Depressive symptoms at old age : proactive management in general practice

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Chapter 8

General discussion

8.1. INTRODUCTION

This chapter considers the studies described in this thesis, starting with a general overview of the background, aim and results of the PROMODE study (PROactive Management Of Depression in the Elderly). This is followed by an appraisal of the basic assumptions underlying the PROMODE study and the secondary studies, and a discussion of factors that may have influenced the results.
In addition, suggestions are made for alternative approaches and for future research related to the management of common psychological problems, such as depression, among older people in primary care.

Background of the PROMODE study
The reasons for starting the PROMODE study were that depressive symptoms in older people are highly prevalent, under-recognised and under-treated, and that a pro-active approach in primary care by screening for depressive symptoms followed by an intervention offer to those who screened positive, may help to detect and relieve the suffering associated with these symptoms.
The idea that a pro-active approach might have a beneficial effect on the well-being of older people with depressive symptoms, was based on several ideas.
Firstly, among old(er) people depressive symptoms are common and associated with an overall decreased functional status and quality of life,[1-3] and with increased mortality.[4-6] This was confirmed using data from the Leiden 85-plus Study, in which 25% of the persons aged 90 years screened positive for depressive symptoms. These data also showed that the presence of depressive symptoms was associated with an overall decreased functional status, decreased quality of life, and increased mortality. The study also revealed that concurrent anxiety did not further intensify these negative consequences (chapter 2).[7]
Secondly, a pro-active program combining screening and intervention might increase recognition and improve treatment of depressive symptoms at old age. The rationale for this emerged from several screening-intervention programs for depressive symptoms that proved to reduce depressive symptoms[8] and suicidal ideation[9] among people aged 60 years and over.
Based on these data and ideas we designed and conducted the PROMODE study.

Aim of the primary study
The aim of the PROMODE study, and the primary aim of this thesis, was to investigate in a pragmatic way both the effectiveness (in terms of improvement of depressive symptoms) and the cost-effectiveness of a pro-active combined screening-intervention program for the 'oldest old' in general practice. In this program, all people aged 75 years and over would be systematically screened for untreated depressive symptoms, and those who screened positive would be offered an intervention.

Main results of the PROMODE study

In the PROMODE study the overall yield of *untreated* screen-positive persons aged 75 years and older in general practice was 2.2%.[10] However, the stepped-care intervention offer to those who screened positive proved not to be effective. Compared to the 'usual care' group the intervention group did not show more improvement on the severity of depressive symptoms; this can probably be attributed to a low intervention uptake (chapter 6).

8.2. DISCUSSION OF ASSUMPTIONS AND MAIN RESULTS

The poor yield of screening for undetected depressive symptoms and the negative results of our intervention study, thus failed to confirm our basic assumption that a pro-active and combined screening-intervention program in general practice would improve the management of depressive symptoms among the oldest old.

However, to better understand these results we need to address some issues related to these underlying assumptions and discuss factors that might have influenced the results. In addition, we discuss the clinical implications of our results and make some suggestions for future research. In particular, we focus on screening for depressive symptoms at old age, the effectiveness and acceptance of an unsolicited intervention offer, the adequacy of outcome instruments in primary care, and the external validity of the study results.

8.2.1. Screening for depressive symptoms at old age

With respect to screening for depressive symptoms in older people, we had made several assumptions. Firstly, we assumed that systematic screening of *all* older persons in general practice would reveal undetected depressive symptoms in a substantial proportion of older persons and that screening would improve detection compared to usual care. Secondly, we assumed that participation in the screening program and the yield of screen-positive older people would be enhanced by a personal approach (i.e. administration of the screening questionnaire during a home visit). However, do our results support these ideas?

Does screening enhance the detection of depressive symptoms?

In the PROMODE study the overall yield of *untreated* screen-positive persons among those aged ≥75 years in general practice was only 2.2%. Remarkably, we found that almost 6% of the older persons were excluded from the screening study due to current treatment for depression (mostly with antidepressants or surveillance), which was a higher percentage than we had expected (chapter 4).[10] These findings suggest that the general practitioner (GP) in fact detects and treats the majority of older patients with depression or with clinically-relevant depressive symptoms. Moreover, a study among persons aged ≥55 years in Dutch general practice showed that those who were detected by their GP as being depressed, tended to have more serious depression (and more co-morbid anxiety) than those

who were not; this indicates that GPs identify those older depressed patients who are most in need of treatment.[11] These findings imply that the added value of a screening program to improve the detection of depressive symptoms among older people is in fact limited.

