conditions, with very few exclusion criteria, in order to assess the feasibility of the intervention in “real life” conditions. We only excluded patients below a cut-off score of 21 on the MMSE, which is relatively low. We chose this cut-off score because most residents have a low level of education, and we did not want to exclude those who may profit from our relatively simple intervention. However, residents who were not interested in the intervention may have had levels of cognitive functioning or literacy that were too low to enable them to understand this self-help course.

4. The staff of the residential homes reported that they lacked the necessary time to guide residents through the self-help course, and previous research has shown that self-help without guidance is less effective (11;29). The number of visits and time spent on guidance by the coaches in our intervention might have been insufficient, and it is possible that the support during those contacts did not motivate the participants enough to achieve significant effects. If the management of the residential homes provided more time for training and adequate support from care-providers, this might improve the uptake of the intervention.

In the several relevant reviews and meta-analysis that have been carried out (11;29;30), overall guided self-help was found to be much more effective than usual care in which the patients received no treatment. In the present study of the effects of a guided self-help intervention for improving symptoms of depression and anxiety, we found no significant difference in effects between the intervention group and the usual care group. However, the estimated effect sizes (Cohen's $d$) were
large for completers with symptoms of depression, and also large for residents with more severe symptoms of depression at baseline. However, lack of statistical power within these sub-groups may have precluded statistically significant results.

Among the completers, a medium positive effect size was also found for anxiety, which again was not statistically significant. This may be partly due to the low level of anxiety symptoms at baseline. A score of 8 or higher on the HADS-A is accepted as a cut-off point for more severe symptoms (31), and the mean baseline score in our study population was 3.4.

Finally, guided self-help did not improve the level of participation in organized activities. Although the level of symptoms of depression tended to decrease with activity-scheduling, the number of activities did not increase. A possible explanation is that we only recorded the number of activities which were organized in the residential home. Residents who improved after the intervention may have undertaken more activities outside the regular activities that were organized in the residential home.

The results of our study contribute to the existing body of knowledge about the prevention of depression and anxiety in the elderly. The hypothesis that activity-scheduling as a self-help intervention is more effective than usual care in lowering symptoms in a very old residential home population with a high risk for depressive and anxiety disorders, can not be confirmed on the basis of this trial, mainly because of the limited uptake. Although it is an attractive approach, self-help is difficult to achieve in vulnerable elderly people, and further research is necessary to improve the acceptability, level of participation and uptake in such interventions. Future research could focus on how to develop a beneficial relationship with a care-giver, before acknowledgement issues can be discussed. A minority may indeed benefit, so a flexible approach, in which the intervention is offered as an option to residents who are interested, together with adequate guidance from care-providers, would seem to be the most promising approach at the moment.
Reference List


(26) Roijen Lv, Straten Av, Tiemens B, Donker MCH. Handleiding Trimbos/iMTA questionnaire for costs associated with psychiatric illness (Tic-P). 2002. Ref Type: Electronic Citation


Chapter 8

Prevention of Depression in Residents in Homes for the Elderly; do effects sustain after two years?

Els Dozeman
Harm W.J. van Marwijk
Digna J.F. van Schaik
Max L. Stek
Filip Smit
Aartjan T.F. Beekman
Henriëtte E. van der Horst
Abstract:

Objectives
To evaluate the two years effects of a stepped care programme to prevent the onset of depressive disorder in elderly people living in residential homes.

Design
A pragmatic randomised controlled trial.

Setting
14 residential homes in the Netherlands participated in the study.

Participants
A total of 185 residents with a minimum score of 8 on the Center for Epidemiologic Studies Depression Scale (CES-D), who did not meet the diagnostic criteria for a depressive disorder, and were not suffering from severe cognitive impairment, were recruited between April 2007 and December 2008.

Intervention
Participants were randomised to a stepped care programme (n=93) or to usual care (n=92). Stepped care participants sequentially underwent watchful waiting, a self-help intervention, life review, and a consultation with the general practitioner.

Measurements
The primary outcome measure was the incidence of a major depressive disorder (MDD) during a period of two years, according to the Mini International Neuropsychiatric Interview (MINI).

Results
The application of a stepped care prevention programme reduced the risk of developing a depressive order in one year (Incidence Rate Ratio (IRR) 0.26; 95% confidence interval [CI] 0.12-0.80). In two years, the IRR of MDD was 0.98; 95% CI 0.54 to1.81. In the 76 residents who completed the two-years measurements the IRR was 0.53; 95%CI ranging from 0.32 to 0.87.

Conclusion
The effect of the stepped care intervention on prevention of depression did not sustain over two years in the intention to treat analysis. However, it did sustain in the subgroup of residents who completed all measurements.
Introduction

Mental disorders like depression and anxiety are very common in the elderly population, and they are associated with excess mortality and reduced quality of life (1-4). Given the large number of people who are affected, it is unlikely that even the most resourceful health services will be able to provide adequate treatment for them all. Therefore, preventive strategies may be a more feasible way to reduce the burden for the population, and are increasingly applied (5).

Several preventive interventions studies were successful in reducing the incidence of anxiety and depressive disorders in the elderly population (6;7). However, Cuijpers (2008) indicated a decreasing effect over time of preventive interventions in a meta-analytic review. “In fact, we found that the length of the follow-up period was inversely associated with the incidence rate ratio; although not statistically significant, this relationship can be seen as an indication of effect decay over time, which could point to a delay of incidence rather than prevention” (8). In the same time, in a study in the Netherlands carried out among people of 75 years and older living in the community, the application of a stepped care prevention programme reduced the risk of developing a depressive or anxiety disorder by 57.9% (7), and effects were retained over two years (9). Preventive interventions aim to empower persons at risk in handling the factors that contribute to the risk of the incidence of mental disorders. The risk factors themselves, like chronic illnesses, disability, and older age, are not likely to disappear. One can hypothesise that preventive activities need to be maintained to ensure ongoing effects, and therefore more studies on the longer terms effects of preventive interventions are needed.

In our study in the Netherlands carried out among people living in residential homes, the application of a stepped care prevention programme reduced the risk of developing a depressive order in one year (IRR 0.26; 95% confidence interval [CI] 0.12-0.80). The intervention was not effective in reducing the incidence of the combined outcome of depression and anxiety (IRR=0.50 and a 95% CI ranging from 0.23 to 1.12), and in reducing the incidence of anxiety disorders alone (IRR 1.32; 95% CI 0.48-3.62). Because the intervention was not effective in preventing anxiety disorders we only assessed the longer term effects of the intervention on depression. We hypothesised that the effect of the stepped care intervention on reducing incident depression might not hold, and we re-assessed the effectiveness of our intervention over two years.
Methods

Design
We tested a stepped care programme in a pragmatic randomised controlled trial with two parallel groups. In brief, 14 residential homes in Amsterdam and surroundings were willing to participate in the trial. The 14 participating homes covered several areas in and surrounding the city, including both more affluent and deprived areas of Amsterdam. The randomisation of consenting residents, stratified according to residential home, took place after the baseline measurements in blocks of four with an equal allocation ratio, carried out by an independent statistician using random number tables.

The central clinical outcome in this follow-up study was the cumulative incidence of DSM-IV depressive disorder over a period of two years, as measured with the Mini International Neuropsychiatric Interview (MINI) (10). The Medical Ethics Committee of the VU University Medical Center approved the study protocol.

Participants
Interviewers visited every address, and asked the resident(s) for permission to screen for depressive symptoms with the Center for Epidemiologic Studies Depression Scale (CES-D) (11). Respondents with a minimum score of 8, i.e. above average (12), were invited for a follow-up interview in which a diagnostic and cognitive assessment took place. Respondents who met the criteria for MINI/DSM-IV depressive disorder were excluded, as were residents with evidence of substantial cognitive impairment, measured with a cut-off score of 21 for the Mini Mental State Examination (MMSE) (11;13).

Steppe-care programme

Step-up rules
After one month of watchful waiting, assessments took place in cycles of three months. Participants were invited to step up to the next level of the intervention if the level of their symptoms had not improved by at least 5 points on the CES-D. We used this definition of improvement because a 5-point change on the CES-D is both clinically relevant and statistically reliable, and has also been used in earlier studies (14-16). If at any measurement point a participant was found to have developed a DSM-IV depressive or anxiety disorder, the preventive intervention was considered to have failed, and this failure was recorded as a clinical end-point. These residents were referred to their general practitioner for possible psychological or pharmacological treatment. Participants with a decrease in symptoms of 5 points or more were not offered the next step of the stepped care programme, but were monitored for the next three months. Two years after baseline measurement a final follow up measurement took place. The stepped care programme consisted
of four steps: watchful waiting, activity-scheduling, life review and consultation with the general practitioner, and finally, a visit to the general practitioner for additional treatment.

**Usual care**
Residents in the usual care group had unrestricted access to any form of health care that was considered to be appropriate. Health care utilisation of the residents in the care as usual group was recorded, including the prescription of medication.

**Measures**
Major depressive disorder was assessed with the MINI, which is a short, structured diagnostic interview to assess DSM-IV mental disorders. Symptoms of depression were measured with the CES-D, which consists of 20 items, with total scores ranging between 0 and 60.

**Sample size**
Based on the results of longitudinal studies (3;17), the (original) combined incidence rate of depression and anxiety disorders together was expected to be 35% in the usual care group and 20% in the intervention group after two years. We calculated a sample size of 67 participants per group was needed for five follow-up measurements (18;19), assuming a two-sided test at an alpha=0.05 and 1-beta=0.80. With a drop-out of 20%, at least 168 participants were needed.

**Blinding**
The interviewers were not informed about the randomisation status of the participants. However, in this type of intervention it is not possible to conceal randomisation status from the participants themselves.

**Analysis**
We first investigated possible baseline differences in demographic and clinical characteristics across the conditions (t-tests for continuous data, and Chi-square tests for categorical data). To check for possible selective attrition, we compared the prognostically relevant characteristics of dropouts and completers in the intervention group and in the usual care group. We also compared the reasons for dropout between the groups.

The main analyses were conducted on an intention-to-treat basis. This approach implies that the analyses are based on all randomised patients, and this requires the imputation of missing end-points. We replaced missing end-points by their most likely values as those obtained with the Little and Rubin EM algorithm, as implemented in SPSS (15.0). By way of a sensitivity analysis, we also used 2
other imputation strategies. First, regression imputation as implemented in SPSS 15.0, and second, multiple imputation. For this last, we used the Stata hotdeck procedure stratified for dichotomised predictors of outcome and loss to follow-up. We finally performed a “completers-only analysis”, based on the data of the participants who completed the interviews.

To estimate the extent to which the intervention reduced the risk of depressive disorder compared to usual care, we performed a Poisson regression analysis of the MINI/DSM-IV depressive cumulative incidence (1=developed a disorder and 0=remained disorder-free) on the treatment indicator (0=usual care, 1= intervention). In this way, we obtained an incidence rate ratio (IRR) which describes the difference between the incidence rate in the intervention group and in the usual care group. The superiority of the intervention would be supported if the IRR falls below 1, and would be significant at P < 0.05, 2-tailed.

Figure 1. Flowchart of participants in the trial
The regression analyses were performed with Stata (version 9.1), while taking into account the clustering effect that the multi-site trial (with participants ‘nested’ within each of the 14 residential homes) introduced in the data. We therefore computed robust 95% CIs and test statistics by applying the first-order Taylor-series linearisation method. All regression models were specifications of the generalized linear model (GLM).

Results

Participants
Recruitment took place between April 2007 and December 2008. We randomised 185 residents to the stepped care programme (n=93) or to the usual care group (n=92) (Figure 1). Of the 185 participants, 82 (44.3 %) dropped out during the two years of the study. 27 participants developed a depressive or anxiety disorder or both, and therefore fell out of the study and were referred to their general practitioner for possible psychological or pharmacological treatment.

Baseline characteristics
The participants were mainly women (73%), with a mean age of 84.3 (SD=6.5), and most had 2 or more chronic diseases (76.3%) and poor daily functioning (51.4%). Most of the participants were living alone (83.2%), and felt lonely (70.8%). There were no significant differences between the intervention group and the usual care group at baseline, indicating that randomisation had resulted in a balanced distribution of these variables over the two groups (Table 1).

Analysis of drop-out
Dropout was associated with lower anxiety status at baseline (t=2.69, df=183, P=0.008), and higher MMSE score at baseline (t=3.29, df=183, P=0.001). No other predictors for dropout were found. In the intervention group, 13 of the 93 participants died, compared with 11 of the 92 participants in the usual care group.

Outcomes
Higher CES-D score at baseline, lower MMSE score at baseline, and the length of stay in the residential home were predictors for the incidence of a major disorder, and HADS-A and MMSE score at baseline was a predictor for drop-out. We used these significant predictors in the imputation procedures. Based on the intention-to-treat analysis with EM imputation, the incidence of depressive disorders was 15 out of 93 participants in the intervention group, and 15 out of 92 in the usual care group, resulting in an IRR of 0.98 (95% CI 0.54 to1.81).
<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention Group (N=93)</th>
<th>Usual Care Group (N=92)</th>
<th>Total* (N=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female gender (%)</td>
<td>67 (72.0)</td>
<td>68 (73.9)</td>
<td>135 (73.0)</td>
</tr>
<tr>
<td>Age on entry in the trial (SD)</td>
<td>84.5 (6.7)</td>
<td>84.2 (6.4)</td>
<td>84.3 (6.5)</td>
</tr>
<tr>
<td>Age-range</td>
<td>61.8 – 100.3</td>
<td>62.1 – 94.9</td>
<td>61.8 – 100.3</td>
</tr>
<tr>
<td>MMSE (SD)</td>
<td>27.0 (2.1)</td>
<td>27.1 (2.0)</td>
<td>27.1 (2.1)</td>
</tr>
<tr>
<td>Married or living with a partner (%)</td>
<td>18 (19.4)</td>
<td>13 (14.1)</td>
<td>31 (16.8)</td>
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<td>Education beyond secondary school (%)</td>
<td>20 (21.5)</td>
<td>17 (18.5)</td>
<td>37 (20.0)</td>
</tr>
<tr>
<td>Number of chronic diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0 (%)</td>
<td>4 (4.3)</td>
<td>5 (5.4)</td>
<td>9 (4.9)</td>
</tr>
<tr>
<td>1 (%)</td>
<td>13 (14.0)</td>
<td>22 (23.9)</td>
<td>35 (18.9)</td>
</tr>
<tr>
<td>2 (%)</td>
<td>34 (36.6)</td>
<td>29 (31.5)</td>
<td>63 (34.1)</td>
</tr>
<tr>
<td>&gt;2 (%)</td>
<td>42 (45.2)</td>
<td>36 (39.1)</td>
<td>78 (42.2)</td>
</tr>
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<td>CES-D score (SD)</td>
<td>14.9 (5.7)</td>
<td>14.4 (5.3)</td>
<td>14.7 (5.5)</td>
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<tr>
<td>HADS-A score (SD)</td>
<td>3.6 (2.8)</td>
<td>3.2 (2.6)</td>
<td>3.4 (2.7)</td>
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<tr>
<td>Loneliness score (SD)</td>
<td>3.4 (0.9)</td>
<td>3.4 (0.8)</td>
<td>3.4 (0.8)</td>
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<td>Loneliness categorical (%)</td>
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<td></td>
<td></td>
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<tr>
<td>Not lonely</td>
<td>29 (31.2)</td>
<td>33 (35.9)</td>
<td>62 (33.5)</td>
</tr>
<tr>
<td>Lonely</td>
<td>64 (68.8)</td>
<td>59 (64.1)</td>
<td>123 (66.5)</td>
</tr>
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<td>ADL score (SD)</td>
<td>35.1 (5.7)</td>
<td>34.4 (6.3)</td>
<td>34.7 (6.0)</td>
</tr>
<tr>
<td>Major difficulties ADL (%)</td>
<td>50 (53.8)</td>
<td>45 (48.9)</td>
<td>95 (51.4)</td>
</tr>
<tr>
<td>Suffering from feelings of depression/anxiety in the past (%)</td>
<td>48 (51.6)</td>
<td>53 (57.6)</td>
<td>101 (54.6)</td>
</tr>
<tr>
<td>Length of stay in residential home</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1 year (%)</td>
<td>29 (31.2)</td>
<td>24 (26.1)</td>
<td>53 (28.6)</td>
</tr>
<tr>
<td>&gt;1 year (%)</td>
<td>54 (58.1)</td>
<td>64 (69.6)</td>
<td>118 (63.8)</td>
</tr>
<tr>
<td>&gt;10 years (%)</td>
<td>10 (10.8)</td>
<td>4 (4.3)</td>
<td>14 (7.6)</td>
</tr>
<tr>
<td>Hearing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no problems</td>
<td>51 (54.8)</td>
<td>52 (56.5)</td>
<td>103 (55.7)</td>
</tr>
<tr>
<td>serious problems</td>
<td>43 (46.2)</td>
<td>40 (43.5)</td>
<td>82 (44.3)</td>
</tr>
<tr>
<td>Vision</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no problems</td>
<td>47 (50.5)</td>
<td>55 (59.8)</td>
<td>102 (55.1)</td>
</tr>
<tr>
<td>serious problems</td>
<td>46 (49.5)</td>
<td>37 (40.2)</td>
<td>83 (44.9)</td>
</tr>
</tbody>
</table>

