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# Effectiveness of case management

AMONG OLDER ADULTS WITH DEMENTIA SYMPTOMS  
AND THEIR INFORMAL CAREGIVERS

The studies presented in this thesis were performed at the EMGO Institute of the VU University Medical Center, Amsterdam, the Netherlands. The EMGO Institute participates in the Netherlands School of Primary Care Research (CaRe), which was re-acknowledged in 2006 by the Royal Netherlands Academy of Arts and Sciences (KNAW).

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**Effectiveness of case management among older adults with dementia symptoms  
and their informal caregivers**

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**Effectiveness of case management  
among older adults with dementia symptoms  
and their informal caregivers**

ACADEMISCH PROEFSCHRIFT

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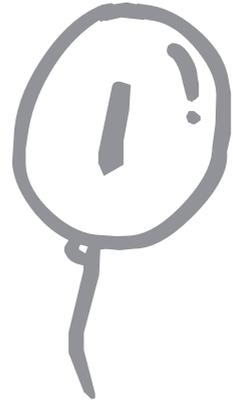
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# General introduction

The main focus of this thesis is the effectiveness of a case management intervention for older adults with dementia symptoms and their primary informal caregivers. The older adults are 65 years of age or older and live at home. District nurses carry out the intervention that focuses on both informal caregivers and older adults. The intervention is a multi-component case management programme: case managers provide caregivers and older adults with a variety of services. The case management programme is executed after screening and cognitive testing on indication of general practitioners (GPs) to identify patients with dementia symptoms and subsequent recruitment of them and their primary informal caregivers. In this chapter we will introduce and define the main concepts used in this thesis. At the end of this chapter, the objectives and an outline of this thesis are provided.

### **Persons with dementia symptoms**

In this thesis persons with dementia symptoms are defined as persons with multiple cognitive impairments (i.e. memory impairment and at least one other of the following impairments: aphasia, apraxia, agnosia, disturbances in executive functioning) that lead to significant limitations in social functioning and progressive decline in general functioning. This definition is derived from the criteria of the American Psychiatric Association as published in the Diagnostic Statistical Manual of Mental Disorders (DSM-IV)<sup>1</sup> and covers the first and second criteria of dementia of the Alzheimer's type, vascular dementia, dementia due to other general medical conditions, dementia due to multiple aetiologies, dementia not otherwise specified, amnesic disorder (not otherwise specified), and cognitive disorder not otherwise specified. According to these criteria the following symptoms are present:

- A. Multiple cognitive deficits manifested by both memory impairment and one or more of the following: aphasia, apraxia, agnosia and disturbances in executive functioning;
- B. The cognitive deficits represent a decline from previous functioning and cause significant impairment in social or occupational functioning.

Our definition of dementia symptoms implies that it covers cognitive impairment, amnesic disorder, pre-diagnostic dementia or dementia in its early stages.

### **Informal caregivers**

Informal caregivers are persons who provide unpaid assistance to relatives and friends who have health problems or functional needs. They play an essential role in providing long-term care to community-dwelling older adults with cognitive impairment and with dementia.<sup>2;3</sup> Informal caregiving is generally unplanned and most informal caregivers gradually adopt their role because of the insidious nature of cognitive impairment and dementia.<sup>4</sup> The experience of providing care may provide emotional benefits to caregivers, but for many caregivers it has also adverse financial, physical, social, and psychological consequences.<sup>2;3</sup> Providing informal care is associated with an increased risk of anxiety, depression and psychiatric illness in general.<sup>2</sup> Moreover, there is even increasing evidence that providing informal care may not only lead to health problems for caregivers, but that it may also increase their risk of mortality.<sup>5</sup> Even in patients with early dementia symptoms, providing informal care may have a major impact on informal caregivers because of the chronic progressive and depersonalising nature of the symptoms.<sup>6-8</sup>

Definitions of informal care vary with regard to the level of involvement (i.e. kind and amount of caregiving tasks performed, as well as the frequency of contact between caregiver and care recipient) and the type of relationship existing between caregiver and care recipient.<sup>9;10</sup> In this thesis informal caregivers were spouses, children or other relatives and friends responsible for the informal care and they provided at least one hour of unpaid care a week. Only primary informal caregivers were included: the informal caregivers responsible for the co-ordination of the caring process or providing the most hours of care to the care recipient.