Influence of a personal screening approach on participation and yield

Since we assumed that at old age a personal screening approach would enhance screening participation and increase the yield of screen-positive individuals, our study was started by visiting all those who agreed to participate: we called this 'direct screening'. However, this resulted in a lower screening yield than expected. Therefore we had to adopt a less time-consuming and less costly way of screening: namely, 'stepped screening'. In this second approach, the screening questionnaire (the 15-item Geriatric Depression Scale: GDS-15) was sent by mail to be completed at home by the older persons themselves (i.e. self-administration). This was followed by a home visit for an interviewer-administered GDS-15 only if the score on the self-administered GDS-15 was at least 4 points. Comparison of these two screening methods showed that the yield of *untreated* screen-positive persons of 75 years and older in general practice was only slightly higher in direct screening than in stepped screening (2.6% versus 1.9%), whereas estimated screening costs would be about twice as high for direct screening as for stepped screening.[10] Although in women the rate of screening participation and the yield of screen-positive persons of direct screening were somewhat higher compared with stepped screening, the overall participation rates in direct and stepped screening were very similar (54% versus 50%). Thus, these results did not confirm our idea that at old age a personal and costly screening approach by visiting all older people at home is a necessary investment for acceptable participation rates.

Screening by self-administered or interviewer-administered GDS-15

During PROMODE screening we changed from 'direct screening' to 'stepped screening', which implied a change from an interviewer administered GDS-15 to a self-administered method. Consequently, it became relevant to establish whether the way of administration had an effect on the GDS-15 scores. Therefore, we performed a secondary study that revealed that the total scores on the self-administered GDS-15 were (on average) 0.7 points higher than on the interviewer-administered GDS-15. For some items, more respondents indicated being 'depressed' on the self-administered GDS-15 than on the interviewer-administered GDS. We concluded that reports of screening studies should provide, in addition to cut-off scores, information about the way of administration, in order to make it possible to compare screening results between studies (chapter 5).

Screening by mail and self-administration of the GDS-15 is far less costly; however, in our study interviewer administration had the advantage that none of the items were left unanswered. When the GDS-15 is self-administered, respondents with unanswered items sometimes require direct contact in order to check whether the cut-off point for being screen-positive might be reached. Although this makes screening by mail less efficient than intended, it remains far less time consuming and costly than direct screening, whereas both

methods have a comparable yield. Therefore, for systematic and repeated screening of large groups of older persons 'stepped screening' starting with a self-administered GDS-15 is the preferred screening method.

Which population should be screened?

In the PROMODE study, screening was targeted at *all* persons from the age of 75 years registered in a GP-practice. This systematic and 'unselective' way of screening aimed to identify persons with untreated depressive symptoms, with a subsequent intervention offer to those who screened positive. Our approach showed no improvement of depressive symptoms compared to usual care. However, Schoevers et al. showed that a preventive strategy, targeted at older persons with depressive symptoms not reaching the threshold for the diagnosis of depression ('indicated prevention'), was the preferred option to prevent transition to late-life depression;[12] second best would be a 'selective prevention' approach targeted at high-risk groups, focusing on people who had lost their partner and those with chronic illness(es).[12] This was done by Lamers et al. who focused their prevention program on a high-risk group of chronically ill older people, offering a minimal psychological intervention to those who screened positive for minor (or mild to moderate) depression.[13] This latter intervention, aimed at increasing self-efficacy of patients with chronic obstructive pulmonary disease or diabetes, was effective on severity of depressive symptoms and quality of life.[13] These studies indicate that it would be more effective to direct preventive interventions to high-risk groups ('selective prevention') and, within these groups, targeting at sub-threshold depressive symptoms (combined selective and indicated prevention). Implementation of such a high-risk-group approach would be feasible in general practice, because most information necessary for this approach is available in the patient's electronic medical records of GPs.

8.2.2. Effectiveness and acceptance of an intervention offer to screen-positive older persons

When we started the intervention trial we assumed that older people who screened positive for depressive symptoms could benefit from an intervention that was developed to help them cope with their depressive symptoms. We also assumed that, after screening, the role of the GP in the process of individual counselling and motivation for the intervention offer would be limited, and to a large extent be taken over by a specialised psychiatric nurse. The following sections discuss these assumptions in relation to our results.