* There are no significant differences between groups (t-test/Chi-square test)

Table 1. Baseline demographic and clinical characteristics of the participants
Sensitivity analyses
To assess the robustness of the outcomes, we performed several sensitivity analyses, and first repeated the intention-to-treat analysis, basing it this time on regression imputation. The two-year incidence of depressive disorders then was 14 out of 93 participants in the intervention group, and 17 out of 92 in the usual care group, resulting in an IRR of 0.82 (95% CI 0.48 to 1.39). Finally, we repeated this analysis based on multiple imputations, which resulted in a similar IRR of 0.82 (95% CI 0.36 to 1.88). In a completers’ analyses, however, no new cases of depression occurred in all the residents who completed the study. The incidence therefore remained the same after two years (5 out of 35 participants in the intervention group, and 12 out of 44 in the usual care group). This indicates that the results after one year did hold for the subgroup of 76 residents who completed all measurements (IRR 0.53 and a 95% CI ranging from 0.32 to 0.87 [SE=0.13 z= -2.51 P= 0.012]).

Discussion
We hypothesised that the effect of the stepped care programme on depression, based on monitoring and evidence-based interventions, after one year would not sustain after two years. The effects of the stepped care programme did, indeed, not hold in the follow-up year. Only in the “completers-only analysis”, the effects remained equal to the effects in the first year. The sustained effects after two years in a similar study in a very old population the community (9) could not be confirmed.

A limitation to the study concerns the high dropout rates. Dropout of the study after two years is n= 82 (44.3%), which is very high, but can be expected in this very old and vulnerable population. Although the preventive effect of the intervention after one year on depression is encouraging, the two years results show that only a selected group of residents is able to benefit from the intervention on a longer term. The intention to treat analyses showed that the incidence of depression increased in the second follow up year, when no preventive activities were offered. Residents that dropped out in the second follow up year of the study are likely the residents at highest risk for developing a disorder, because of their vulnerable health status, and might have benefited when interventions would have been offered. Therefore, monitoring of symptoms and offering interventions should be ongoing in this high risk population.

Another limitation of the study concerns the sample size calculation. This was based on the combined outcome of depression and anxiety. In our study on the effects after one year, we found a significant effect only on incidence of depression. We therefore measured the follow-up effect of depression only. However, because the incidence rate of depression was lower than we had anticipated beforehand (16% vs.35%), resulting in a lack of power of our study, some caution is needed.
with regard to our conclusions. Nevertheless, the point-estimate of the effect size confirms the disappearance of the effect after two years.

Strengths of the study include the fact that the study design was a pragmatic trial, with very few a priori exclusion criteria, which enhances generalisation to usual care in residential homes in the Netherlands. Other strong features include the use of structured psychiatric diagnoses to independently measure outcome and the use of a stepped care format, including evidence-based interventions. Finally, a two year period of follow up is a strength in itself, because it offers rare information on the sustained effects of a preventive intervention.

The considerable burden of common mental disorders on residents in homes for the elderly, in combination with a lack of resources for treatment, combine to make prevention an interesting option for health promotion in this setting. To our knowledge, this is the first study that evaluates the effects of a stepped care preventive programme in a residential home setting over two years. Although our programme prevented depression in the first year, effects did not hold. The frailty of the population might be the cause of a limit to longer term effects.

Participation in a preventive intervention is optional, and people in high risk groups may not acknowledge the urge to participate and modify their behaviour. This may result in some amount of self-selection of the most healthy residents in the population in which the positive effects of the intervention are sustained.
Reference List


Chapter 9

Cost-effectiveness of a stepped care program to prevent anxiety and depression in homes for the elderly: a randomised controlled trial

J.E. Bosmans
E. Dozeman
Harm W.J. van Marwijk
Digna J.F. van Schaik
Max L. Stek
Aartjan T.F. Beekman
Henriette E. van der Horst

Submitted
Abstract:

Background
Depression and anxiety are common in residents of elderly homes. Both disorders have negative effects on functioning, well being and healthcare utilization. Besides treatment, prevention can be an option to reduce the burden of mental disorders.

Objective
The objective of this study was to evaluate the cost-effectiveness of a stepped care programme to prevent the onset of depression and anxiety disorders in residents of elderly homes compared with usual care from a societal perspective.

Methods
Outcomes were incidence of depression and/or anxiety, severity of depressive and anxiety symptoms and quality-adjusted life years. Healthcare utilization was measured during interviews. Multiple imputation was used to impute missing cost and effect data. Uncertainty around cost-differences and incremental cost-effectiveness ratios was estimated using bootstrapping. Cost-effectiveness planes and acceptability curves were created.

Results
The incidence of depression and anxiety combined in the intervention group was not reduced in comparison with the usual care group. There was also no effect on the other outcomes. Mean total costs in the intervention group were €838 higher than in the usual care group, but this difference was not statistically significant (95% CI -593 to 2420). Cost-effectiveness planes showed that there was considerable uncertainty. Cost-effectiveness acceptability curves showed that the maximum probability of the intervention being cost-effective in comparison with usual care was 0.46 for reducing the incidence of depression and anxiety combined.

Conclusion
A stepped care programme to prevent depression and anxiety in elderly people living in elderly homes was not considered cost-effective in comparison with usual care.
Introduction
Compared with community-dwelling elderly people, elderly people living in long-term care facilities have an increased prevalence of psychiatric disorders with prevalence estimates of clinically relevant symptoms of depression and anxiety as high as 35% (1-3). Depression and anxiety disorders in the elderly often follow a chronic intermittent course (4;5). Both depression and anxiety disorders have a profoundly negative impact on the functioning and well-being of elderly people. These disorders are also associated with increased health care utilization and mortality rates and worsen the outcomes of many medical illnesses (6-9).

The burden of depressive and anxiety disorders can be reduced in two ways: treating existing cases and preventing new cases. Most research has focused on the treatment of these disorders. However, even under ideal circumstances (100% coverage and optimal treatment), the burden of depressive and anxiety disorders can be reduced by maximally 35% and 50%, respectively (10). Thus, prevention may also play an important role in reducing the burden of depressive and anxiety disorders in elderly people.

Several prevention strategies are possible. Universal prevention is directed towards the whole population, selective prevention targets that portion of the population with known risk factors, and indicated prevention people who have already developed some signs or symptoms of the disorder but at an early or subsyndrome stage (11). Smit et al showed that the incidence of new cases of depression can be reduced by 40% if the occurrence of full-blown depressive disorder is prevented in all elderly people with depressive symptoms (12). Therefore, indicated prevention seems like a viable option to reduce the burden of depressive and anxiety disorders in elderly people. Van ’t Veer-Tazelaar et al showed that a stepped care prevention programme reduced the incidence of depressive and anxiety disorders by 50% at affordable costs and that these effects were sustained over 24 months (13-15). Dozeman et al evaluated a similar stepped care programme to prevent depressive and anxiety disorders in residents of homes for the elderly with above average levels of symptoms of depression or anxiety, but not yet meeting the diagnostic criteria for a disorder. They already showed that this intervention was effective in preventing depressive disorders in this frail elderly population with multiple risk factors (16). However, implementing such a programme requires scarce resources that otherwise could be employed elsewhere. Therefore, the aim of the study was to evaluate the cost-effectiveness of this stepped care prevention programme in comparison with usual care from a societal perspective.
Methods
Design
The economic evaluation was performed alongside a pragmatic randomised controlled trial evaluating a stepped care prevention programme in comparison with usual care from a societal perspective. The follow-up of the study was 10 months. Fourteen residential homes in Amsterdam and surroundings participated in the trial. Randomisation of participants, stratified for residential home, took place after the baseline measurements in blocks of four with an equal allocation ratio and was carried out by an independent statistician using random number tables. Details of the study design have been described in detail elsewhere (17). The Medical Ethics Committee of the VU University Medical Center approved the study protocol.

Participants
Interviewers visited the residential homes and asked residents for permission to screen for depressive symptoms using the Center for Epidemiologic Studies Depression Scale (CES-D) (18). Respondents with a CES-D score of 8 or more (19), were invited for a follow-up interview consisting of a diagnostic (Mini International Neuropsychiatric Interview, MINI) and cognitive (Mini Mental State Examination, MMSE) assessment (20;21). Residents who met the criteria for a DSM-IV depressive or anxiety disorder, or with substantial cognitive impairment (MMSE score of 21 or less) were excluded. Residents who gave written informed consent and had sufficient command of the Dutch language were eligible for participation in the study.

Stepped care prevention programme
The intervention was designed in such a way that participants were first offered the least intensive intervention, and if necessary more intensive care was offered. The intervention started off with one month of watchful waiting and was then structured in cycles of 3 months. If the resident’s level of symptoms had not improved by at least 5 points on the CES-D, the resident stepped up to the next level of care. The stepped care programme consisted of the following steps:
1) watchful waiting during one month;
2) activity-scheduling: a module from the self-help course “Coping with Depression”(22;23) with coaching by the staff in the residential homes;
3) life review and consultation with the general practitioner: mental health nurses provided this brief structured personal intervention (24;25), while participants were also advised to consult their general practitioner;
4) visit to the general practitioner for additional treatment: participants who had a CES-D score of 16 or more after the third follow-up interview were advised to consult their general practitioner about treatment with antidepressants or a referral to a mental health specialist.
Usual care
Residents in the usual care group had unrestricted access to any form of health care that was considered to be appropriate.

Clinical outcome measures
Clinical outcomes were measured at baseline and at 1, 4, 7 and 10 months of follow-up. The primary clinical outcome in this study was the incidence of major depressive disorder and anxiety disorders assessed using the MINI, a short structured interview to diagnose DSM-IV mental disorders (20).

Secondary outcomes included depressive and anxiety symptoms, and quality of life. Depressive and anxiety symptoms were measured using the CES-D which consists of 20 items with total scores ranging between 0 and 60. (18) The CES-D was originally designed to measure depressive symptoms, but has also been found to be useful to assess both depressive and anxiety symptoms in this setting (26).

Quality of life was measured using the EuroQol questionnaire (EQ-5D) (27). Utility scores were calculated using the Dutch tariff developed by Lamers et al. (28) QALYs were calculated by multiplying the utilities with the amount of time a patient spent in a particular health state. Transitions between health states were linearly interpolated.

Cost measures
Costs were measured from a societal perspective during interviews based on the Trimbos/iMTA questionnaire for Costs associated with Psychiatric illness (TiC-P). (29) Since all participants were living in a home for the elderly, lost productivity costs and costs for home care and informal care were not considered relevant and, thus, not included in this study. All direct costs were included, because it is difficult to indicate which costs are related to mental disorders and which are not. Costs were calculated by multiplying the units of resource use by their cost price according to the Dutch guidelines for health economic evaluations. (30) Medication costs were valued using prices of the Royal Dutch Society for Pharmacy plus the pharmacy dispensing costs of €5.30 (30;31). Table 1 lists the cost categories and prices used in the economic evaluation. All costs were adjusted to the year 2008 using consumer price indices if necessary (32). The year 2008 was chosen, because most cost data were collected during this year.

The intervention costs were calculated using a bottom-up approach. The average cost of screening the residents was estimated to be €10.17. This cost price includes 15 minutes of administration and interview time by the staff of the residential home (€7.08) and the time needed by the participants to complete the interview (€3.09). The first step of the intervention consisted of watchful waiting to which
no costs were attached. The second step of the intervention consisted of activity scheduling. Costs that were included in the cost price calculation for this step were the printing costs of the booklet participants received (€11.77), the costs of coaching and administration time invested by the residential home staff (€28.32 per hour), the time costs of the residents (€12.35 per hour), and the costs associated with training the residential home staff (€13.18 per resident). The third intervention step involved life review consisting of 4 sessions with a duration of 1 hour. Costs of this step included the time spent by the mental health nurses on the life review sessions (€209.01), travel time costs for the mental health nurses (€107.49), participant time costs (€49.40), and training and supervision costs (€22.85). Costs of the fourth intervention step, the advice to visit the general practitioner, were considered to be included in the interviews during which healthcare utilization was measured.

### Statistical analysis

The statistical analyses were performed according to the intention-to-treat principle. Multiple Imputation (MI) as implemented in SPSS-17 was used to impute missing cost and effect data. Variables that were found to be related to missing follow-up data, were included in the MI model. By MI 20 imputed data sets were created, each of which was analyzed separately. The results of the 20 analyses were pooled using Rubin’s rules (33).

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Unit</th>
<th>Unit cost (€, 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practitioner</td>
<td>Consultation</td>
<td>27.65</td>
</tr>
<tr>
<td>Regional mental health service</td>
<td>Contact</td>
<td>168.89</td>
</tr>
<tr>
<td>Psychologist</td>
<td>Contact</td>
<td>79.01</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>Treatment session</td>
<td>35.56</td>
</tr>
<tr>
<td>Social worker</td>
<td>Contact</td>
<td>64.20</td>
</tr>
<tr>
<td>Medical specialist at outpatient clinic</td>
<td>Consultation</td>
<td>71.11</td>
</tr>
<tr>
<td>Day treatment, elderly home</td>
<td>Half day</td>
<td>44.44</td>
</tr>
<tr>
<td>Day treatment, nursing home</td>
<td>Half day</td>
<td>117.53</td>
</tr>
<tr>
<td>Day treatment, hospital</td>
<td>Day</td>
<td>247.90</td>
</tr>
<tr>
<td>Hospital admission, academic hospital</td>
<td>Day</td>
<td>567.91</td>
</tr>
<tr>
<td>Hospital admission, general hospital</td>
<td>Day</td>
<td>429.63</td>
</tr>
</tbody>
</table>

Table 1. Cost categories included and cost prices used.
Costs generally have a highly skewed distribution. Therefore, bootstrapping with 5000 replications was used to estimate “approximate bootstrap confidence” (ABC) intervals around cost differences (34;35).