### **Prevalence and incidence**

In Europe, the prevalence rate of dementia among adults aged 65 to 95 is 6.6%,<sup>11</sup> whereas figures on the incidence of dementia vary between 0.8% and 2.5% among adults aged 55 years and older.<sup>12-16</sup> There are no figures available on the prevalence and incidence of dementia symptoms. Two-third of the demented older adults live at home.<sup>17</sup> Informal caregivers take care of the majority of these older adults. The number of informal caregivers of persons with dementia symptoms is unknown. However, we assume that informal caregivers of older adults with dementia symptoms play a similar role as in older adults with dementia.

### **Awareness of dementia in primary care**

GPs are frequently unaware of the presence of cognitive impairment and dementia in their older patients.<sup>18-22</sup> Estimations reveal that 40 to 70% of the patients with dementia are unknown to their GP.<sup>18-22</sup> Moreover, there is evidence that their vulnerable informal caregivers remain unnoticed by health care professionals until they are at a point of crisis.<sup>23</sup> GPs consider timely detection of dementia desirable, but few test patients unless impairment is already apparent. This leads to a diagnostic delay, often by several years.<sup>24</sup> Several barriers hinder timely detection and diagnosis of dementia. GP related barriers are their diagnostic uncertainty in early stages, lack of diagnostic routine because of the low annual incidence per practice, perceived lack of therapeutic options, and disbelief in the value of early detection. An important patient related barrier is the absence of a request for help.<sup>25;26</sup> This absence can be attributed to denial, labelling cognitive impairment as an accepted aspect of normal ageing, lack of awareness of the disease process, or the idea that nothing can be done.<sup>26;27</sup>

### **The caregiver-stress model**

To interpret the situation of informal caregivers and to guide the development and evaluation of the case management programme, Lazarus and Folkman's stress-coping model was used.<sup>28</sup> Lazarus and Folkman state that informal caregivers who take care of persons with dementia symptoms experience stress. They commonly face numerous types of stressors. Apart from stressors in general, they experience caregiving related stressors. The person with dementia symptoms him- or herself may be a stressor (e.g. patient's behaviour, patient's impairments in memory and impairments in performing instrumental activities of daily living (IADL)), but there may also be stressors in providing assistance with patient self-care. Not the stressor itself, but caregivers' appraisal of the stressor and caregivers' adaptive capacities determine the level of burden that is experienced. Burden refers to the multidimensional stress facing caregivers. This burden can lead to deterioration in health status and well-being. Adaptive capacities and appraisal mediate the effect of stressors on health outcomes and well-being.<sup>29-33</sup>

To estimate how a case management programme may affect the situation of informal caregivers over time it is important to know how psychological

well-being in caregivers may develop over time. In caregiver research, three models exist on how psychological well-being in caregivers can develop over time in connection with the decline in the older adults' functioning. The tear and wear model or cumulative stress model states that psychological well-being decreases progressively over time due to the decline of the patient's functioning and exhaustion of physical and psychological resources of the caregiver. The adaptation model states that caregivers learn to adapt to the changing situation and as a consequence, that well-being stabilises or even increases over time. Lastly, the trait model states that well-being remains stable despite the worsening of patients' symptoms, due to caregiver stable resources like coping strategies.<sup>33-36</sup>

### **Previous studies: psychosocial interventions**

It is important to take into account the results of earlier studies that focused on similar groups in developing and evaluating our case management programme. To assist informal caregivers of older adults with dementia, several psychosocial support programmes have been developed, such as support groups, respite care, stress-management, social skills training, psycho-educational groups, and case management programmes. Previous studies have evaluated interventions similar to our multi-component case management programme or included at least a major component of our intervention, such as home visits for older adults,<sup>37;38</sup> family-counseling,<sup>39-41</sup> primary care based collaborative care,<sup>42</sup> case management and care management,<sup>43-46</sup> and support by home-helpers for older adults with diagnosed dementia and their informal caregivers.<sup>47</sup>

The results of studies evaluating the preventive effects of home visits for frail older adults are inconclusive. However, reviews using pooled analyses reported that home visits may reduce nursing home admission and mortality,<sup>37;38</sup> provided that they are targeted at persons who are at lower risk of death (elderly < 80 years), and that they are based on a multi-dimensional geriatric assessment and include multiple follow-up home visits.<sup>38</sup>