(Cost-)effectiveness of the intervention

In the PROMODE study the intervention offer consisted of a stepped-care intervention program with the 'Coping with depression' course[14] as the core element. This course is adapted to old age groups and has proven effective for depressed older persons who seek help. However, in our study, screen-positive persons aged ≥ 75 years who were offered the intervention did not show more improvement on severity of depressive symptoms

compared to persons who received usual care. Furthermore, the program was not cost-effective (chapter 6, Appendix Economic evaluation). These negative findings are not in line with earlier studies that showed positive results of the studied intervention compared to usual care. However, our study differs from the other studies with respect to age (for example, two studies included individuals from the age of 60 years onwards[8;9]); moreover, the various interventions under study are heterogeneous. Furthermore, in one study inclusion was not exclusively based on screening,[8] and some studies had different primary outcomes, such as reduction of suicidal ideation[9] or reduction of the risk to develop a major depression,[15] whereas we focused on improvement of depressive symptoms. Nevertheless, a more obvious explanation of why our intervention lacks effectiveness is the low uptake of the offered course, which was only 19% (chapter 6).

Intervention uptake after screening: why is it so low?

In a systematic review, Cuypers et al. showed that interventions that had proven effective in help-seeking depressed persons were not effective among people with depressive symptoms who were detected by screening. This was mainly due to the low intervention uptake by screen-positive persons.[16] Also in the PROMODE study, the uptake of the main part of the intervention was only 19%. Therefore, we performed a qualitative study, parallel to our randomised control trial, to explore the limiting and motivating factors that played a role in the acceptance of the offered 'Coping with depression' course. We found that interviewed persons who had accepted the course offer all felt depressed or lonely, and had positive expectations about the course. Important reasons to decline the course offer were: not feeling depressed, or having negative thoughts about the course effect, about group participation, or about being too old to change and learn new things. Although perceived needs to relieve depressive symptoms largely matched the elements of the offered course, most persons were not (yet) motivated or prepared to accept the intervention offer (chapter 7). This phenomenon of a low uptake and ineffectiveness of the intervention was also seen in the study by Baas et al., after screening for major depression in high-risk persons aged 18-70 years.[17] Screening programs in the somatic domain also reveal a similar pattern. For example, among people aged 85 years who screened positive for severe hearing loss, the motivation to accept and use a hearing aid was low. Although people were conscious of their limited hearing ability, the majority declined auditory rehabilitation because they had successfully coped with the negative consequences of their hearing loss and did not perceive that the use of a hearing aid was necessary for daily functioning.[18] This result suggests that the majority of people will not consider and accept an unsolicited intervention, unless they perceive a clear need for help to relieve a subjectively meaningful problem. Furthermore, it indicates that it will be difficult to show (cost-)effectiveness of screening-intervention programs in which the subjective suffering and perceived needs of the majority of screen-positive persons are minor or even absent.

Were GPs sufficiently involved?

At the start of our study, we assumed that individual counselling and assessment of the motivation to participate in the course could best be done by the community psychiatric nurse for two reasons. First, we assumed that the psychiatric nurse, who would also provide the course, could best inform people about the content of the course and the practical aspects of participation. Second, we assumed that GPs did not have sufficient time to start this counselling process with all their screen-positive patients (estimated at 8-10 per practice) in the required short time period of this study phase. These assumptions led to an approach in which we restricted the role of the participating GPs, i.e. we only asked them to contact and motivate their screen-positive patients for referral to the community mental health centre. However, in our qualitative study, several older persons explicitly stated they would have appreciated more involvement from their GP after screening, to discuss what was going on in their life, how they felt about it, and how to cope with these feelings (chapter 7). In addition, several older persons felt inhibited about discussing these problems with their GP, fearing to claim too much time or to be seen as 'mad' or 'a complainer'. Some simply did not realise that mood problems can be discussed with the GP and that effective treatment options exist. In retrospect, a stronger involvement of the GPs and/or nurse practitioners in the screening program and its outcomes would probably have been beneficial. This might have created the opportunity to start further exploration of the symptoms and needs before offering an (unsolicited) intervention, paying special attention to emotional items (such as feelings of being too old to change, fear of being considered insane) and to personal preferences such as group versus individual treatment. Furthermore, experience with the screening questionnaire, sound knowledge on the meaning of the screening outcome, and better knowledge of the 'Coping with depression' course, would enable GPs to better inform their patients about the outcome, and discuss referral in a more informed and motivated way. Moreover, when sufficiently motivated, GPs could implement this screening-intervention program themselves. This will probably result in better outcomes, since there is evidence that caregivers' motivation for psychological treatment and belief in its effects are related to the quality of their communication skills[19] and patient outcomes.[20] However, it remains unclear whether a stronger involvement of the GP is in fact feasible. In a recent focus group study, 18 Dutch GP-registrars indicated that they considered it their task to diagnose mental health problems adequately, to offer their patients a compassionate ear, and to offer patients *some* treatment.[21] Although this implies that we could have asked the GPs to play a more prominent role, we should not be too optimistic because 'lack of time' was the most frequently mentioned reason by GPs to refrain from participation in the PROMODE study.