Incremental cost-effectiveness ratios (ICERs) were calculated by dividing the difference in total costs between the intervention and usual care group by the difference in clinical effects. Non-parametric bootstrapping was also used to estimate the uncertainty surrounding the incremental cost-effectiveness and cost-utility ratios (5000 replications). The bootstrapped cost-effect pairs were plotted on a cost-effectiveness plane (CE plane) and used to estimate cost-effectiveness acceptability curves (CEA curves). In a CE plane, incremental costs between the intervention and usual care are plotted on the y axis and incremental effects on the x axis resulting in four quadrants. The northeast quadrant indicates that the intervention is more expensive and more effective than usual care. In the southeast quadrant the intervention dominates usual care, i.e. is less expensive and more effective than usual care. In the southwest quadrant the intervention is less expensive and less effective than usual care. Finally, in the northwest quadrant the intervention is dominated by usual care (more expensive and less effective). Most newly developed interventions are more expensive and more effective than usual care, which implies that a trade-off needs to be made whether the additional benefits justify the additional costs. This decision depends on the societal willingness to pay (WTP) for an additional unit of effect. However, this WTP is generally not known. CEA curves show the probability that the intervention is cost-effective in comparison with the control treatment for a range of WTP values (36).

Results
Of the 1784 residents invited for the screening interview, 754 (51%) participated. Of these, 459 (61%) scored 8 points or more on the CES-D. Informed consent was given by 270 (59%) participants, but another 85 participants were excluded because they were suffering from a mental disorder, cognitive impairment, or both. Thus, in total 185 participants were included in the trial (93 intervention and 92 usual care participants). Thirty-five (38%) intervention participants dropped out and 20 (22%) usual care participants. Complete follow-up on the questionnaires was available for 96 (52%) participants for clinical effects and for 91 (49%) participants for costs.

Almost 75% of the participants were female and the mean age was 84 years (Table 2). A minority of the participants was married or living together with a partner (17%). Around 40% of the participants had 3 or more chronic conditions. There were no significant differences in baseline characteristics between the intervention and usual care group.

Participants with complete data were more likely to be randomized to the usual care group, less depressed, more lonely, less cognitively impaired, and had more
problems with their activities of daily life than participants without complete follow-up.

Clinical outcomes
The clinical outcomes were extensively described in the accompanying clinical paper (16), and are shortly summarized here. The multiply imputed clinical outcomes after 10 months are presented in Table 3. The incidence of any disorder was similar in both groups. The incidence of major depression was halved in the intervention group (0.09) in comparison with the usual care group (0.17). However, the incidence of anxiety was more than doubled in the intervention group. None of the differences in incidences were statistically significant. The intervention group

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Intervention group (n=93)</th>
<th>Usual care group (n=92)</th>
<th>Total (n=185)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>67 (72%)</td>
<td>68 (74%)</td>
<td>135 (73%)</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>84 (6.7)</td>
<td>84 (6.4)</td>
<td>84 (6.5)</td>
</tr>
<tr>
<td>MMSE score, mean (SD)</td>
<td>27.0 (2.1)</td>
<td>27.1 (2.0)</td>
<td>27.1 (2.1)</td>
</tr>
<tr>
<td>Married or living with a partner, n (%)</td>
<td>18 (19%)</td>
<td>13 (14%)</td>
<td>31 (17%)</td>
</tr>
<tr>
<td>Education, n(%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>39 (44%)</td>
<td>41 (45%)</td>
<td>80 (45%)</td>
</tr>
<tr>
<td>Middle</td>
<td>29 (33%)</td>
<td>33 (36%)</td>
<td>62 (35%)</td>
</tr>
<tr>
<td>High</td>
<td>20 (23%)</td>
<td>17 (19%)</td>
<td>37 (21%)</td>
</tr>
<tr>
<td>Number of chronic diseases, n (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>4 (4%)</td>
<td>5 (5%)</td>
<td>9 (5%)</td>
</tr>
<tr>
<td>1</td>
<td>13 (14%)</td>
<td>22 (24%)</td>
<td>35 (19%)</td>
</tr>
<tr>
<td>2</td>
<td>34 (37%)</td>
<td>29 (32%)</td>
<td>63 (34%)</td>
</tr>
<tr>
<td>3 or more</td>
<td>42 (45%)</td>
<td>36 (39%)</td>
<td>78 (42%)</td>
</tr>
<tr>
<td>CES-D score, mean (SD)</td>
<td>14.9 (5.7)</td>
<td>14.4 (5.3)</td>
<td>14.7 (5.5)</td>
</tr>
<tr>
<td>HADS score, mean (SD)</td>
<td>3.6 (2.8)</td>
<td>3.2 (2.6)</td>
<td>3.4 (2.7)</td>
</tr>
<tr>
<td>Loneliness score , mean (SD)</td>
<td>3.4 (0.87)</td>
<td>3.4 (0.80)</td>
<td>3.4 (0.83)</td>
</tr>
<tr>
<td>Major difficulties ADL, n (%)</td>
<td>43 (46%)</td>
<td>50 (54%)</td>
<td>95 (51%)</td>
</tr>
<tr>
<td>Utility score , mean (SD)</td>
<td>0.66 (0.26)</td>
<td>0.66 (0.24)</td>
<td>0.66 (0.25)</td>
</tr>
</tbody>
</table>

Table 2. Baseline demographic and clinical characteristics of the participants.
The difference in QALYs was small and statistically insignificant.

**Costs**
Step 1 of the intervention (watchful waiting) was attended by all participants. Forty-five (48% of the intervention participants) participants received step 2 of the intervention (activity scheduling) and 31 (33%) participants step 3 (life review). Mean total intervention costs amounted to €209 per participant.
Table 4 presents mean total costs and differences in costs between the intervention and usual care group. Total costs in the intervention group were €838 higher than in the usual care group, but this difference was not statistically significant (95% CI -593 to 2420). Ambulatory care and medication costs in the intervention group were statistically significantly higher than in the usual care group, and hospital admission costs were substantially higher in the usual care group albeit not statistically significantly.

**Cost-effectiveness and cost-utility**

The results of the cost-effectiveness and cost-utility analyses are described in Table 5. Regarding the combined incidence of depression or anxiety, the conclusion is that the intervention was not cost-effective in comparison with usual care. The CE plane shows that 47% of the bootstrapped cost-effect pairs was situated in the
northwest quadrant and 40% in the northeast quadrant (Figure 1), confirming that there were no statistically significant differences in effects and costs. The accompanying CEA curve shows that the probability that the intervention was cost-effective ranged from 0.13 if WTP is €0 to 0.46 if WTP is +∞ (Figure 2).

The ICER for the incidence of depression was -10293, meaning that prevention of depression in 1 patient extra in the intervention group is associated with an extra cost of €10,293 in comparison with usual care (Table 5). Most bootstrapped cost-effect pairs (79%) were situated in the northeast quadrant of the CE plane, indicating that the intervention was more expensive and more effective than usual care. The accompanying CEA curve shows that for WTP rates of €0, €5000, €10,000 and €20,000 the probability that the intervention was cost-effective in comparison with usual care was 0.13, 0.28, 0.48 and 0.72, respectively.

The intervention was not considered cost-effective in comparison with usual care for preventing anxiety disorders, since the incidence of anxiety was increased.

Figure 2. Willingness to pay (€ per prevented case of depression or anxiety).
in the intervention group. The distribution of the bootstrapped cost-effect pairs on the CE plane confirms this with the majority of the pairs lying in the northwest quadrant (more expensive, less effective). The cost-effectiveness analysis of improvement in CES-D score indicated greater effectiveness of the intervention accompanied by non-significantly higher costs. The probability of the intervention being cost-effective in comparison with usual care was 0.95 or more for WTP values of €3500 or more. With regard to QALYs the intervention was not considered cost-effective in comparison with usual care (probability intervention was cost-effective according to the CEA curve ranged from 0.13 if WTP is €0 to 0.85 if WTP is +∞).

**Discussion**

This study shows that a stepped care prevention programme for people in elderly homes was unsuccessful in preventing depressive and anxiety disorders together compared with usual care. The incidence of depression in the intervention group was substantially lower than in the usual care group, but this difference was not statistically significant. Moreover, the incidence of anxiety was statistically non-significantly higher than in the usual care group. Costs in the intervention group were non-significantly higher than in the usual care group. Based on these findings, the stepped care intervention was not considered cost-effective in comparison with usual care.

There is a discrepancy between the findings of the clinical paper and this analysis with regard to incidence of depression. Although the difference between the intervention and usual care group is equal in both analyses (8%), despite the

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Costs</th>
<th>Effects</th>
<th>ICER</th>
<th>NE</th>
<th>SE</th>
<th>SW</th>
<th>NW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence depression</td>
<td>838 (-593 ; 2420)</td>
<td>-0.08 (-0.21 ; 0.04)</td>
<td>-10293</td>
<td>79%</td>
<td>12%</td>
<td>1%</td>
<td>8%</td>
</tr>
<tr>
<td>Incidence anxiety</td>
<td>838 (-593 ; 2420)</td>
<td>0.08 (-0.03 ; 0.19)</td>
<td>10328</td>
<td>6%</td>
<td>1%</td>
<td>12%</td>
<td>81%</td>
</tr>
<tr>
<td>Incidence depression or anxiety</td>
<td>838 (-593 ; 2420)</td>
<td>0.01 (-0.14 ; 0.16)</td>
<td>85521</td>
<td>40%</td>
<td>6%</td>
<td>7%</td>
<td>47%</td>
</tr>
<tr>
<td>Improvement CES-D</td>
<td>838 (-593 ; 2420)</td>
<td>-2.3 (-4.8 ; 0.21)</td>
<td>-364</td>
<td>84%</td>
<td>13%</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>QALYs</td>
<td>838 (-593 ; 2420)</td>
<td>0.03 (-0.03 ; 0.09)</td>
<td>26890</td>
<td>73%</td>
<td>12%</td>
<td>1%</td>
<td>14%</td>
</tr>
</tbody>
</table>

Table 5. Results of the multiply imputed cost-effectiveness analyses.
different imputation methods used, this difference was statistically significant in the clinical analyses and non-significant in this cost-effectiveness analysis. This discrepancy is caused by the difference in analysis methods. In the clinical analyses, the results were adjusted for clustering and variables related to dropout, while unadjusted estimates are presented here.

The mean total costs of the stepped care prevention programme were €209 per resident. This compares favourably with the costs of the programme evaluated by Van ‘t Veer-Tazelaar et al (€532). This difference can be mainly explained by the fact that residents were coached by the residential home staff during the self-help intervention in this study instead of more expensive nurses as employed by Van ‘t Veer-Tazelaar et al. However, this may also be a (partial) explanation for the lack of effect of the programme evaluated in this study. Total societal costs in our study were considerably higher than in the study by Van ‘t Veer-Tazelaar et al. This is in line with our expectations, since this study included a residential population, while the study by Van ‘t Veer-Tazelaar et al included a community-dwelling population. To the best of our knowledge, no other papers have been published that present a cost-effectiveness analysis of an intervention to prevent depression and/or anxiety in an institutionalised population.

The most important limitation of this study is the dropout rate. The poor response is probably due to the overall poor functional status of the residents living in elderly homes (which is why they live in these homes). Dropout was related to allocation status, indicating potential bias due to selective loss of participants. We tried to overcome this limitation by applying multiple imputation to estimate missing values for participants with incomplete data. Multiple imputation is a technique that incorporates the uncertainty associated with estimating values for missing data. Research indicates that this imputation method provides more accurate estimates of missing data in economic evaluations than naïve methods, like (conditional) mean imputation and last observation carried forward (LOCF) (37;38). However, the selective dropout also indicates that implementation of the stepped care programme was difficult in this vulnerable population. The cost-effectiveness of the stepped care programme in comparison with usual care may be improved, if the acceptability and uptake of the programme can be increased. Another limitation is the statistical power of the study. The study was powered on clinical outcomes. However, during the analysis phase it turned out that the study was underpowered for both clinical and economic outcomes. Therefore, the results of the study should be interpreted cautiously.

Strengths of this study include the fact that this was a pragmatic study with few a priori exclusion criteria resembling usual circumstances as much as possible. This greatly enhances the generalisability of our results to other residential homes in The Netherlands. A second strength is that costs were measured from a soci-
etal perspective which enabled us to monitor whether there were important shifts in healthcare costs due to the intervention. Thirdly, a stepped care approach was implemented in this study. This approach ensures that only people in need of more intensive care receive this care. This is important, since resources are scarce and need to be reserved for people really needing them. Finally, a structured diagnostic interview was used to diagnose anxiety and depressive disorders, which enhances the credibility of the outcomes reported in this trial.

In conclusion, the stepped care prevention programme tested in this study was not cost-effective in comparison with usual care. The positive effect on depressive disorders is encouraging, but should be investigated further especially considering the negative effect on anxiety. Research should indicate which elements of the intervention are effective and how these elements can be offered in a cost-effective way to residents of elderly homes at risk for depression. However, it is also possible that the emphasis on mental functioning of the intervention investigated in this study may have scared off the participants. Perhaps integrated care interventions similar to the one evaluated by Boorsma et al with a wider scope and aiming to influence both mental and physical functioning,(39) are the way forward.
References


(32) Statistics Netherlands. 2007. Voorburg/Heerlen, Centraal Bureau voor de Statistiek (CBS). Ref Type: Internet Communication


Chapter 10

General discussion
The primary aim of this thesis was to evaluate the (cost)effectiveness of a stepped care programme on the prevention of depression and anxiety in residential homes for the elderly. We hypothesised that a stepped care programme would be superior to care as usual in preventing the onset of new cases of depression and anxiety in residential homes for the elderly in and around the city of Amsterdam in the Netherlands. The considerable burden of common mental disorders on residents in homes for the elderly, in combination with a lack of resources for treatment, combine to make prevention an interesting option for health promotion in this setting. Although caregivers in the homes recognise the impact of mental health problems, symptoms of depression and anxiety are rarely identified and labelled as such. Symptoms of depression and anxiety disorder like apathy and weariness may also be ascribed to physical illnesses or seen as a normal reaction to circumstances. This makes that symptoms of anxiety and depression are often interpreted only as consequences of decline rather than problems that require intervention. Moreover, as the population is ageing rapidly and the policy in the Netherlands is to facilitate independent living as much as possible, the level of psychological and physical frailty in homes for the elderly has been increasing rapidly. At the same time, medical care is also changing: General Practitioners, who are responsible for medical care in the residential homes in the Netherlands, have for instance halved the number of house visits since 1987. In addition, most homes suffer from staff deficits, in which the quality of care is thereby threatened. Therefore, the efficient use of the available, scarce resources, as supplied by this stepped care protocol, is of great importance.

The research questions in this thesis were successively:
1. Is it feasible to screen and recruit residents with a high risk of depressive and/or anxiety disorders in a residential home setting for participation in a stepped care prevention programme?
2. Is the CES-D an adequate instrument to screen for depression and anxiety in this setting?
3. What is the incidence rate for symptoms of depression in a vulnerable and very old population?
4. Is a stepped care programme more effective in preventing new cases of depression and anxiety in a residential home setting compared to care as usual?
5. What is the effectiveness of a guided self-help course in activity-scheduling, compared to care as usual, on the reduction of symptoms of depression and anxiety in residents?
6. Are effects of the stepped care programme after one year sustained after another follow up year?
7. Is the stepped care programme cost-effective as compared to care as usual?
In this final chapter, we reflect on the above questions, and we discuss the methodological considerations of our study. Finally, the implications for daily practice and future research are listed.