In research on informal caregivers of persons with dementia, multi-component interventions that provide caregivers with diverse services and individually tailored interventions were found to be the most effective programmes.<sup>48-54</sup> Interventions that focus on both patient and caregiver seem to be more effective than those that focus on the caregiver only.<sup>50</sup> However,

in general, if beneficial effects are found, they are rather modest.<sup>51;55</sup> The beneficial effects reported on informal caregivers included increased sense of competence,<sup>43;47</sup> stabilized well-being<sup>56</sup>, reduced depressive symptoms,<sup>41;42</sup> less distress,<sup>42</sup> decreased burden,<sup>43</sup> and prevention of increased burden.<sup>45</sup> Furthermore, even though some trials found a delay in patients' institutionalisation<sup>39;44</sup> overall, no reductions were found on rates of patients' institutionalisation<sup>42;44;57</sup> and death.<sup>42</sup>

It appears that most of the studies that reported positive effects were efficacy studies in which the interventions were performed in research settings under ideal conditions and not in regular care settings under normal conditions as in effectiveness studies. In addition, there is a lack of studies among persons with dementia symptoms in contrast to studies among persons with diagnosed dementia.

### **The case management programme**

#### *Motives for the development and execution of a case management programme*

Caring for patients with (early) dementia symptoms may already have a major impact on informal caregivers.<sup>6-8</sup> However, there is evidence that vulnerable informal caregivers remain unnoticed by health care professionals until they are at a point of crisis,<sup>23</sup> while general practitioners (GPs) are frequently unaware of the presence of cognitive impairment and dementia in their older patients.<sup>18-22</sup> In contrast to conventional care, pro-active care with timely detection followed by structured care focusing on both patients and informal caregivers, may be more suitable for this vulnerable group. By identifying patients with dementia symptoms and their caregivers before they are in a crisis, interventions may be offered to prevent adverse consequences of caregiving for both caregiver and patient. Moreover, both the patient and the caregiver can prepare future care and benefit from facilities that offer information and support when patient's insight is still relatively preserved.

As described earlier, among community-dwelling older adults with diagnosed dementia and their primary informal caregivers, some studies showed promising effects for case management programmes and home visits on caregivers' sense of competence,<sup>43;47</sup> well-being and burden,<sup>45;56</sup> and on institutionalisation rate and mortality of older adults.<sup>37-39;43;44;47;58</sup> We expect that case management will also be effective among older adults with dementia

symptoms and their informal caregivers, because both older adults with early detected dementia symptoms and their primary informal caregivers may yield a profit of early identification with subsequent case management. However, the assumption that earlier diagnosis with subsequent early intervention is beneficial was never tested yet in detail.

In co-operation with general practitioners and an organisation for home care in West-Friesland, a region in the north-western part of the Netherlands, we developed an early intervention: case management by district nurses aimed at both the care recipients with dementia symptoms and their primary informal caregivers. Preferably, the identified older adults and their informal caregivers did not receive dementia related care yet. As a manner of speaking, the older adults and their informal caregivers were situated before 'the gate or front door' of primary care. Therefore we applied the exclusion criteria 'assistance from an outpatient geriatric or psychiatric team for cognitive problems' for patients. We aimed to identify the care recipients with dementia symptoms a) by means of a screening and b) cognitive testing as indicated by general practitioners.

### *Screening*

Screening is a public health activity in which members of a defined population, who do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications.<sup>59</sup> In our study, the screening for dementia symptoms was part of a broader screening that screened for depressive symptoms and general functional vulnerability as well. We aimed to identify dementia symptoms by means of a two-stage screening method, preferably in an early stage of the symptoms. We decided the most efficient strategy would be to identify high-risk persons with a postal questionnaire (stage 1), followed by targeted cognitive assessments among these high-risk persons (stage 2).

### *Cognitive testing on indication of GPs*

GPs identified persons suspected of dementia or with prevalent dementia on a list of their patients who were 75 years of age and older and who lived at home. GPs also identified patients of whom insufficient information was available to provide a judgement about the presence or absence of dementia.

## *Chapter 1*

Persons who were identified were asked to participate in targeted cognitive assessments. These cognitive assessments were similar to those used in the second stage of the screening for dementia symptoms described in the paragraph above.

### *Case management*

Case management programmes focus on the integral care needs of patients and their social system. Programmes roughly entail the following phases: assessment of the integral care needs of the patients and their social system, development of a care plan, arrangement of suitable care, monitoring the quality of care and maintaining contact with the participants, and evaluating the goals achieved and/or reassessment of the care needs of participants.<sup>46;60</sup> When goals are not achieved or needs are not met, participants and case managers can go through the cyclic phases again. The case is closed when goals are achieved and needs are met.<sup>61</sup> However, there are many different models of case management that vary with regard to processes and structures and the content of the role of the case managers. Roughly, case managers may differ in their focus on the function of coordination, the function of acting as people's advocate and the function of being a budgetary control.<sup>61</sup> In our study, the main function of the case manager was intended to be the coordination of care.