Nevertheless, a stronger GP involvement might have been beneficial for the patient-caregiver relationship and may have met the older persons' needs to discuss their screening outcome and treatment options with their own GP. Therefore, it is important that GPs are

aware that most older people highly appreciate being able to discuss their well-being, psychosocial problems and treatment options with them (or another familiar caregiver) in an open, interested and empathic way. Furthermore, GPs should not hesitate to take the initiative to discuss psychosocial problems with older people.

Further implications: a stronger focus on perceived needs

Low uptake of an unsolicited intervention by screen-positives is an important drawback of screening programs, both for psychological and somatic symptoms. Also in the PROMODE study, most screen-positive individuals had no intention to seek help for their symptoms and even declined to accept help when it was actively offered (chapter 7). This implies that mere detection of psychological symptoms is an inefficient way to reach those people who really need the available help. Efficiency may be increased by means of stronger focus on perceived suffering, impaired (social) functioning, and the actual need for help. It was shown that adding a question about the need for help to screening tools, improves their specificity to detect depression.[22;23] Moreover, exploration of a person's need for help indicated their readiness to change, promoted their self-determination and allowed them to prioritise the issues that they wished to address.[23]

8.2.3. Adequacy of instruments to measure severity of depressive symptoms at old age in primary care

In the PROMODE study the Montgomery Åsberg Depression Rating Scale (MADRS) was used to measure changes in severity of depressive symptoms over time as primary outcome measure. The MADRS is a semi-structured interviewer-rated observation scale with scores ranging from 0 to 60, higher scores indicating more severe depression.[24] It includes several items about the presence of somatic symptoms, such as loss of appetite, sleeping disorders and fatigue, which are characteristics of more severe depression. This scale was developed and validated (although not specifically for the oldest old) to assess and monitor depression severity in psychiatric patients and it is also much used in research. In specialised psychiatric settings, severe depressions with scores higher than 30 are common. In our study in primary care, baseline median MADRS scores were around 13 points with an interquartile range from 8 to 18. MADRS scores higher than 20 points were uncommon and scores higher than 30 points were very rare (chapter 6). In the PROMODE study, although we did not expect to detect many persons with a (very) high MADRS score, those who screened positive with the GDS-15 had even lower MADRS scores than we had expected. This meant that in our study population with relatively low MADRS scores at baseline, room for improvement on MADRS scores over time was small, and probably too small to detect whether meaningful changes in depression symptom severity had taken place.

In search of good instruments to measure severity of depressive symptoms in primary care

Although the MADRS was proven valid for use in specialised psychiatric settings for older patients, we used it in the PROMODE study because no validated instrument was available for use in an older population in primary care. Initially, we considered using the GDS-15 since this scale was specifically developed for and validated among older people. However, although the psychometric qualities of the GDS-15 as a screening instrument are good,[25] its ability to monitor changes over time is not yet established.[26] Even for younger age groups, adequate instruments for use in primary care are lacking. Within the context of the Quality Outcome Framework program in the UK, GPs get incentives when they measure depression severity at the start of treatment of all diagnosed cases of depression (in order to improve targeting of depression treatment). Kendrick et al. investigated the validity and acceptability of the three recommended instruments used, namely the Patient Health Questionnaire-9 (designed both as screening instrument and severity measurement, and assessed as a responsive, valid and reliable measure of severity in several studies[27;28]), the depression sub-scale of the Hamilton Anxiety and Depression Scale (developed for screening), and the Beck Depression Inventory-II (developed as a severity measurement, but not yet validated for use at old age). They conclude that the recommended threshold scores for intervention should be changed in order to make them more valid, more consistent with practitioners' clinical judgement, and more acceptable to practitioners in primary care as a way of classifying patients.[29] This illustrates that for meaningful measurement of depression severity in primary care, the currently available instruments need validation as well as adaptation of the threshold scores. In this process, the use of instruments in older age groups require specific attention.