**Main findings**

1. In a pilot study, we evaluated the screening procedure that we wanted to apply in the main study. Motivating the residents for filling out the screening questionnaire proved to be more difficult than expected. 51% of the residents consented to a screening interview. The reasons for not participating were physical vulnerability (23%), mental problems (20%), lack of motivation (35%), or other, unknown reasons (22%). The prevalence of symptoms of depression or anxiety was in line with our assumptions of a prevalence of 30 to 35%, because 29 of 78 (37%) scored above the cut-off on the Center for Epidemiologic Studies Depression Scale (CES-D) (1). Our conclusion was that residents in homes for the elderly with this score and higher, were often also the most vulnerable residents (physically and mentally), who were not able or not willing to participate in our prevention programme. (Chapter 3).

2. In a substudy we examined the suitability of the CES-D for screening in an residential home population. Our screening instrument the CES-D had satisfactory criterion validity for depressive disorders and for any combination of depressive and/or anxiety disorders. With a desired sensitivity of at least 80%, the optimal cut-off scores varied between 18 and 22. The predictive power of the CES-D in this population was the best for major depression and dysthymia (Area Under the Curve, AUC 0.87), closely followed by the score for any combination of depressive and anxiety disorder (AUC 0.86). The use of one single instrument to screen for both depression and anxiety disorders at the same time has obvious advantages in this very old population. The CES-D seems to be a suitable instrument for this purpose (Chapter 4).

3. For the estimation of incidence rates in the main study, we used existing data on the combined incidence of anxiety and depressive disorders derived from the Longitudinal Aging Study Amsterdam (2). This is a very conservative estimate because LASA is a community based longitudinal study, whereas our study is conducted in residential homes. The residents in our study are on average much older and move to the residential home for reasons that coincide to a large extent with known risk factors for anxiety and depression. We, therefore, studied incidence rates in a comparable, very old and vulnerable population, with data that were collected during a longitudinal cohort study of vulnerable elderly persons in primary care in the Netherlands (3). We found that the inci-
dence rate of clinically relevant depressive symptoms after 18 months was 48% (95% confidence interval [CI] 44.2-51.8). This was a considerably higher estimate than those previously found in elderly populations living in the community. These findings support our hypothesis that the incidence of mental disorders in a very old and vulnerable population, as is living in residential care, is very high (Chapter 5).

4. We analysed the effectiveness of a stepped care intervention on the incidence of combined major depression and anxiety disorders and on the incidence of major depression or anxiety disorders alone. We found no significant difference between the intervention and control group in reducing the incidence of the combined outcome of depression and anxiety (IRR=0.50 and a 95% CI ranging from 0.23 to 1.12). However, the intervention was superior to the usual care in reducing the risk of the incidence of a major depression disorder (IRR 0.26; 95% CI 0.12 to 0.80), in contrary to the prevention of anxiety disorders (IRR 1.32; 95% CI 0.48 to 3.62) (Chapter 6).

5. Although the study aimed to assess the effects of a stepped care programme as a whole, we also evaluated the effect of the first step in our intervention programme, a guided self help module. For the very old and vulnerable group of inhabitants of residential homes, it proved to be difficult to complete the self help exercises (21% of the participants completed all exercises). Although we found some large positive effect sizes on the CES-D, none of these effects were statistically significant (Chapter 7).

6. We hypothesised that preventive activities need to be maintained to ensure ongoing effects, and therefore we studied the longer term effects of the stepped care programme. The promising effects on the prevention of major depression were indeed not sustained in the intention to treat analysis in the second follow-up year, in which no interventions were offered. However, the effect did hold in the subgroup of residents who completed all the measurements (IRR 0.53; 95% CI 0.32 to 0.87) (Chapter 8).

7. We showed that the stepped care programme was effective in preventing depressive disorders in this frail elderly population with multiple risk factors (Chapter 6). However, implementing such a programme requires scarce resources that otherwise could be employed elsewhere. Therefore, the aim of this study was to evaluate the cost-effectiveness of this stepped care prevention programme compared with the usual care from a societal perspective. The mean total costs in the intervention group were €838 higher than in the usual
care group, but this difference was not statistically significant (95% CI -593 to 2420). Cost-effectiveness planes showed that there was considerable uncertainty. Cost-effectiveness acceptability curves showed that large investments are necessary to reach an acceptable probability of the intervention being cost-effective. Based on this study, the stepped care prevention programme is not considered cost-effective compared with the usual care (Chapter 9).

**Methodological considerations**

**Study design**
We wanted to know if a stepped care programme that was found to be very effective in an elderly population living at home (4) was also effective in residential care conditions. We, therefore, conducted a “pragmatic clinical trial”, which refers to the fact that we were conducting an effectiveness study in contrast to an efficacy study. The aim of an effectiveness study is to examine the effect of a treatment under “normal” conditions, and not in standardised (“ideal”) conditions. To assess the effect of our intervention in “real life” conditions, we used very few exclusion criteria. At the same time, other ongoing treatments are being monitored. Given a quite well developed health service for older people in the Netherlands, this amounts to quite a tough test, as the intervention is not tested against a placebo condition and also because in both conditions other interventions are allowed. The effect of these two is to weaken the distinctions between the two conditions. However, in the case of a positive effect of the intervention, as was found in our trial for the prevention of depression, the results of an effectiveness study can be more easily translated to every day practice.

**Selection of residential homes**
Residential homes in and around Amsterdam were very interested in participating in our trial. In the Netherlands groups of residential homes are usually organised within larger organisations. We approached five major organisations for residential elderly care, in and surrounding the city of Amsterdam. Of these, four were willing to participate in the trial. The fifth organisation declined participation because it was already involved in another research project at that time. The four participating organisations contain the 14 residential homes that participated in the study. Although we did not study this, we have no reasons to believe that there are important differences between the homes of the four participating organisations and the non-participating one. The 14 participating homes covered several areas in and surrounding the city, including both more affluent and deprived areas of Amsterdam. The results of our study are roughly generalisable to other regions in the Netherlands because residential homes in the Netherlands are comparable; they share the same sex ratio of residents (M/F: ¼), mean residents age (85 years), care
methods and admission criteria. However, homes in rural areas tend to be slightly smaller. A recent study in a rural area in the Netherlands (5) found lower prevalence rates of depressive symptoms compared to former studies (6-8). Therefore, some restraints are needed with regard to the generalisation of our results to rural areas.

Use of CES-D
The use of the CES-D as a screening instrument was based on several considerations. In the first place, we wanted to use an instrument that enabled us to compare our results with similar studies, and that was suited for use in an elderly population. Furthermore, the CES-D was designed specifically to screen for depressive symptoms, but it has also been used to screen for anxiety symptoms (9;10). We favoured the use of one single instrument to screen for both depression and anxiety disorders at the same time because we wanted to avoid the burden of an exhausting interview, and in the same time use a validated instrument. The CES-D is designed as a self-report scale, but we used it in a personal interview. This might have lowered the scores of the respondent because they might have felt shame towards the interviewer and underreported their symptoms. Furthermore, we noticed that the use of four answer categories (never, sometimes, most of the time, always) was sometimes difficult to understand for the residents. Sometimes it was difficult for the respondents to stick to one category instead of extensively reporting their feelings, as is also reported in other studies (11-13).

Initially, we chose a cut-off score of 16 points on the CES-D for inclusion in our study. This cut-off point refers to clinical significant symptoms, and is widely used (14;15). After performing our pilot study (Chapter 3) we concluded that residents in homes for the elderly with this score and higher, were often also the most vulnerable residents (physically and mentally), who were not able or not willing to participate in our prevention programme. We therefore decided to lower the cut-off score to 8 points on the CES-D, which refers to the mean score in the elderly population in the community (16). In other prevention studies varying cut-off scores are used, ranging from a score of 5 to 11 (17;18). With this decision, we changed the design of our prevention programme from indicated prevention (clinical significant symptoms) to a combination of indicated prevention (mild symptoms) and selective prevention (high risk population), which also impacts the estimation of the incidence rates. The incidence rates for depression and anxiety in the elderly population varies worldwide from 7% (19;20) to 24.5% (21) in one year, but no studies were found that specifically focused on the incidence of depressive or anxiety symptoms among the most vulnerable oldest people. We therefore decided to perform a study on incidence rates in a frail and very old population, and concluded that the incidence rates were even higher than expected (48% in 18 months, 95% CI 44.2-51.8) (Chapter 5). We concluded that despite the lowering of the threshold on the
screening instrument, we still included a population with a very high risk on developing mental disorders.

Finally, the use of the CES-D as a screening instrument, may ask for a review in light of the effectivity of a stepped care programme for both depression and anxiety. As mentioned above, we chose the CES-D for several reasons. One reason for our choice was because the instrument screens for symptoms of depression and anxiety, which was confirmed in our study on the predictive value of the CES-D in this particular population (Chapter 6). However, when components more specifically directed towards the prevention of anxiety disorders will be integrated in the programme, also a screening tool that directly divides between depression and anxiety may be more appropriate. Options are, for instance, the Four Dimensional Symptom Questionnaire (4DSC) (22), or the Depression Anxiety Stress Scale (DASS-21) (23). Validation and practical applicability of these instruments in this elderly and vulnerable population need to be further studied. Another possibility is the use of a general assessment tool such as the Resident Assessment Instrument (RAI), which is already implemented in several Dutch nursing homes (24), and also consists in some items on depression and anxiety separately. Again, the validation of this instrument on criterion validity for depression and anxiety needs more study. The advantage of the use of general assessment tools is that the focus on screening and monitoring is directed towards integrated care, instead of focussing on the mental health aspect only.

**External validity**
Do the included residents in our trial resemble the population of elderly people living in residential homes who were eligible for our trial? And is it, therefore, allowed to generalise the results for all those residents? Selection bias may be a cause of a lack of external validity of our programme, which might be caused by selective response in the screening procedure. Our screening procedure yielded 185 of 1784 (10.4%) participants from the target population. This might be a biased subgroup. As we learned in our pilot study, a large proportion of the residents were physically and mentally not able to participate in the trial. Those residents are probably on a higher risk of developing, or already suffering from, depressive or anxiety symptoms. If that was the case, the trial could have showed larger effects with the inclusion of the less healthy residents. On the other hand, a selective response may be caused by residents who were not motivated for the trial because they were feeling well. Those residents might not have needed an intervention to remain “disorder free”. This makes the unwillingness to comply with the intervention less important from a clinical viewpoint.
Diagnosis of depression and anxiety
Our primary clinical outcome was the incidence of depression or anxiety, as was assessed with a short diagnostic interview, the Mini International Neuropsychiatric Interview (MINI) (25). Diagnosing mental disorders with this interview is different from the everyday clinical setting. General practitioners hardly ever use questionnaires and diagnostic instruments. They know the background of the patient and their medical situation and use this information in the diagnostic process unlike the procedure in the standardised interview. Although contextual information enables the general practitioner to select those residents who are most likely to profit from an intervention, they also might be biased by this information. They might not recognise mental disorders, especially when symptoms are not (yet) very severe (26). For research purposes, it is very important to make use of this standardised diagnosis because it makes our findings comparable with other results.

Randomisation
We randomised our residents to the intervention or care as usual groups in an individual randomisation design, and did not use a cluster randomisation design. We wanted to profit from the advantages of individual randomisation, such as a smaller sample size and optimal comparability. In a cluster randomised design, the risk of confounding is increased because the allocation of the individual characteristics over both groups is diminished. However, in choosing an individual randomisation design we were aware of the possible contamination effects, when trained care workers could supply their knowledge to residents in the care as usual group. We paid attention to possible contamination in the following manner: only care-workers who guided a resident in the intervention group were trained in the self-help course. In addition, they only received the self-help materials for their residents in the intervention group, and were not aware of the participation of other residents in the care as usual group. All trained care workers were insistently instructed to deliver the materials only to the assigned residents, and we explained why this was important. We do not expect to find that the contrast in our study was diminished by contamination, because the risk of contamination was small, and it only could have occurred in one of four steps in the programme.

The stepped care programme
We assessed the effects of a stepped care programme compared to care as usual. The aim of stepped care models is to maximise the effectiveness of the available effective interventions while making the best use of available resources and tailoring the interventions to individual needs. The primary effect of the intervention was analysed on the basis of the programme as a whole. The stepped care programme consisted of several elements that were discussed with the residents. Residents
were allowed to choose whether they wanted a specific intervention, and in the case their symptom level was diminished no other intervention steps were offered. The compliance of the residents to the programme was difficult for many, and we think that this is the main reason for the disappointing outcomes. Furthermore, the coordination of the stepped care programme was carried out by the research team, instead of a professional in the home. As was said before, resources in the homes were lacking to organise such a coordinating function. The compliance to the programme may be improved when it is more effectively coordinated within the residential home.

Contrast with care as usual
When offering interventions in real life conditions, the care as usual might fluctuate in an unexpected manner. Interventions offered unexpectedly in the care as usual condition might diminish the contrast between both conditions. We, therefore, recorded the health care utilisation in both groups, and we know that the use of psychological counselling besides the stepped care programme did not differ between groups ($\chi^2=0.29$, df =1, $P=0.59$), as was also the case for use of antidepressant medication ($\chi^2=1.81$, df=1, $P=0.18$) and anxiolytic medicines ($\chi^2=0.17$, df =1, $P=0.90$). The fact that residents in both groups received personal interviews in their own home might also lead to some concern with respect to the contrast between the intervention and care as usual group. As the attention with respect to mental well-being is minimal in residential care settings, most of the participants valued these interviews. They told us that they appreciated the attitude of the interviewers, and the repeating questions about their well-being every three months. This highly valued attention might be a protective factor with regard to the incidence of new disorders. Although it is unlikely that attention only equals the effects of evidence based interventions, we were affected by the impact of the given attention in a situation where the majority of the residents reported feelings of loneliness.

Drop out rates
Drop out rates in our study turned out to be high, 55 residents (30%) dropped out during the first year, and another 27 residents dropped out during the second year of the study, leading to a drop out of 82 residents in total (44.3%). 24 (29%) of them died during the study period, and 32 (39%) were too ill to continue participation. In a comparable study on the prevention of depression and anxiety in elderly people of 75 years or more, living in the community, the total drop out in two years was 24% (27). Almost half of them (49%) dropped out because of unwillingness, where in our trial 32% was not willing to continue further participation. The high drop out rates were largely caused by the vulnerability of our population, and are therefore unavoidable. Another reason for the high dropout rate that we encountered in our
study is that attrition is very common in a prevention trial. Acknowledgement of the risk of finally developing a disorder is generally low, which might diminish the motivation of the participants to complete the interventions.

Because of these large drop out rates we had to use imputation techniques, in order to be able to provide information on the effectivity of the intervention for the selected baseline population. Although in the scientific community much discussion is going on about the pros and cons with regard to imputation techniques, we regard this method as a sound way to supply unbiased information on the population that might benefit from the intervention. To test the robustness of our outcomes we always compared and reported the outcomes of several imputation techniques. We also analysed the result for those residents who completed all the measurements. The latter outcomes may be biased because of selective attrition; only the “best” participants (mentally and physically) were able to complete all measurements. Because the interventions are mostly simple and cheap and, therefore, affordable for a broad population, we are particularly interested in discovering as to which people were finally attracted by the interventions. Completers analyses supply information about those who are most likely to profit from a preventive intervention and, therefore, are also important.