### *Rationale of the case management intervention*

The rationale of the case management intervention was derived from Lazarus and Folkman's Stress process model<sup>28</sup> and is to create buffers against the burden of stressors in caregiving in order to prevent negative health outcomes in caregivers. Buffers can be created by improving mastery, coping responses, and social support. Negative outcomes in patients may be prevented or postponed because the case management intervention aims to tackle actual and potential health problems in patients and to optimise and prolong the care at home both by supporting the informal caregivers and bringing in formal caregivers if necessary.

### *Evaluation of the case management intervention*

We performed a randomised clinical trial to observe the effectiveness and the cost-effectiveness of case management by district nurses. Of the cost-effectiveness part of the study, only the study protocol will be discussed in

this thesis. To our knowledge this is the first trial on the (cost-)effectiveness of case management in community-dwelling older adults with dementia symptoms and their primary informal caregivers.

### **Objective and outline of this thesis**

The general objective of this thesis is to determine the effectiveness of a case management programme by district nurses directed towards older adults with dementia symptoms and their primary informal caregivers.

In *chapter 2* the study protocol of the randomised clinical trial is presented. This protocol includes an extensive description of the content of the case management programme, the screening for dementia symptoms and the subsequent recruitment of informal caregivers.

*Chapter 3* deals with the general objective of this thesis. This chapter presents the results of the randomised clinical trial on effectiveness of case management among older adults with dementia symptoms and their primary informal caregivers compared to usual care. Outcomes of interest are caregiver's sense of competence, quality of life, psychological well-being, and burden, and patient's quality of life, days of temporary institutionalisation, and days until permanent institutionalisation and death. We hypothesize that:

1. Informal caregivers in the case management group will improve on sense of competence, quality of life, psychological well-being, and perceived burden, while informal caregivers in the usual care group will be stable or decline on these outcomes (which is in line with both the tear and wear model and adaptation model);
2. Care recipients in the case management group will improve on quality of life, while care recipients in the usual care group will be stable or decline on this outcome;
3. Patients in the case management group will spend fewer days in institutions than patients in the usual care group;
4. Time until permanent institutionalisation and death of patients will be prolonged among patients in the case management group as compared to patients in the usual care group.

## *Chapter 1*

*Chapter 4* describes a process evaluation on the delivery of the case management intervention. We investigated whether the intervention was delivered as designed. For implementation purposes it is important to pay attention to the evaluation of the intervention process and to describe it clearly. Describing the process may yield valuable information for researchers and health care professionals planning to implement similar interventions. Furthermore, this evaluation will contribute to the understanding of the effectiveness of case management.

*Chapter 5* presents a psychometric evaluation of the main outcome measure of the randomised clinical trial: the Sense of Competence Questionnaire (SCQ). This questionnaire was originally developed and validated for informal caregivers of patients with diagnosed dementia. In order to study the validity and usefulness of the SCQ when applied to informal caregivers of older adults with dementia symptoms, we investigated its construct validity, feasibility, subscales, homogeneity, and floor and ceiling effects in this new target group.

*Chapter 6* and *7* are related to the screening for dementia symptoms.

*Chapter 6* presents a psychometric evaluation of the self-report Informant Questionnaire on Cognitive Decline (IQCODE-SR). The IQCODE-SR was the first stage of the two-stage screening for dementia symptoms. The original proxy version of the IQCODE has been successful in identifying demented persons in a general population. However, we administered the IQCODE in a different way: we used self-reports (with or without help from a proxy) instead of proxy reports only. Therefore, we investigated feasibility, homogeneity and construct validity of the IQCODE-SR.

In *chapter 7* a cross-sectional comparison between two methods to identify older adults with dementia symptoms is presented: the usual identification of dementia by general practitioners (GPs) and a two-stage screening method that we used to identify older adults with dementia symptoms. We examined whether a new screening method that identified patients with cognitive impairment who needed further examination yielded patients who were not detected by their GP and we identified factors associated with GPs' awareness of patients identified by the screening.

Some of the chapters 2 to 7 are overlapping in their description of the methodology because they were written as separate papers for publication in scientific journals.

*Chapter 8* summarises the main findings and conclusions of the chapters of this thesis. Important topics related to the trial will be discussed in more depth, as well as methodology used. Finally, recommendations for further research and daily health care will be proposed.

This thesis will be concluded with a summary in both English and Dutch.