8.2.4. External validity of the PROMODE results

In general, circumstances in daily practice are less ideal than in a research setting, due to local limitations, hectic daily practice, and not having a research team with specific interest in making the project as successful as possible. This often makes it difficult to replicate study results in a daily practice setting. On the other hand, it is worthwhile to consider whether some elements of an intervention might perform better in daily practice than in a research setting. To assess the external validity of the results of the PROMODE study, which was conducted in a pragmatic way, we also explored whether there are indications suggestive for contamination of the 'usual care' group which might have biased the results.

Intervention performance in a pragmatic study

In the PROMODE study, we offered an intervention in which several caregivers working in general practices, as well as community mental health care centres, were involved in the provision of the different steps. Several problems regarding the provision of the intervention were encountered, such as a (too) long interval between screening and referral, and various practical problems (e.g. course participants who could not find the right

location). It also proved difficult to adequately communicate the screening results, such as avoiding the suggestion that being screen positive meant that a depression was already diagnosed.
We are convinced that most problems with the provision of and adherence to the intervention that we encountered would also arise when this intervention (with several caregivers and various steps) had been implemented in daily practice. However, some circumstances in daily practice could make a difference, such as the role of the GP in the intervention. On the one hand it can be seen as an advantage that we restricted the extra workload for participating GPs in our study; in this way we could recruit a wider range of GPs than only the most highly motivated GPs - which would have comprised external validity of the results. On the other hand, retrospectively, the choice to limit the extra workload for participating GPs can be seen as a disadvantage, because this might have bypassed the patients' needs and the importance of a good patient-caregiver relationship for building a strong therapeutic alliance.

Contamination of the usual care group
An important issue within a pragmatic study is how to avoid contamination of the usual care control group. Our literature review of pragmatic trials with a usual care control group showed that the risk of (unwanted) behavioural changes among caregivers and patients in the usual care group is often present, even in a cluster randomised trial (chapter 3). This emphasises the need for researchers to decide to what extent caregivers and patients in the control group need to be informed about the allocation to and the content of the intervention.[30] In the PROMODE study, designed as a cluster randomised trial, we took several precautions to avoid bias and contamination. Practices were not randomised before screening was completed, and research nurses (who performed all measurements) were not informed by the study team about the allocation status of the practices or patients. Furthermore, to ensure continuation of usual care (which could imply all intervention options available) GPs in control practices were not informed about which older persons had screened positive.

8.3. CONCLUSION

The PROMODE study shows that screening of all older people for untreated depressive symptoms, followed by an unsolicited intervention, does not result in less depressive symptoms compared to usual care during a follow-up period of one year. A Dutch multidisciplinary panel of 11 experts (including 4 GPs), recently considered that screening of the population aged 60 years and over for depression and anxiety was inappropriate, mainly because evidence for effective interventions was lacking.[31]

When prevention of depression for older people in general practice is considered, more efficient and effective strategies of prevention are needed. The results of the PROMODE study, together with the growing evidence on beneficial effects of screening-intervention programs, can help in the planning of future prevention programs. Instead of a 'universal' approach, in which all people above a certain age are screened, a more selective case-finding approach targeted at high risk-groups seems more efficient in detecting depressed older people who are most in need of help. A crucial point in combined screening-intervention programs is that the majority of screen-positive persons decline the intervention offer, finding it either lacking in appeal or in relevance. This strongly suggests that effectiveness can be increased if screening or case finding would focus not only on the detection of depressive symptoms but also on *perceived problems* and *perceived need for help*. Furthermore, when screening is considered in primary care, this should be embedded in a well-organised care system which ensures that screen-positive persons are carefully and professionally informed about the screening outcome, that symptoms and perceived needs are further explored, and that treatment options and patient preferences are discussed. This individually-tailored diagnostic process should preferably be done by a caregiver who is known and trusted by the patient, such as a GP or nurse practitioner, before a referral or an (unsolicited) intervention is offered.

In our aim to help older people with common psychological problems to improve their quality of life and/or prevent their problems from getting worse or becoming chronic, we should consider a more comprehensive and functional approach of psychosocial problems that people perceive as relevant for their well-being. In order to make progress in this field, future studies should also aim at a better understanding of what depressive symptoms mean to people, especially in terms of impaired (social) functioning. In addition, more information is needed about older people's perceptions of how to improve their own quality of life.
Finally, to gain further insight into patient's perceptions on sadness, depressive symptoms and the need for help among the oldest old who screened positive for depressive symptoms, our group is currently performing a new study.

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