Implications for daily practice
Acceptability of the programme
The organisation of the stepped care programme was very challenging, but the reactions from care workers, mental health nurses and residents were encouraging. Care workers were enthusiastic about opportunities to provide attention to mental health problems. They valued the availability of a simple tool to work together with the residents on monitoring and improving their mood. However, they often reported a lack of time to guide the residents in an appropriate way through the self-help course. Moreover, they reported difficulties in motivating the residents in starting and complying with the intervention. The life review intervention was offered by mental health nurses, and they were enthusiastic about the rationale of the intervention; they valued the positive orientation of the intervention, which is in contrast with the more problem oriented techniques they often use. They also valued the simplicity of the intervention which made it approachable for themselves as well as for the residents.

The residents liked the regular checkups on their mental health. As mentioned before, the simple fact that somebody paid attention to their mental well-being on a regular basis was highly valued. The reactions of the residents to the various elements in the programme were diverse. The self help course was not received well by a majority of the residents. However, a minority valued the booklet highly. We, therefore, suggest that the self-help should only be offered to residents who are
interested and motivated. Most of the residents were confident with the life review intervention, which is an important aspect in the light of further implementation in residential care. Most of them mentioned their positive experiences when they were visited for the next interview on their mental health condition.

The advice to visit the General Practitioner was often received well, but in a number of cases the residents told us that they had a lack of confidence in the possibilities of the GP to take care for their mental health problems. The GP seems (too) often to be seen as someone who only cares for their physical well-being.

**Screening**

There still is an ongoing discussion on whether we should screen for depression and anxiety on a regular basis (28;29). Opponents of regular screening warn about the risk that screening may not add much to the recognition in daily practice. However, the recognition of depression and anxiety in older people seems to be more complicated compared to the adult population (25;30). Especially in the case of a high risk population like residents of homes for the elderly, screening may be an efficient manner to improve early recognition. However, screening is justified when a couple of conditions are met, because earlier identification is not automatically beneficial to the person being screened (31):

1. the condition is an important health problem
2. the natural history of the condition is understood
3. an effective treatment is available
4. there must be evidence that early identification changes the natural history in a beneficial way without negative effects such as labelling
5. a suitable instrument is available (high sensitivity/high specificity)
6. the test is acceptable in the screened population
7. the health system has the capacity to apply the test and deal with the consequences
8. case-finding should be an ongoing process
9. the total cost of finding a case should be economically balances in relation to medical expenditure as a whole.

A couple of these conditions need to be further developed before a screening programme with a stepped care programme for the prevention of depression and anxiety in residents of homes for the elderly may be truly acceptable.

In the first place, the results of qualitative studies in the elderly population show that depression is often seen as something for weaklings (32-34). In the context of a residential home the status of weakling among the others is something that residents strongly want to avoid, maybe even more than in the open community. Exclusion and gossip can be strong mechanisms within the social environment that influence the well-being of the resident. Therefore, attention has to be paid to the
effects of stigmatisation with respect to mental disorders in the residential homes setting. For instance, more common information about (the prevention of) mental problems could be supplied in lectures, films, and leaflets. This information might better be applied in a “light” way (for example in “game format”), in order to avoid unnecessary worrying of the residents.

Secondly, serious concerns can be expressed about the capacity of the health system for this programme in a very old and vulnerable population. As the elderly population is growing rapidly, the healthcare costs in this population are expanding. The economic resources impose restrictions, which already affect the quality of care, and the quality of life for elderly people, specially for those living in residential homes. Preventive interventions aim to lower the burden of disorders on a population level, but also aim to lower population health care costs. We therefore have to make serious efforts to improve this, or similar programmes, in a way that more people can profit, and the effects are enlarged for depression as well as anxiety. The cost-effectiveness of the programme shall improve along the way. It is only then that the programme might be acceptable for implementation in the future.

**Improvement of prevention**

A very important issue with respect to this stepped care programme is the fact that it appears that the intervention had a diverging effect on depression compared to anxiety. The intervention was clearly favourable for depression. The effect on anxiety was in the opposite direction, with those participating in the intervention reporting approximately 30% more anxiety disorders than those in the control group. This is not a spectacular effect and it was not statistically significant, but it does warrant concern. For the prevention of anxiety the programme would need to be improved, for example by including components that focus more specifically on anxiety disorders.

Although the perception of the helpfulness of any mental health intervention is low in this population, some aspects might provide further insights for the improvement of preventive strategies. In the first place, active and personal attention to problems of well-being is valued by a subgroup of the residents. Monitoring of “well-being” may therefore be more recommended than the monitoring of symptoms. Furthermore, the privacy of the residents among others appeared to be very important, a trustful “outsider” may be an important condition in the prevention and treatment of mental problems. Finally, residents who believe that mental problems “just happen” and cannot be avoided, deserve to receive more information about helpful activities in a non-threatening, personal and positive way.
Recommendations on future research

In the first place, we need to know more about effective preventive interventions on anxiety in this population. Depression and anxiety symptoms often overlap to a large degree, and similar interventions are often found to be effective for both. Cognitive behaviour programmes and similar medication are found to be effective in both conditions. Although research into the prevention of anxiety has increased in the past few years, the knowledge on the prevention of late life anxiety is still lagging behind. Anxiety often already interferes with life at a young age and attention is, therefore, largely focused on prevention in younger age groups (35). In the Netherlands, several group interventions are applied for elderly people with mild anxiety symptoms, all based on behavioural principles. These interventions are valuable “Good practices”, but no scientific evidence is available as yet. The feasibility and effectiveness in the residential homes population is not known, and should be studied. Our experiences when we visited the residents was that ruminating was highly frequent in this population. Themes that were often mentioned were worries about suffering at the end of life stage, further deterioration of their health and independence, and also the fear of having to move to a nursing home or a special unit for residents with cognitive impairment. One might hypothesise that the intervention programme even induces anxiety in this vulnerable population, because it confronts the residents with their own situation, and therefore this issue needs carefully further study, both in epidemiological studies and in future trials.

The results of this study underline the dimension of the symptoms of depression and anxiety in residents of homes for the elderly. However, we noticed that the motivation to participate in a preventive trial was less than expected. One could say that the residents showed ambivalence with respect to mental disorders; on the one hand, residents showed recognition of the burden of these disorders and, on the other hand, a large group of them was reluctant to acknowledge and take action with respect to these problems. Resistance to change, avoiding strategies and objection to interference might be aspects of this lack of motivation. A method of coping with these aspects could be the use of Motivational Interviewing (36). The application of motivational interviewing to the stepped care programme may be an option to enlarge the participation and to lower the attrition of the programme, and should be studied in this population.

The need for research on the effectiveness and feasibility of evidence-based methods in residential care remains evident. However, the most vulnerable residents with more severe cognitive and functional limitations, possibly already being considered for nursing homes, are not within scope of this stepped care programme. For this group of residents we need to look more closely at their needs and opportunities by conducting more research, including by using qualitative designs.
Concluding remarks

When I started this study, I worked as a mental health care nurse for many years. Nursing is a profession that has been undergoing major developments in recent years. The role of nurses is changing, in turn leading to a more evidence based “tool kit”, and new positions in the organisation of care. For instance in primary care, mental health care nurses are increasingly taking over specific tasks in the general practices, for instance they supply mental health interventions. Another recent development is the function of the (mental health) nursing specialist who has autonomous responsibilities in the organisation and execution of care. The studied stepped care programme seems a promising way to improve mental health care in an environment with restricted resources. However, the programme may gain (cost-)effectiveness, when the compliance of the residents could be improved. (Mental health) nurses are excellently competent to fulfil the tasks of motivating and coordinating such a programme. Of course, this can best be accomplished in a stimulating and effectively coordinated organisation, in which a (mental health) nurse may be the connection between the general practice and the residential home.

This thesis started with the story of Miss White, a story about the challenges of becoming (very) old in a residential home setting. I was very moved by her story, and those of the other residents. Their stories reflect the great task that our society is currently facing. We are looking for solutions to becoming old in a demanding society, with little attention for those who we see as no longer being a part of it. The stepped care model that we presented in this study may be an example of focusing on tailor made care, which implicates that attention is not only paid to physical, but also on mental components in daily care. However, in our programme the social and spiritual component lacked attention. Living in a residential home may have a serious impact on elderly people. Residents need to adjust to a situation in which their social role in society is drastically changed, and they struggle with the balance between dependence and autonomy. Symptoms of depression and anxiety are also viewed in the context of this situation, and are often seen as a normal reaction to circumstances. Residents express their needs for individual and personal attention for their well-being, and they often lack this kind of care.
Reference List


Depressive and anxiety disorders are a very common, serious and underdetected problem in homes for the elderly. As the number of elderly persons aged 75 years or older increased, the group of very old persons in homes for the elderly has been increasing rapidly. In addition, the levels of psychological and physical frailty are increasing. Elderly persons in residential homes are at high risk for developing major depressive and anxiety disorders, and deserve attention with regard to prevention. The aim of this thesis therefore was to evaluate the (cost)effectiveness of a stepped care programme on the prevention of depression and anxiety in residential homes for the elderly.

Chapter 1. General introduction
Chapter 1 starts with a case vignette in order to illustrate some of the complexities of becoming old while living in a residential home. Depression and anxiety disorders are often considered to be consequences of physical vulnerability, rather than problems that deserve attention in their own right. Therefore, the focus of treatment and care for elderly people living in a residential home is mainly restricted to physical disability and disease. From there on depression and anxiety disorders in older people are described, followed by the mechanisms and the importance of preventive activities. Following, Chapter 1 describes the stepped care prevention programme that we used in our study. This programme is a model to organise the expertise in efficient way, and may be particularly relevant for an environment of limited resources. The Chapter ends with a description of the objectives and the outline of this thesis.

Chapter 2. Study design
Chapter 2 presents the protocol of the pragmatic randomised clinical trial. This protocol describes a randomised trial on the feasibility and (cost) effectiveness of a stepped care programme for the prevention of depressive and anxiety disorders in homes for the elderly. The main outcome measure is the incidence of depressive and anxiety disorder in one year with a two-year follow up. Secondary outcomes are symptoms of depression and anxiety, quality of life, direct health care costs and satisfaction with treatment. The number of studies examining the effects of preventive interventions on the incidence of mental disorders in the elderly population is very small. However, indicated prevention by means of a stepped care programme seems to be an important option for decreasing the burden of illness for residents and their caregivers. This study contributes to the body of knowledge in this field.

Chapter 3. Pilot study for the screening procedure
Chapter 3 describes the problems that we met when screening for depressive and anxiety disorders in elderly persons in residential homes. The proposed preven-
tion protocol has been developed for elderly persons who have a certain level of self-reliance, but who are part of an at-risk group in relation to the development of a depressive and/or anxiety disorder. A comparable protocol was found to be feasible with fragile elderly persons (75+) in the general population and it, therefore, also seemed to be a suitable method for elderly persons in residential homes. Of all the residents approached, 44% were prepared and/or able to fill in the screening list, with help if required. This was lower than we had expected on the basis of the previously mentioned research in the general population, in which two thirds completed this list. Of the residents who filled in the questionnaire, 37% appeared to have symptoms of depression and/or anxiety. It can be derived from this that the prevalence of the symptoms of depression and anxiety in this residential home is certainly as high as expected. However, we were subsequently expecting, on the basis of comparable research in the general population, that 80% of these residents with symptoms were prepared to participate. This was not the case. We concluded that a personal approach, performed by familiar persons, directed at the more independent inhabitants is most likely to succeed. The need for research on the effectiveness and feasibility of evidence-based methods in residential care remains evident. However, the more vulnerable residents, possibly already being considered for nursing homes, have other needs.

Chapter 4. Criterion validity of the screening instrument
Chapter 4 concerns the characteristics of our screening instrument, the Center for Epidemiological Studies Depression Scale (CES-D) in a residential home population. The CES-D is an instrument that is commonly used to screen for depression in community-based studies of the elderly, but the characteristics of the CES-D in a residential home population have not yet been studied. The aim of this study was to investigate the criterion validity and the predictive power of the CES-D for both depressive and anxiety disorders in a vulnerable, very old population living in residential homes. We found that the CES-D had satisfactory criterion validity for depressive disorders and for depressive and/or anxiety disorders together. With a desired sensitivity of at least 80%, the optimal cut-off scores varied between 18 and 22. We concluded that the use of one single instrument to screen for both depression and anxiety disorders at the same time has obvious advantages in this very old population. The CES-D seems to be a suitable instrument for this purpose.

Chapter 5. Incidence of clinically relevant depressive symptoms
Chapter 5 focuses on the incidence rates of clinically relevant depressive symptoms and their predictors in a vulnerable elderly population living in the community. Very old people with a vulnerable health status are under-represented in studies focussing on incidence and risk factors, while the risk of developing depressive
symptoms is expected to be very high in this group. As we know that people living in a residential home often have a very vulnerable health status, the aim of this study was to test our assumption of high incidence rates of depression and anxiety in people living in residential homes. In a community-based cohort, 651 vulnerable elderly (75+) people were identified by means of the COOP-WONCA charts. After 18 months, we found that the incidence rate of all clinically relevant symptoms of depression was 48% (95% CI 44.2-51.8). No specific risk factors were identified within this population. These results do confirm the high risk of developing symptoms of depression in people in this selected vulnerable and older population.

Chapter 6. The results of the stepped care programme after one year
Chapter 6 evaluates the feasibility and effectiveness of the first intervention in the stepped care programme, activity scheduling as a guided self-help intervention for the prevention of depression and anxiety in elderly people living in residential homes. We hypothesised that participation in the intervention would probably be difficult in this old and vulnerable population, and that uptake would be an important determinant of effect. We did, indeed, observe that a minority of the residents were able to complete the intervention (14/67=21%). The drop out rate in the intervention group was significantly higher than in the usual care group. Although guided self-help may be promising in the prevention of depression and anxiety, it proved to be difficult to apply in this very old and vulnerable group of inhabitants of residential homes. Although we found some large positive effect sizes on the CES-D, none of the effects were statistically significant. The results of our study contribute to the existing body of knowledge about the prevention of depression and anxiety in the elderly. The hypothesis that activity-scheduling as a self-help intervention is more effective in lowering symptoms than usual care in a very old residential home population with a high risk for depressive and anxiety disorders, cannot be confirmed on the basis of this trial, mainly because of limited uptake.

Chapter 7. Activity-scheduling as a guided self-help intervention
Chapter 7 evaluates the effectiveness of a stepped care programme to prevent the onset of depression and anxiety disorders in elderly people living in residential homes after one year.

Previous research has suggested that prevention is most likely to be effective when targeted at those with a high a priori risk of developing the disorder. This can be achieved either by focusing on people with established risk factors for a disorder (selective prevention), or by targeting people with early symptoms of the disorder, but have not yet developed the full-blown disorder (indicated prevention). We combined both strategies by focusing on a frail elderly population exposed to multiple risk factors, with above average levels of symptoms of depression and
anxiety, but not yet meeting the diagnostic criteria for a disorder. We hypothesised that the stepped care prevention programme would be superior to the usual care in preventing the onset of depressive and anxiety disorders in residents in homes for the elderly. The intervention was not effective in reducing the incidence of the combined outcome of depression or anxiety (IRR=0.50 and a 95% confidence interval [CI] ranging from 0.23-1.12). However, the intervention was superior to the usual care in reducing the risk of MDD incidence (IRR 0.26; 95% CI 0.12-0.80), in contrary to anxiety incidence (IRR 1.32; 95% CI 0.48-3.62). For the prevention of anxiety, the programme would need to be improved, for example by including components that focus more specifically on anxiety disorders. Nevertheless, the preventive effect on depression is encouraging, and suggests that prevention may be a viable option, even in very old frail residents of residential homes.