## REFERENCES

1. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Washington, DC: American Psychiatric Association, 2000.
2. Beach SR, Schulz R, Yee JL, Jackson S. Negative and positive health effects of caring for a disabled spouse: longitudinal findings from the caregiver health effects study. *Psychol.Aging* 2000;15:259-71.
3. Huckle PL. Review: families and dementia. *Int.J.Geriatr.Psychiat.* 1994;9:735-41.
4. Mittelman M, Epstein C, Pierzchala A. Counseling the Alzheimer's Caregiver: a Resource for Health Care Professionals. Chicago: AMA Press, 2003.
5. Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. *JAMA* 1999;282:2215-9.
6. Braekhus A, Oksengard AR, Engedal K, Laake K. Social and depressive stress suffered by spouses of patients with mild dementia. *Scand.J.Prim.Health Care* 1998;16:242-6.
7. Garand L, Dew MA, Eazor LR, DeKosky ST, Reynolds III CF. Caregiving burden and psychiatric morbidity in spouses of persons with mild cognitive impairment. *Int. J.Geriatr.Psychiatry* 2005;20:512-22.
8. Thommessen B, Aarsland D, Braekhus A, Oksengaard AR, Engedal K, Laake K. The psychosocial burden on spouses of the elderly with stroke, dementia and Parkinson's disease. *Int.J.Geriatr.Psychiatry* 2002;17:78-84.
9. Stone R. Defining family caregivers of the elderly: implications for research and public policy. *Gerontologist* 1991;31:724-5.
10. Barer BM, Johnson CL. A critique of the caregiving literature. *Gerontologist* 1990;30:26-9.
11. Hofman A, Rocca WA, Brayne C, Breteler MM, Clarke M, Cooper B *et al.* The prevalence of dementia in Europe: a collaborative study of 1980-1990 findings. Eurodem Prevalence Research Group. *Int.J.Epidemiol.* 1991;20:736-48.

## Chapter 1

12. Brayne C, Gill C, Huppert FA, Barkley C, Gehlhaar E, Girling DM *et al.* Incidence of clinically diagnosed subtypes of dementia in an elderly population. Cambridge Project for Later Life. *Br.J.Psychiatry* 1995;167:255-62.
13. Copeland JR, Dewey ME, Davidson IA, Saunders PA, Scott A. Geriatric Mental State-AGECAT: prevalence, incidence and long-term outcome of dementia and organic disorders in the Liverpool study of continuing health in the community. *Neuroepidemiology* 1992;11 Suppl 1:84-7.
14. Fratiglioni L, De Ronchi D, Aguero-Torres H. Worldwide prevalence and incidence of dementia. *Drugs Aging* 1999;15:365-75.
15. Morgan K, Lilley JM, Arie T, Byrne EJ, Jones R, Waite J. Incidence of dementia in a representative British sample. *Br.J.Psychiatry* 1993;163:467-70.
16. Ott A, Breteler MM, van Harskamp F, Stijnen T, Hofman A. Incidence and risk of dementia. The Rotterdam Study. *Am.J.Epidemiol.* 1998;147:574-80.
17. Gezondheidsraad (Health Council of the Netherlands). Dementia. Den Haag: Gezondheidsraad, 2002.
18. Chodosh J, Petitti DB, Elliott M, Hays RD, Crooks VC, Reuben DB *et al.* Physician recognition of cognitive impairment: evaluating the need for improvement. *JAm.Geriatr.Soc.* 2004;52:1051-9.
19. Eefsting JA, Boersma F, Van den Brink W, Van Tilburg W. Differences in prevalence of dementia based on community survey and general practitioner recognition. *Psychol.Med.* 1996;26:1223-30.
20. O'Connor DW, Pollitt PA, Hyde JB, Brook CP, Reiss BB, Roth M. Do general practitioners miss dementia in elderly patients? *BMJ* 1988;297:1107-10.
21. Valcour VG, Masaki KH, Curb JD, Blanchette PL. The detection of dementia in the primary care setting. *Arch.Intern.Med.* 2000;160:2964-8.
22. van Hout H. Studies on recognition of dementia by primary care physicians are inconsistent. *Arch.Intern.Med.* 2001;161:1238-9.
23. Butler SS, Turner W, Kaye LW, Ruffin L, Downey R. Depression and caregiver burden among rural elder caregivers. *J.Gerontol.Soc.Work* 2005;46:47-63.
24. Borson S. Should older adults be screened for cognitive impairment? *Med.Gen.Med* 2004;6:e48.
25. Iliffe S, Manthorpe J, Eden A. Sooner or later? Issues in the early diagnosis of dementia in general practice: a qualitative study. *Fam.Pract.* 2003;20:376-81.
26. van Hout H, Vernooij-Dassen M, Bakker K, Blom M, Grol R. General practitioners on dementia: tasks, practices and obstacles. *Patient.Educ.Couns.* 2000;39:219-25.
27. Ross GW, Abbott RD, Petrovitch H, Masaki KH, Murdaugh C, Trockman C *et al.* Frequency and characteristics of silent dementia among elderly Japanese-American men. The Honolulu-Asia Aging Study. *JAMA* 1997;277:800-5.
28. Lazarus RS, Folkman S. Stress, appraisal, and coping. New York: Springer Publishing Company, 1984.
29. Meiland FJ, Kat MG, Van Tilburg W, Jonker C, Dröes RM. The emotional impact of psychiatric symptoms in dementia on partner caregivers: do caregiver, patient, and situation characteristics make a difference? *Alzheimer Dis.Assoc.Disord.* 2005;19:195-201.