Chapter 8. The sustained effects of the stepped care programme after two years

Chapter 8 describes the re-assessment of the effectiveness of a stepped care programme over two years. We hypothesised that the effect of the stepped care programme on depression, based on monitoring and evidence-based interventions, after one year would not sustain after two years. In two years, the IRR of MDD was 0.98; 95% CI 0.54 to 1.81. In the 79 residents who completed the two year of measurements the IRR was 0.53; 95% CI ranging from 0.32 to 0.87. The effects of the stepped care programme did, indeed, not hold in the follow-up year. It was only in the “completers-only analysis” that the effects remained equal to the effects in the first year. The frailty of the population might be the cause of a limit to longer term effects. Participation in a preventive intervention is optional, and people in high risk groups may not acknowledge the urge to participate and modify their behaviour. This may result in some amount of self-selection of the healthiest residents in the population in which the positive effects of the intervention are sustained.

Chapter 9. Cost-effectiveness of the stepped care programme

Chapter 9 evaluates the cost-effectiveness of a stepped care programme to prevent the onset of depression and anxiety disorders in residents of elderly homes compared with usual care from a societal perspective. The stepped care intervention was not effective for the combined outcome, but it was effective in preventing depressive disorders in this frail elderly population with multiple risk factors. However, implementing such a programme requires scarce resources that otherwise could be employed elsewhere. Therefore, the aim of the study was to evaluate the cost-effectiveness of this stepped care prevention programme in comparison with usual care from a societal perspective. The incidence of depression and anxiety combined in the intervention group was not reduced in comparison with the usual care group. There was also no effect on the other outcomes. Mean total costs in
the intervention group were €838 higher than in the usual care group, but this difference was not statistically significant (95% CI -593 to 2420). Cost-effectiveness planes showed that there was considerable uncertainty. Cost-effectiveness acceptability curves showed that the maximum probability of the intervention being cost-effective in comparison with usual care was 0.46 for reducing the incidence of depression and anxiety combined.
Chapter 12

Summary in Dutch
Preventie van depressie en angst bij bewoners van verzorgingshuizen

Bewoners van verzorgingshuizen vormen een hoog risicogroep voor het ontwikkelen van een depressie en/of een angststoornis. Deze stoornissen hebben een grote impact op het welzijn en functioneren van bewoners, komen veel voor en worden vaak slecht herkend. Er is daarom grote behoefte aan effectieve interventies om deze stoornissen te behandelen en te voorkomen. Preventie is extra belangrijk omdat deze stoornissen grote aantallen mensen treffen, en de verwachting is dat dit in de komende jaren alleen maar zal toenemen.

Dit proefschrift beschrijft een onderzoek naar de haalbaarheid en de effectiviteit van een stapsgewijs preventief programma bij bewoners van verzorgingshuizen die een verhoogd risico hebben op het ontwikkelen van een depressie en/of angststoornis. We hebben tevens bekeken wat de kosten zijn van een dergelijke aanpak. In tien hoofdstukken worden de verschillende aspecten van dit onderzoek besproken. Deze Nederlandse samenvatting is bestemd voor lezers zonder medische of wetenschappelijke achtergrond.

Hoofdstuk 1. De aanleiding voor het onderzoek.

Het aantal mensen in Nederland dat in een verzorgingshuis woont is de afgelopen jaren afgenomen, vooral omdat het overheidsbeleid er op gericht is om ouderen zo lang mogelijk in hun eigen woning te kunnen laten wonen. Tegelijkertijd is het aantal ouderen van 75 jaar en ouder toegenomen. Dat betekent dat in toenemende mate de bewoners van verzorgingshuizen tot de meest kwetsbare groep ouderen horen. Het verschil tussen een verzorgingshuis (voorheen “het bejaardenhuis”) en een verpleeghuis is daarmee ook aan het verdwijnen.

In het eerste hoofdstuk wordt met behulp van een interview met een van de bewoners de complexiteit en de impact van depressie en angst voor bewoners van verzorgingshuizen toegelicht. Zowel bewoners, familieleden, verzorgend personeel als huisartsen zijn geneigd de kenmerken die kunnen wijzen op een (beginnende) depressie of angststoornis te beschouwen als iets dat normaal is gezien de fysieke problemen en de (leef)omstandigheden van de bewoner. Vaak gaat veel zorg uit naar deze fysieke problemen, maar wordt te weinig aandacht gegeven aan de tekenen van een psychische stoornis. Een Nederlands onderzoek bij mensen van 75 jaar en ouder die thuis wonen, heeft recent laten zien dat een preventieve benadering met een stapsgewijze inzet van verschillende interventies heel effectief kan zijn. Bij de ouderen die de stapsgewijze interventie kreeg werd de kans dat zij een depressie of een angststoornis ontwikkelden met de helft verminderd. Wij hebben dit programma als uitgangspunt genomen om te onderzoeken of een dergelijke aanpak ook mogelijk en effectief is voor de meer kwetsbare groep ouderen die in verzorgingshuizen woont.
Hoofdstuk 2. De opzet van het onderzoek naar een stapsgewijze preventieve aanpak van depressie en angst bij bewoners van verzorgingshuizen.

Bij aanvang van het onderzoek worden alle bewoners van verschillende verzorgingshuizen in en in de omgeving van Amsterdam, uitgezonderd de bewoners van de Psycho Geriatrische afdeling voor bewoners met ernstige cognitieve problemen, onderzocht op het bestaan van symptomen van depressie of angst. Hiervoor wordt een vragenlijst, de Center for Epidemiological Studies Depression Scale (CES-D), gebruikt. Bewoners die boven het vastgestelde afkappunt scoren wordt gevraagd of ze mee willen doen aan het onderzoek. Om mee te kunnen doen wordt vervolgens met behulp van een diagnostisch interview vastgesteld of de klachten niet reeds zo ernstig zijn dat we kunnen spreken van een stoornis. Ook wordt gekeken of de bewoners voldoende cognitief vermogen hebben om te kunnen profiteren van de preventieve interventies. Wanneer bewoners al te ernstige klachten hebben op cognitief of mentaal gebied, worden zij verwezen naar hun huisarts en komen ze niet in aanmerking voor het onderzoek.

Het stapsgewijze programma bestaat vervolgens uit vier stappen. De eerste stap bestaat uit afwachten of de klachten vanzelf overgaan, omdat bekend is dat dit in de helft van de gevallen gebeurt. Na drie maanden wordt de ernst van de klachten opnieuw beoordeeld met behulp van de CES-D. Wanneer de klachten dan niet zijn afgenomen (of zijn toegenomen) wordt de eerste interventie aangeboden, een zelfhulp boek. Met behulp van de uitleg en de oefeningen uit dit boek kan de bewoner, in samenwerking met de daarvoor toegewezen verzorgende, zelf de klachten aanpakken. De uitleg en de opdrachten zijn gericht op het vermeerdere van plezierige en zinvolle activiteiten. Uit eerder onderzoek is gebleken dat dit een effectieve aanpak is om klachten van somberheid en gespannenheid te verminderen. Tegelijkertijd wordt een signaal aan de huisarts afgegeven dat de bewoner meedoet aan het onderzoek en op dit moment lichte klachten van somberheid en/of angst heeft. Wanneer de klachten na het werken met dit boekje niet zijn afgenomen wordt de volgende interventie aangeboden, het “dierbare herinneringen interview”. Dit is een viertal individuele gesprekken met een verpleegkundige, gericht op het heractiveren van specifieke positieve herinneringen. Ook wordt een advies aan de bewoner gegeven om de huisarts te bezoeken om mogelijke somatische oorzaken van de klachten te laten uitsluiten. Wanneer de klachten na deze stap weer niet voldoende zijn verminderd wordt de bewoner doorverwezen naar de huisarts om te overleggen of een specialistisch consult of medicatie noodzakelijk is. Elke keer wanneer de CES-D wordt afgenomen, wordt ook het diagnostisch interview afgenomen om te onderzoeken of de bewoner een stoornis heeft ontwikkeld. Wanneer dit het geval is wordt de bewoner onmiddellijk doorverwezen naar de huisarts en stopt daarmee de deelname aan het onderzoek.
De belangrijkste uitkomst van ons onderzoek is de vergelijking tussen het aantal mensen dat een stoornis ontwikkelt gedurende het preventieve programma en het daaropvolgende jaar, in vergelijking met de bewoners die het programma niet volgen. We verwachten, op basis van eerder onderzoek, dat na twee jaar 35% van de bewoners met lichte klachten van somberheid of angst, die het programma niet kregen aanboden een depressie of een angststoornis krijgt. We beschouwen het preventieprogramma als effectief als van de bewoners die het wel volgden niet meer dan 20% een stoornis heeft ontwikkeld.

**Hoofdstuk 3. Verkennende studie naar de methode om mensen met lichte stemmings- en angstklachten te identificeren.**

Verschillende verzorgingshuizen in Amsterdam hebben zich bereid ver klaard om de stapsgewijze preventieve aanpak te toetsen op haalbaarheid en effectiviteit. Vanzelfsprekend dient het opsporen en motiveren van de bewoners vooraf te gaan aan deelname aan het preventie programma. In januari 2007 startten wij een verkennende studie in een van de huizen om de door ons voorgestelde opsporingsmethode te toetsen. Het opsporen van bewoners met een verhoogd risico bleek gecompliceerder te verlopen dan we verwacht hadden, vooral vanwege de grote zorgzwarte van de bewoners. Ten tijde van de proefperiode woonden 177 bewoners in het betreffende verzorgingshuis, verspreid over acht afdelingen. 99 (56%) bewoners vulden de vragenlijst niet in: zeven bewoners (4%) overleden in deze periode, 56 (32%) bewoners toonden zich direct niet bereid, of waren niet in staat om mee te doen en 36 bewoners (20%) wilden niet deelnemen nadat ze de vragenlijst in ontvangst hadden genomen en hadden gelezen. 24 van hen gaven aan dat zij “geen zin” hadden in een dergelijk onderzoek. Bij doorvragen werden verschillende aspecten hiervan benoemd: men vond zichzelf te oud om nog te veranderen, men had geen behoefte aan bemoeienis, maar ook vond men een dergelijke confrontatie belastend of werd men er nerveus van. Van de 78 bewoners waarvan wel een score op de vragenlijst kon worden vastgesteld (44% van het totaal) hadden 29 (37%) bewoners klachten van somberheid of angst. De meerderheid van deze bewoners gaf echter aan af te zien van deelname vanwege hun slechte mentale en fysieke conditie. Een belangrijke vinding van deze verkennende studie is dat de meest kwetsbare groep moeilijk te bereiken is met onze methode. Het is nog de vraag op welke wijze deze groep mensen, die dicht tegen de zorgzwarte van verpleeghuisbewoners zit, of al een verpleeghuisindicatie heeft, wel bereikt kunnen worden en welke interventies dan haalbaar zijn. Op basis van deze verkennende studie hebben wij een aantal aanpassingen gedaan in het onderzoeksprotocol. Zo hebben onze onderzoeksmedewerkers alle bewoners individueel benaderd en de vragenlijst mondeling afgenomen met behulp van antwoordkaarten. Tevens hebben we ook de bewoners die minder hoog scoorden op de vragenlijst gevraagd
om mee te doen met het onderzoek, waardoor ook bewoners met lichtere klachten van somberheid of angst in aanmerking kwamen voor het preventieve onderzoek. Hierbij dient opgemerkt te worden dat het aanvankelijk de bedoeling was het meten van de klachten voor het onderzoek (gedeeltelijk) door medewerkers van de verzorgingshuizen zelf te laten doen, met gebruik van bestaande observatie-instrumenten. Dit bleek echter niet haalbaar in dit verzorgingshuis in verband met de onderbezetting en overbelasting van het verzorgend personeel.

**Hoofdstuk 4. De toepasbaarheid van de CES-D in het verzorgingshuis.**

De vragenlijst die wij in dit onderzoek hebben gebruikt om bewoners te selecteren die meer risico lopen op het ontwikkelen van een depressie en/of een angststoornis is de CES-D. Deze vragenlijst wordt veel gebruikt om depressies op te sporen en is ook geschikt gebleken voor het opsporen van depressies bij ouderen. Het is nog niet eerder onderzocht of de vragenlijst ook geschikt is om te gebruiken bij ouderen die in verzorgingshuizen wonen. Hoewel de vragenlijst ontwikkeld is voor het opsporen van depressie, wordt de CES-D ook gebruikt voor het opsporen van angst. Omdat het minder belastend is om voor het opsporen van beide stoornissen 1 vragenlijst te gebruiken, willen we ook graag weten of dit bij verzorgingshuisbewoners ook met deze lijst kan. Op basis van onze meetresultaten kunnen we zeggen dat de CES-D ook geschikt is om depressie op te sporen bij bewoners van verzorgingshuizen, maar dat de waarde op de lijst waarbij er sprake is van een stoornis (het “afkappunt”) hoger ligt bij deze meer kwetsbare ouderen dan bij ouderen die thuis wonen (22 ipv 16). Ook blijkt de CES-D inderdaad geschikt om depressie en angst samen op te sporen, daarbij is het afkappunt ook iets hoger, te weten 18 ipv 16. Voor het opsporen van angststoornissen alleen is de CES-D minder geschikt.

**Hoofdstuk 5. Het ontstaan van depressieve klachten bij ouderen met een kwetsbare gezondheidsstoestand.**

Bewoners van verzorgingshuizen hebben vaak een meer kwetsbare gezondheidsstoestand dan ouderen die thuis wonen. Er is nog niet veel bekend over de omvang van het ontstaan van depressieve klachten bij ouderen die een kwetsbare gezondheid hebben. Het uitgangspunt van onze preventieve aanpak was dat bij kwetsbare ouderen vaker depressieve klachten optreden dan in de gemiddelde oude bevolking. Daarnaast vroegen wij ons af of er bij het ontstaan van depressieve klachten andere risico factoren een rol spelen dan in de gemiddelde oude bevolking. In dit hoofdstuk beschrijven we een aanvullend onderzoek dat we hebben uitgevoerd met gegevens uit een studie naar ouderen met een kwetsbare gezondheidsstoestand. Hierbij werden 651 ouderen van 75 jaar en ouder 1,5 jaar gevolgd en werd zowel na zes maanden als na 1,5 jaar gemeten of deze ouderen last hadden.
gekregen van depressieve klachten. We onderzochten daarbij ook of we specifieke risicofactoren konden vaststellen die in deze groep de kans op het ontstaan van depressieve klachten bepaalden. We keken daarbij onder andere naar leeftijd, geslacht, opleidingniveau, hoogte van de klachten bij de eerste meting, aantal chronische ziekten, problemen met horen of zien, pijn, eenzaamheid, sociale steun en angst om te vallen. Geen van deze mogelijke risico factoren bleek in deze groep een specifieke bijdrage te leveren aan het ontstaan van depressieve klachten. Wel vonden we dat na 1,5 jaar 48% van de kwetsbare ouderen last had gekregen van depressieve klachten. Dat is aanmerkelijk meer dan eerder gevonden percentages in de gemiddelde oude bevolking (7 – 24.5%). Bovendien vonden we dat in de geselecteerde groep van 651 ouderen met een kwetsbare gezondheid al 58% depressieve klachten had bij de eerste meting. Op basis van deze cijfers concludeerden wij dat het hebben van een kwetsbare gezondheid bij ouderen inderdaad een hoog risico met zich meebrengt op het krijgen van depressieve klachten.

Hoofdstuk 6. Het effect van een stapsgewijze preventieve aanpak van depressie en angst bij bewoners van verzorgingshuizen.

185 bewoners van 14 verzorgingshuizen in en om Amsterdam deden mee aan het onderzoek naar het effect van een stapsgewijze preventieve aanpak van depressie en angst. 93 van hen kregen de interventies aangeboden (de “interventie groep”), de andere 92 kregen dat niet (de “controle groep”). De controle groep kreeg dezelfde zorg als altijd, maar werd net als de mensen die de interventies kregen, wel elke drie maanden geïnterviewd om te kunnen meten welke veranderingen in de gemoedstoestand hadden plaatsgevonden. Na 1 jaar waren 55 bewoners (30%) gestopt met het onderzoek. 11 van hen waren overleden, 18 weigerden verdere deelname en 26 bewoners werden ze ziek om nog langer mee te doen. Het viel hierbij op dat er meer bewoners die de interventies kregen verdere deelname weigerden dan bewoners die in de controle groep zaten (14 in de interventie groep en 4 in de controle groep). Het is mogelijk dat de interventies voor sommige bewoners te belastend werden gevonden, waardoor ze niet langer mee wilden doen in het onderzoek. Op basis van onze statistische analyses stelden wij vast dat er na 1 jaar geen verschil was tussen het percentage bewoners in de interventie groep die een stoornis ontwikkelde en het percentage in de controle groep. Het programma was dus niet effectief om depressie en angststoornissen te voorkomen. Bij nadere analyses ontdekten we echter dat het programma wel effectief was om depressie te voorkomen, maar dat het niet werkte om angst te voorkomen. Dat is een verassende bevinding omdat de verschijnselen van depressie en angst gedeeltelijk overlappen, vaak tegelijkertijd voorkomen en vergelijkbare behandelingen vaak zowel voor depressie als voor angst effect hebben. In ons onderzoek was dat niet het geval. Men zou zich zelfs kunnen afvragen of bewoners in verzorgingshuizen
misschien angstig worden van dit programma. De resultaten van ons onderzoek kunnen hier geen duidelijk antwoord opgeven. We weten wel dat het op deze manier mogelijk is om depressies te voorkomen. Om het programma ook geschikt te maken om in de praktijk toe te passen moeten de interventies ook gericht zijn op het voorkomen van angst.

Hoofdstuk 7. Het effect van een zelfhulpboek, gericht op het vermeerderen van plezierige en zinvolle activiteiten, op depressieve- en angstklachten.

In het zevende hoofdstuk beschrijven we de evaluatie van het effect van de eerste interventie in het stapsgewijze preventie programma. De eerste interventie is een zelfhulpboek wat de bewoner met ondersteuning van een verzorgende doorneemt. Het boek geeft de bewoner uitleg over het ontstaan van depressieve- en spanningsklachten en beschrijft vier stappen waarmee men deze klachten kan aanpakken. Eerst wordt gevraagd om gedurende een week de stemming bij te houden door een cijfer te geven voor de gemoedstoestand in de ochtend, middag en avond. Dan wordt een lijst met 48 verschillende plezierige en zinvolle activiteiten aangeboden, die de bewoner doorneemt met als doel in kaart te brengen welke activiteiten passend zijn. Op basis daarvan wordt een activiteitenlijst opgesteld die gedurende een week wordt bijgehouden, om meer inzicht te krijgen in de samenhang tussen de aard en het aantal activiteiten en de stemming. Wanneer hiermee duidelijk wordt welke activiteiten bijdragen aan een betere gemoedstoestand wordt gevraagd een plan te maken om deze activiteiten in voldoende mate te blijven uitvoeren. Het bleek voor bewoners aan wie we dit boek aanboden erg moeilijk om alle stappen van het boek uit te voeren. We vonden dat het uiteindelijk lukte bij 21% (14 van de 67) van de bewoners. We stelden vast dat bij de bewoners die het lukte om het boek helemaal door te nemen wel een groot effect was op de afname van de klachten. We konden echter niet statistisch vaststellen of dit effect meer dan toeval was, waarschijnlijk omdat het aantal bewoners hiervoor te klein was. We concludeerden daarom dat het aanbieden van een zelfhulpboek aan bewoners van verzorgingshuizen geen effect heeft op het verminderen van stemmings- en angstklachten, vooral omdat het niet voldoende lukt om ook daadwerkelijk met de oefeningen aan de gang te gaan. Voor die bewoners die gemotiveerd zijn om het hele boek door te nemen en de oefeningen uit te voeren, kan het mogelijk wel helpen om de klachten te verminderen.

Hoofdstuk 8. Het effect van het stapsgewijze preventie programma op het voorkomen van depressie na 2 jaar.

Twee jaar na de start van het onderzoek hebben we de deelnemers opnieuw geïnterviewd. We wilden weten of de positieve effecten die we na 1 jaar hadden
gevonden op het voorkomen van depressie ook na twee jaar nog aanhielden. Een probleem bij het analyseren van de gegevens was het feit dat bijna de helft van de bewoners na 2 jaar niet meer geïnterviewd kon worden. Van de 185 bewoners die begonnen aan het onderzoek, konden we 82 niet meer interviewen na twee jaar. 27 van hen waren tussentijds verwezen naar de huisarts omdat ze een depressie of een angststoornis of beide hadden gekregen, bovendien waren na 2 jaar 24 van de oorspronkelijke deelnemers overleden. De anderen stopten er om diverse redenen mee. Net als in het onderzoek naar de effecten van het programma na 1 jaar hebben we bij onze analyses gebruik gemaakt van statistische methoden die de gegevens aanvulden van deelnemers die tijdens het onderzoek stopten. Daarnaast hebben we ook aparte analyses gedaan bij die bewoners die ook na 2 jaar nog geïnterviewd konden worden. Met behulp van de analyses met aangevulde gegevens bleek dat het positieve effect op depressie wat na 1 jaar werd aangetoond, na 2 jaar niet meer bestond. Wel bleek dat bij geen van de bewoners die het hele onderzoek volhielden een nieuwe depressie was ontstaan in het tweede jaar. De bewoners die na twee jaar nog meededen kunnen we beschouwen als de relatief gezondste bewoners. Voor hen houdt het effect van het preventieve programma wel aan na 2 jaar. Je zou echter net zo goed kunnen concluderen dat deze bewoners ook zonder preventief programma depressie vrij waren gebleven.

**Hoofdstuk 9. De economische kosten van het stapsgewijze preventie programma.**

We hebben in dit onderzoek bekeken of een preventieve aanpak kan helpen bij het voorkomen van een depressie of angststoornis bij ouderen die in een verzorgingshuis wonen. We konden het effect van deze aanpak wel aantonen voor depressie, maar niet voor angst. Om beide stoornissen samen te voorkomen werkte deze aanpak onvoldoende. Wanneer een dergelijke aanpak ook in de praktijk zou worden uitgevoerd is het van belang om te weten hoeveel dat kost. Het gaat er hierbij immers om schaarse middelen vrij te maken voor zorg, die ook op een andere manier zou kunnen worden ingezet. We vonden dat de kosten van de preventieve aanpak gemiddeld €838 hoger waren dan wanneer mensen deze niet kregen. We konden niet aantonen dat de kosten-baten analyse van deze aanpak voordelig zou uitvallen voor de preventieve aanpak. De grootste beperking bij ons onderzoek is het aantal mensen dat mee wil en kan doen aan een dergelijk programma. Ook het aantal mensen dat niet in staat is om een dergelijk programma in voldoende mate af te ronden vormt een beperking voor het mogelijk succes van deze aanpak. Deze aanpak zou dan ook alleen kostendekkend kunnen zijn als de deelname voor meer mensen haalbaar en aanvaardbaar wordt.
Hoofdstuk 10. Algemene discussie.

In het laatste hoofdstuk worden de belangrijkste bevindingen en de gebruikte methodologie in de voorgaande hoofdstukken besproken.

De uitvoering van het preventieve programma in de dagelijkse praktijk bleek een grote uitdaging. De geringe mogelijkheden om het personeel in de verzorgingshuizen voldoende te betrekken was daarbij een belemmering, evenals de kwetsbare conditie van de bewoners. Toch waren over het algemeen de reacties van het personeel en van de deelnemers heel bemoedigend. We merkten dat veel verzorgenden het belangrijk vonden om uitleg over depressie en angst te krijgen, samen met een eenvoudig boek waarmee ze met een bewoner konden proberen de klachten aan te pakken. Aan enthousiasme ontbrak het de meeste verzorgenden niet, maar wel bleek dat het (blijven) motiveren van de bewoners en het vrijmaken van voldoende tijd hiervoor vaak lastiger was dan gedacht. De SPVen die de gesprekken over dierbare herinneringen uitvoerden, vertelden dat ze het prettig vonden om met bewoners op zoek te gaan naar positieve verhalen. Dit vormde een grote tegenstelling met de probleem georiënteerde gesprekken die ze over het algemeen met hun patiënten voerden. In tegenstelling tot het zelfhulpboek, waar slechts 24% de oefeningen afmaakte, maakten alle bewoners die aan de gesprekken over positieve herinneringen begonnen deze gesprekken ook af. De bewoners die meededen aan het onderzoek gaven in meerderheid aan dat ze het prettig vonden dat er met een duidelijke regelmaat iemand bij hen langskwam om te informeren naar hun welbevinden. De tijd die de interviewer uittrok voor het afnemen van de vragenlijsten en de houding en rust van de interviewers werd hogelijk gewaardeerd. Aangezien veel bewoners tevens aangaven dat ze met enige regelmaat gevoelens van eenzaamheid kenden leek de aandacht van de interviewers te voldoen aan een diepgevoelde behoefte. Het feit dat het hierbij “slechts” ging om het afnemen van gevalideerde vragenlijsten, heeft mij regelmatig geraakt.

We hebben in dit onderzoek de grote effecten van een preventieve aanpak bij ouderen die thuis wonen niet kunnen bevestigen voor ouderen die in een verzorgingshuis wonen. Het meest verassende resultaat is dat we tegengestelde effecten vonden voor de preventie van depressie en voor die van angststoornissen. Omdat we op basis van dit onderzoek niet kunnen aantonen waardoor dit komt, is mijn aanbeveling om in toekomstig onderzoek nauwkeuriger te kijken naar het optreden van angststoornissen bij bewoners van verzorgingshuizen. Hoewel het onderzoek naar angststoornissen bij ouderen de laatste jaren toeneemt, loopt onze kennis hierover bij ouderen nog ver achter in vergelijking tot de kennis over depressie. Het is mogelijk dat juist bij deze hele kwetsbare groep mensen een preventieve aanpak tegengestelde effecten uitlokt. Het is belangrijk om te weten dat we met een preventieve aanpak ook bij bewoners van verzorgingshuizen depressie kunnen voorkomen. Om het programma te kunnen invoeren zal er meer gericht moeten
worden gekeken naar het voorkomen van angst. Een brede aanpak, zoals die bij ouderen die thuis wonen wel werkt, is niet voldoende.

Een ander belangrijk aspect is de lage deelname graad van de bewoners aan een dergelijk programma. Bij preventie is dit een veel voorkomend fenomeen; het blijft ingewikkeld om mensen te motiveren om nu iets te doen of laten waardoor er in de toekomst iets niet zal gebeuren. Bij bewoners van verzorgingshuizen wordt de mogelijkheid om aandacht te geven aan het voorkomen van psychische klachten nog eens extra belemmerd door een kwetsbare fysieke en cognitieve conditie. Dit zijn nu juist ook risicofactoren voor het ontstaan van depressie en angst. Daarnaast hadden veel bewoners grote moeite met het erkennen van depressie of angstklachten. Over het algemeen erkenden de meesten dat dit in hun omgeving veel voorkomt, maar was er een grote weerstand om deze klachten bij zichzelf te benoemen. Ook kregen we op basis van gesprekken met bewoners de indruk dat er binnen de muren van het verzorgingshuis sociale mechanismes optreden, waarbij bewoners bang waren om door medebewoners als zwakkeling te worden gezien. Aandacht voor het bestrijden van deze stigma’s en extra aandacht voor motiverende gespreksvoering zijn aan te bevelen bij toekomstig onderzoek naar preventieve programma’s in deze setting.

Ons onderzoek heeft bevestigd dat klachten van depressie en angst in Nederlandse verzorgingshuizen veel voorkomen. Zowel het management, het personeel als veel bewoners erkennen dat er meer aandacht voor nodig is. De preventieve aanpak zoals wij die in ons onderzoek hebben vormgegeven kent nog teveel tekortkomingen om het programma in de huidige vorm in te voeren. Het feit dat het mogelijk is om depressie te voorkomen is een bemoedigende vaststelling. De komende jaren ligt er een grote uitdaging voor ons om de aandacht voor psychisch welbevinden van ouderen in verzorgingshuizen te verbeteren.
Dankwoord
**Wat kan er veel veranderen in vijf jaar!**

Wie had bijvoorbeeld ruim vijf jaar geleden kunnen denken dat ik ooit nog eens een dankwoord bij een proefschrift zou mogen schrijven? Ik zelf niet, dat moge duidelijk zijn, toch waren er anderen die dit toen al voor zich zagen. Voor dit onmeetelijke vertrouwen ben ik heel veel mensen dankbaar. Niet in de laatste plaats omdat dit vertrouwen gaande weg toch een klein beetje besmettelijk bleek te zijn. Dat maakt dit promotietraject tot zo’n waardevolle verrijking van mijn leven, dat ik het nooit had willen missen. Het is bijna onmogelijk om alle, grote en kleine, bijdragen hier te benoemen, maar ik ga een poging wagen:

In de eerste plaats:

Anneke van Schaik en Harm van Marwijk. Ik geloof dat het niet helemaal volgens protocol is om met de co-promotoren te beginnen, maar jullie waren toch echt de allereersten die een promotietraject met mij wel zagen zitten. Anneke mailde mij: “ik heb misschien een interessant project voor je, zullen we even bellen?” en binnen korte tijd zat ik met jullie om de tafel. Mijn verbazing was groot, maar met jullie durfde ik deze uitdaging wel aan. En terecht, want wat een geweldig koppel zijn jullie voor mij geweest! Anneke: altijd betrouwbaar en precies in de antwoorden op mijn ontelbare vragen. Met jou zette ik de eerste stappen in verzorgingshuizen en je wist mij altijd weer te overtuigen dat het wel goed zou komen. Jij bent voor mij een voorbeeld, waarbij ik veel herken in de manier waarop jij de wereld, in het bijzonder die van de psychiatrie, beschouwt. Helaas hebben we maar een keer onze krachten op de tennisbaan gemeten, maar ook daar zag ik een betere versie van mezelf aan de overkant van het net staan. Ik hoop dat we nog vaak samen zullen sparren!

De overtuiging dat het goed zou komen werd ook nog in dubbele porties over mij uitgestort door Harm. Wat een positivisme, wat een enthousiasme en creativiteit. Daarnaast maakte je me wegwij in de wereld van de huisarts. Ik vond het fijn om met jou allerlei breed uitwaaiende discussies te voeren over de zorg, de verhouding arts/verpleegkundige en het belang om jezelf te blijven in wat voor rol dan ook. Ik weet zeker dat onze wegen zich zullen blijven kruisen.