30. Roth DL, Mittelman MS, Clay OJ, Madan A, Haley WE. Changes in social support as mediators of the impact of a psychosocial intervention for spouse caregivers of persons with Alzheimer's disease. *Psychol.Aging* 2005;20:634-44.
31. Pot AM, Deeg DJ, van Dyck R, Jonker C. Psychological distress of caregivers: the mediator effect of caregiving appraisal. *Patient.Educ.Couns.* 1998;34:43-51.
32. Pearlin LI, Mullan JT, Semple SJ, Skaff MM. Caregiving and the stress process: an overview of concepts and their measures. *Gerontologist* 1990;30:583-94.
33. Aneshensel CS, Pearlin LI, Mullan JT, Zarit SH, Whitlach CJ. Profiles in caregiving: the unexpected career. San Diego: Academic Press, 2007.
34. Haley WE, Pardo KM. Relationship of severity of dementia to caregiving stressors. *Psychol.Aging* 1989;4:389-92.
35. Townsend A, Noelker L, Deimling G, Bass D. Longitudinal impact of interhousehold caregiving on adult children's mental health. *Psychol.Aging* 1989;4:393-401.
36. George LK, Gwyther LP. Caregiver well-being: a multidimensional examination of family caregivers of demented adults. *Gerontologist* 1986;26:253-9.
37. Elkan R, Kendrick D, Dewey M, Hewitt M, Robinson J, Blair M *et al.* Effectiveness of home based support for older people: systematic review and meta-analysis. *BMJ* 2001;323:719-25.
38. Stuck AE, Egger M, Hammer A, Minder CE, Beck JC. Home visits to prevent nursing home admission and functional decline in elderly people: systematic review and meta-regression analysis. *JAMA* 2002;287:1022-8.
39. Mittelman MS, Ferris SH, Shulman E, Steinberg G, Levin B. A family intervention to delay nursing home placement of patients with Alzheimer disease. A randomized controlled trial. *JAMA* 1996;276:1725-31.
40. Mittelman MS, Roth DL, Haley WE, Zarit SH. Effects of a caregiver intervention on negative caregiver appraisals of behavior problems in patients with Alzheimer's disease: results of a randomized trial. *J Gerontol.B Psychol.Sci.Soc.Sci.* 2004;59:27-34.
41. Mittelman MS, Roth DL, Coon DW, Haley WE. Sustained benefit of supportive intervention for depressive symptoms in caregivers of patients with Alzheimer's disease. *Am.J Psychiatry* 2004;161:850-6.
42. Callahan CM, Boustani MA, Unverzagt FW, Austrom MG, Damush TM, Perkins AJ *et al.* Effectiveness of collaborative care for older adults with Alzheimer disease in primary care: a randomized controlled trial. *JAMA* 2006;295:2148-57.
43. Dröes RM, Breebaart E, Meiland FJ, Van Tilburg W, Mellenbergh GJ. Effect of Meeting Centres Support Program on feelings of competence of family carers and delay of institutionalization of people with dementia. *Aging Ment.Health* 2004;8:201-11.
44. Eloniemi-Sulkava U, Notkola IL, Hentinen M, Kivela SL, Sivenius J, Sulkava R. Effects of supporting community-living demented patients and their caregivers: a randomized trial. *J Am.Geriatr.Soc.* 2001;49:1282-7.
45. Weuve JL, Boult C, Morishita L. The effects of outpatient geriatric evaluation and management on caregiver burden. *Gerontologist* 2000;40:429-36.
46. Singh D. Transforming chronic care: a systematic review of the evidence. *Evid.Based. Cardiovasc.Med.* 2005;9:91-4.