De hoogleraren:

Na het gesprekje met Anneke en Harm vond ik dat we meteen maar aan de slag moesten gaan. Dat was een uitermate naïeve gedachte, want uiteraard diende een degelijke toetsing plaats te vinden of hun vertrouwen niet op drijfzand beruste. Ik vond mezelf terug in een sollicitatie gesprek bij Aartjan Beekman en Wim Stalman. Ik werd door jullie beiden streng, doch uitermate plezierig aan de tand gevoeld over motivatie en bagage. Toen het verlossende telefoontje kwam van Wim was ik opgelucht. Beste Wim, ik heb helaas niet lang van jouw begeleiding mogen
genieten, omdat je decaan werd bij het VUmc. Ik voelde me zeer welkom bij je, de twijfels over waar ik nou eigenlijk mee bezig was nam je heel serieus en je hebt me op een prettige manier gestimuleerd door te eisen dat ik binnen het eerste jaar een artikel in het Engels zou publiceren. Het geweldige afscheidfeest van de afdeling bij jou thuis bevestigde mijn eerste indrukken: gastvrij, veel humor en een grote eloquentie.

Aartjan, jou kende ik al van onze tijd in de Valeriuskliniek. Ooit namen we nog eens samen afscheid van de open afdeling, waarna ik op veel verschillende plekken verpleegkundige bleef, maar jij in sneltreinvaart doorstootte naar de top. Hoe jij het voor elkaar krijgt al jouw taken en functies te combineren en toch een vrolijk en toegankelijk mens te blijven is mij een raadsel. In ieder geval zal het iets te maken hebben met je hart voor het werk en de mensen, met je uitzonderlijke scherpzinnigheid en met een heel grote portie doorzettingskracht. Ik voel me een bevoorrecht mens dat ik gedurende vijf jaar door jou ben gevoed en gesteund.

Henriette van der Horst, jij hebt Wim vervangen toen we al op weg waren met het project. Hoewel je je moest inwerken in een nieuwe, helemaal niet makkelijke positie op de afdeling was je er meteen voor mij. Je precieze en kritische commentaren zorgden altijd weer voor verbetering van de artikelen.

Max Stek, ook jij bent ons team later komen versterken. Het was duidelijk dat ons team de specifieke expertise van een specialist in de ouderen psychiatrie miste. Jij het die rol met veel enthousiasme ingevuld. Ik vond het leuk om jou op een andere manier te leren kennen, je was tenslotte voor mij altijd “die man met dat vlinderdasje”. Nu werd je een steunende en positieve leermeeester. Dat je in je eigen tijd aan een paraglyder de bergen afsuist heeft diepe indruk op me gemaakt en heeft mijn bewondering voor jou slechts versterkt.

De co-auteurs:
Filip Smit natuurlijk in de eerste plaats. Zonder jou was ik nooit uit alle ingewikkelde analyses en methodologische vraagstukken gekomen. Met heldere uitleg heb je me steeds stapje voor stapje op weg gebracht en me uiteindelijk de edele kunst, maar vooral het belang van het “imputeren” bijgebracht. Hoe druk je het ook hebt (veel te druk), je maakte altijd weer tijd voor me vrij.

Ernst Bohlmeijer, je hebt me onmiddellijk besmet met het reminiscentie virus. Ik wist al heel snel dat jouw onderzoek en ervaring met betrekking tot life review een belangrijke aanvulling in ons programma diende te zijn. Toen je bij onze eerste ontmoeting op het station in Utrecht enthousiast meldde dat we ook op werkbezoek
naar Madrid zouden moeten, vroeg ik me wel oprecht af in wat voor wereld ik nu toch terecht was gekomen. Toen het bezoek met jou en Bas Steunenberg uiteindelijk plaatsvond heb ik met volle teugen kunnen genieten van jouw aanstekelijke levenskunst. De trainingen die je de SPVen hebt gegeven waren een plezier om mee te maken. Ik hoop dat we elkaar nog regelmatig zullen tegenkomen, zodat we later veel vrolijke herinneringen hebben opgebouwd.

Hein van Hout, samen met jou, met data van jouw PIKO onderzoek, ben ik gaan “oefenen met SPSS”. Dat er vervolgens ook nog een gepubliceerd artikel uit is voortgekomen vond ik aanvankelijk een onwerkelijke ervaring. Ook jij bent iemand die vooral kansen en mogelijkheden ziet en deze met aanstekelijk enthousiasme en vooral veel ironie met anderen deelt. Fijn dat je mijn “chair” was in Bologna!

Judith Bosmans, ongelofelijk dat je in zo korte tijd een grondige KEA uit je mouw schuwt. En dat terwijl je moet verhuizen, kinderen fotograferen, oma bezoeken, man uitzwaaien, zelf nog even op congres, neuzen snuiten, muziek op facebook zetten…en natuurlijk gezellig met ons lunchen. Kortom je bent een formidabele duizendpoot waarmee ik fijn heb samengewerkt!

De leescommissie:
Prof. Dr. Marieke Schuurmans, Prof dr. Roos van der Mast, Prof dr. Richard Oude Voshaar, Prof dr. AnneMargriet Pot, Prof dr. Kees Hertog en dr. Annemieke van Straten, hartelijk dank voor het beoordelen van mijn manuscript.

Alle deelnemers aan het onderzoek:
In het proefschrift staat jullie bijdrage in getallen beschreven; 14 verzorginghuizen waar vele managers, verzorgenden, cliëntenraden, huisartsen en 1487 bewoners zich open hebben gesteld voor dit onderzoek. Ik hoop dat de uiteindelijke resultaten een beetje zullen bijdragen aan een verbetering van het welzijn van ouderen in ons land. Het is mij in ieder geval duidelijk geworden dat er nog genoeg te winnen is, ondanks de enorme inzet van jullie allemaal om het met de huidige middelen zo goed mogelijk voor elkaar te krijgen. Ik ben onder de indruk van de betrokkenheid die ik bij velen van jullie heb gezien. Dank jullie wel voor het gestelde vertrouwen!

De collega’s op de afdeling (in willekeurige volgorde, want met wie te beginnen?):
Toch niet helemaal willekeurig: Bettine zonder jou had ik überhaupt nooit meer een stap in de universiteit gezet. Je hebt me besmet met het onderzoeksvirus, maar bent uiteindelijk vooral een goede vriendin geworden. Heel flauw dat jij zo snel promoteerde en samen met Ingrid de afdeling achterliet, die echt nooit meer zo lollig is geworden als met jullie twee. Ik houd van jouw onorthodoxe kijk op het leven,
“hilarisch, maar iemand moet het doen”. PST heeft nog steeds de toekomst en dat gaan we samen weer eens even flink onder de aandacht brengen. Daarna gaan we winkelen, want dat kan ik niet zonder jou.

Nelleke, je vroeg je af of je wel de goede dingen tegen me had gezegd, toen ik kwam informeren of het onderzoeken van een “stepped care programma” wel iets voor mij zou zijn. Kennelijk wel. Jouw nuchtere, maar tegelijkertijd enorm betrokken houding ten aanzien van onderzoek doen, heeft me door moeilijk tijden heen geloodst. Jij deed het tenslotte allemaal voor “je oudjes” en dat kan ik alleen maar met je eens zijn.

Els, beter dan jou kon ik niet treffen om samen de Elsen-kamer te vormen. We hebben uiteindelijk bijna 5 jaar lief en leed gedeeld, want op een Elsen-kamer zet je geen anderen neer. Ook bij jou kon en kan ik altijd terecht met vragen, met klachten en met nieuwe ideeën. Onze wens om samen kwalitatief onderzoek te doen is helaas niet uitgekomen, maar die fantastische cursus in Antwerpen pakken ze ons niet meer af. We hebben de Elsen-kamer in moeten ruilen voor donderdaglunches…ik hoop dat er nog vele zullen volgen!

Karlijn, samen vormden we de laatste jaren de promovendi van Mental Health op de afdeling. En dan was ik de helft van de tijd ook nog eens bij de “echte” mental health aan het werk. Desondanks heb ik enorm veel steun van je gehad. Stata kent geen geheimen meer…tenminste, als jij in de buurt bent. Als jij zegt dat ik echt wel goed bezig ben, dan geloof ik dat onmiddellijk. Nou moet jij dat toch ook eens gaan geloven als ik datzelfde van jou vindt! Bologna was super, samen met jou.

Annemarie, je was meer dan welkom op de Elsen-kamer want als H aiotho paste je natuurlijk prima op de plaats van Els. Gelukkig heb je nu een kamer met je eigen naam bordje…Het was fijn om mijn laatste maanden op de afdeling bij jou door te brengen en je hebt me een onvergetelijke vakantie aan de door jou zeer geliefde Lot gebracht. Dank!

Alle ganggenoten, ook die ik vergeet, heel erg bedankt voor de mogelijkheid altijd even binnen te lopen en tips, adviezen, thee of zo maar een praatje te ontvangen: Sandra, Iris, Otto, Joan, David, Marinda, Ingrid, Pim, Amber, Esther, Koen, Uriel, Nathalie, Francois, Wim, Danielle, Karolien, Stephanie, Giel, Nettie, Valentina, Sietske, Loes, Jeroen, Els, Berend, Carry, Laura en Babette. Wim Kraan en Kees de Boer, dank voor de steun bij alle datamanagement. Patrick, Len en Bram, de redende engelen voor computerklunzen zoals ik. Marcel, dank voor je vele preken en de voortdurende belangstelling of het boekje “nu nog niet af is”, naast de subtiele
aandacht voor impactfactoren. Petra, ik draag de trilogie aan jou op, met name de flow-charts hebben genoten van jouw bewondering. Ook je persoonlijke steun in moeilijke tijden heeft me heel goed gedaan.

Ineke, je werkt niet op de HAG-gang, maar als assistente van Aartjan ben je een onmisbare schakel in het grote geheel. Dank voor alle thee en vrolijke ontvangsten.

Geen onderzoek zonder onderzoeksassistenten:
Lieve Jet, we hebben wel wat uitgevochten aan het begin, maar dat heeft dan ook mooie dingen opgeleverd! De bloemen-kaarten, de persoonlijk aandacht voor de deelnemers en de interviewers, je ordelijke mappen en mapjes, je volledige loyaliteit toen je er eenmaal in ging geloven…zonder jou was het niet gelukt!

Lief en leed wordt gedeeld met Marianne, helaas meer leed dan ons lief is, maar vakanties in Italië al of niet op de ski’s maken jou een aanstekelijke levenskunstenaar. Dank voor je betrokkenheid en alle hand- en spandiensten.

Paulien, ik snap niet hoe de nieuwe promovendi hun onderzoek op poten moeten zetten nu jij niet meer op de afdeling werkt. Wat was ik gruwelijk blij met jouw rust, wijsheid en ongelimiteerde inzet. Ik hoop dat je nog lang gaat genieten van je kleinkinderen en je prachtige tuin!

En dan ook nog een bijzondere groep interviewers:
Joske, de eerste zullen de laatsten zijn. Van begin tot eind was je erbij, en daarbij bleef je me verzekeren dat het “echt heel belangrijk werk” was wat ik deed. Ook door jou ben ik daar steeds een beetje meer in gaan geloven. Je bent een mens met heel veel talenten, ik vind het geweldig dat je meerdere van die talenten met mij hebt willen delen. Jammer dat het langlaufen er nooit van is gekomen…je kaartjes in donkere perioden hebben me er doorheen geholpen!

Iris, Mona, Marijke, Franka en Marjan, in wisselende samenstelling vormden jullie samen met Joske de interview club. Jullie hebben een geweldig hart voor het onderzoek gehad en ook steeds gelaagd in de bijdrage van deze studie aan een betere en rechtvaardiger aandacht voor bewoners van verzorgingshuizen. Heel leuk dat sommigen van jullie nu zelf op het onderzoekspad terecht zijn gekomen. Ik denk met veel plezier terug aan onze intervisies en de jaarlijkse etentjes.

De SPVen van het ouderen circuit: Eric, Mieke, Gerdine, Gabrielle F, Gabrielle M en Joanneke, dank voor jullie inzet en enthousiasme bij de life review interventie. Drea en JanWillem, dank voor jullie steun om linksom of rechtsom de deelname van de
verpleegkundigen mogelijk te maken.

Collega’s van Prezens preventie in Amsterdam:

Familie en vrienden:
Onmogelijk iedereen voldoende recht te doen die in deze vijf jaar naast mij heeft gelopen. Zonder de liefde en humor van jullie allemaal had ik het niet gered. De roeidames, de tennismaatjes, de basketball- en fietsmeiden, diverse skigezelschappen en natuurlijk de wandelclub…aan sportieve verstuiving gelukkig geen gebrek. Fijn dat jullie me toch elke keer weer mee laten doen.

Hemo, Hujo en Adan, we delen al heel lang lief en leed, wat mij betreft blijft dat eeuwig doorgaan. Geke, David en Sara, we hebben met elkaar vele mooie herinneringen opgebouwd tijdens vakanties en vele “dinertjes”. Ook voor jullie is er in de afgelopen periode veel gebeurd, we zullen met elkaar in een andere vorm weer verder bouwen. Lies, jij hebt het woord onvoorwaardelijk uitgevonden. Margot, zonder jou had ik het leven nooit binnen durven stappen.


Joan! Paranimf forever! Als er iemand in me geloofde was jij het wel. Nog voordat ik beseft wat ik ging doen had jij je al aangemeld. Natuurlijk ben je veel meer dan een paranimf, je bent de vriendin waarbij ik werkelijk voor alle, maar dan ook alle dingen terecht kan. Jij bent er al die tijd onvoorwaardelijk bij geweest en als iemand weet hoe nodig dat was dan ben jij het. Maar bovenal ben ik natuurlijk heel trots dat zo’n veelzijdig mens als jij mij de moeite waard vindt. Geert! Ook jij durft het aan om straks op het podium naast me te gaan staan. Uiter-
aard, want op de eerste drie-en-een-half jaar van mijn leven na, heb je altijd naast me gestaan. Samen hebben we voor heel wat hete vuren gestaan, maar gelukkig ook heel veel lol gehad. Niemand die beter weet hoeveel er veranderd is in de afgelopen vijf jaar dan jij. Wat ben ik trots op je en blij voor je dat je in Frieke een nieuwe grote liefde hebt gevonden waarmee je samen mijn wonder-neef op de wereld hebt gezet. Flauw dat Edzo niet bij de promotie mag zijn.

Maar helaas, er zijn er meer die er niet bij mogen zijn.

Vader, de tijd heeft me al bijna afgeleerd het woord tot u te richten. Vreemd om te beseffen dat ik nu een stap zet, waar u zo lang naar op zoek bent geweest. U heeft me de richting gewezen.

Moeder, tot u richt ik nog dagelijks het woord. De trots en onvoorwaardelijke liefde in uw ogen staan me op het netvlies gebrand. Het begin van dit promotietraject heeft u meegemaakt, met veel interesse las u elk artikel wat ik schreef. Het is ongelofelijk dat u er deze feestelijke dag niet bij bent, ook al heeft u beloofd van een wolkje mee te kijken. Een wijzere gids in het leven kan een dochter zich niet wensen.

Paul, het laatste woord is voor jou. Trouw, eerlijk, lief, verstandig, een leraar in hart en nieren, een gepassioneerd surfer, basketballer, tennisher, skiër, kok, wijnproever en bijna-golfer. Onweerstaanbaar als je de tranen in je ogen lacht bij een hele flauwe film. Kortom, de liefde van mijn leven. De laatste vijf jaar hebben dat alleen maar bevestigd.

“And what is life?
A crazy quilt;
Sorrow and joy,
And grace and guilt,
With here and there
A square of blue
For some old happiness
We knew——

Douglass Malloch
“a Crazy Quilt”