## Chapter 1

47. Vernooij-Dassen M, Huygen F, Felling A, Persoon J. Home care for dementia patients. *J.Am.Geriatr.Soc.* 1995;43:456-7.
48. Acton GJ, Kang J. Interventions to reduce the burden of caregiving for an adult with dementia: a meta-analysis. *Res.Nurs.Health* 2001;24:349-60.
49. Bourgeois MS, Schulz R, Burgio L. Interventions for caregivers of patients with Alzheimer's disease: a review and analysis of content, process, and outcomes. *Int.J Aging Hum.Dev.* 1996;43:35-92.
50. Brodaty H, Green A, Koschera A. Meta-analysis of psychosocial interventions for caregivers of people with dementia. *J.Am.Geriatr.Soc.* 2003;51:657-64.
51. Peacock SC, Forbes DA. Interventions for caregivers of persons with dementia: a systematic review. *Can.J Nurs.Res* 2003;35:88-107.
52. Pusey H, Richards D. A systematic review of the effectiveness of psychosocial interventions for carers of people with dementia. *Aging Ment.Health* 2001;5:107-19.
53. Schulz R, Burgio L, Burns R, Eisdorfer C, Gallagher-Thompson D, Gitlin LN *et al.* Resources for Enhancing Alzheimer's Caregiver Health (REACH): overview, site-specific outcomes, and future directions. *Gerontologist* 2003;43:514-20.
54. Sorensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist* 2002;42:356-72.
55. Zarit SH, Gaugler JE, Jarrott SE. Useful services for families: research findings and directions. *Int.J Geriatr.Psychiatry* 1999;14:165-77.
56. Newcomer R, Yordi C, DuNah R, Fox P, Wilkinson A. Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. *Health Serv. Res.* 1999;34:669-89.
57. Miller R, Newcomer R, Fox P. Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. *Health Serv.Res* 1999;34:691-714.
58. Gaugler JE, Kane RL, Kane RA, Newcomer R. Early community-based service utilization and its effects on institutionalization in dementia caregiving. *Gerontologist* 2005;45:177-85.
59. National Screen Committee of the UK. <http://www.nsc.nhs.uk> (accessed February 2007)
60. Bergen A. Case management in community care: concepts, practices and implications for nursing. *J.Adv.Nurs.* 1992;17:1106-13.
61. Lee DT, Mackenzie AE, Dudley-Brown S, Chin TM. Case management: a review of the definitions and practices. *J.Adv.Nurs.* 1998;27:933-9.



**(Cost-)effectiveness of case management by district nurses among primary informal caregivers of older adults with dementia symptoms and the older adults who receive informal care:**

***design of a randomised controlled trial  
[ISCRTN83135728]***

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## ABSTRACT

**Background** Dementia is an incurable disease with devastating consequences for both patients and their relatives. The objective of this study is to describe the study protocol of a randomised controlled trial with assignment to either usual care or case management by district nurses, among informal caregivers of older adults with dementia symptoms who live at home and the older adults who receive informal care.

**Methods/Design** In this randomised controlled trial, effectiveness as well as cost-effectiveness of case management is evaluated. It concerns case management in early-detected patients with dementia symptoms and their primary informal caregivers. Participants are followed up to twelve months after baseline assessment. The main outcome measure of the effect evaluation is the caregiver's sense of competence to care for the older person with dementia symptoms. The economic evaluation is performed from a societal perspective.

**Discussion** This is one of the first trials on case management that includes an economic evaluation. In addition, it concerns a tailor-made intervention in early-detected patients with dementia symptoms and their caregivers. The results of this randomised controlled trial will provide valuable information for health professionals and policy makers on effectiveness and cost-effectiveness of early tailor-made case management for patients and their informal caregivers. Moreover, positive effects will challenge current health care systems to move to more pro-active approaches for this group.

## **BACKGROUND**

Dementia is a major public health problem with enormous costs to society.<sup>1</sup> It is an incurable progressive disease with devastating consequences for both patients and their relatives. The estimated prevalence rate of dementia among older adults aged 65 to 95 is 6.6%.<sup>2</sup> Over the next years the number of demented older adults will increase substantially as a result of aging populations.<sup>3</sup>

Initially, informal caregivers, such as relatives, neighbours and friends, care for most patients with dementia. Caregiving is generally unplanned and most informal caregivers gradually adopt their role because of the insidious nature of dementia.<sup>4</sup> However, informal caregivers often experience adverse psychological, physical, social, and financial consequences.<sup>5</sup> Compared with non-caregivers, they live shorter and report more depressive symptoms.<sup>6;7</sup> Besides, caring for a demented person is marked by losses of previous roles in a relationship. Moreover, many caregivers reduce or give-up the time spent on paid jobs and social activities.<sup>4</sup>

Timely detection of dementia is important for both patients and their caregivers as it enables care support and prepares future care.<sup>8</sup> However, there is evidence of underdetection<sup>9;10</sup> and diagnostic delay.<sup>11</sup> An important patient related barrier to timely recognition is the absence of a request for help. This absence can be attributed to denial, labelling cognitive impairment as an accepted aspect of normal ageing, lack of awareness of the disease process, or the idea that nothing can be done.<sup>12;13</sup> In contrast to conventional care, pro-active care with timely detection followed by structured care focusing on both demented patients and informal caregivers, may be more suitable for this vulnerable group. So far, randomised controlled trials of such pro-active disease management systems have not been reported. Yet, up till now, to assist informal caregivers of demented older adults, several psychosocial support programs have been developed, such as support groups, respite care, stress-management, social skills training, psycho-educational groups, and case management. On the whole, multi-component interventions that provide caregivers with diverse services and supports, and individually tailored interventions showed larger effects on caregivers' well-being than other, narrowly focused interventions.<sup>14-18</sup> We use the concept 'sense of competence' to denote the caregiver's feeling of being capable to care for the demented person. Interventions showed increased caregivers'

sense of competence,<sup>19;20</sup> stabilized caregivers' well-being<sup>21;22</sup> to sustained benefit in reducing depressive symptoms,<sup>23</sup> changed caregiver's appraisals of patient behavioural problems,<sup>24</sup> and, lastly, postponement of patients' institutionalisation,<sup>19;20;25-28</sup> although there is lack of strong findings in general.<sup>17;29;30</sup> Trials on case management, showed a deferral or no reduction in patients' institutionalisation rate,<sup>27;31</sup> and on the whole did not impact caregivers' levels of depression and burden, in spite of small reductions at some sites.<sup>21</sup> Few studies have performed economic evaluations of interventions for community-dwelling dementia patients.<sup>32-34</sup> Cost-effectiveness analyses and cost-utility analyses are even rare.<sup>35</sup>

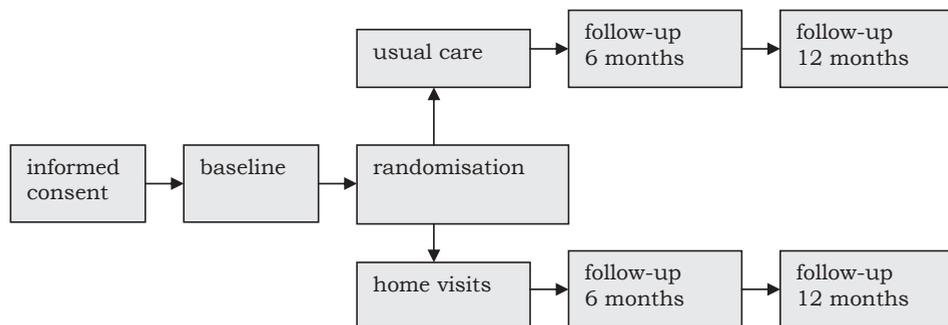
An innovative initiative to support dementia patients and their caregivers was set up by the Department of General Practice of the VU University medical center, GPs and district nurses in West-Friesland, the Netherlands. We developed a pro-active program, in which the key elements consist of timely detection of dementia symptoms followed by case management by district nurses among detected patients and their primary informal caregivers. A randomised controlled trial (RCT) is performed to observe effectiveness and cost-effectiveness of case management.

The objective of this paper was to describe the study protocol of this RCT among informal caregivers of men and women aged 65 years or over with dementia symptoms who live at home, and the men and women they take care of. The main research questions of this RCT concern whether case management is more effective than usual care in improving caregiver's sense of competence, and whether case management is cost-effective compared to usual care when assessed from a societal perspective. A secondary research question is whether case management is more effective than usual care in improving caregiver's quality of life, caregiver's psychological well-being, caregiver's burden, patient's quality of life, and in decreasing hospital days, days until institutionalisation and death of the patients.

## **METHODS/DESIGN**

### **Design**

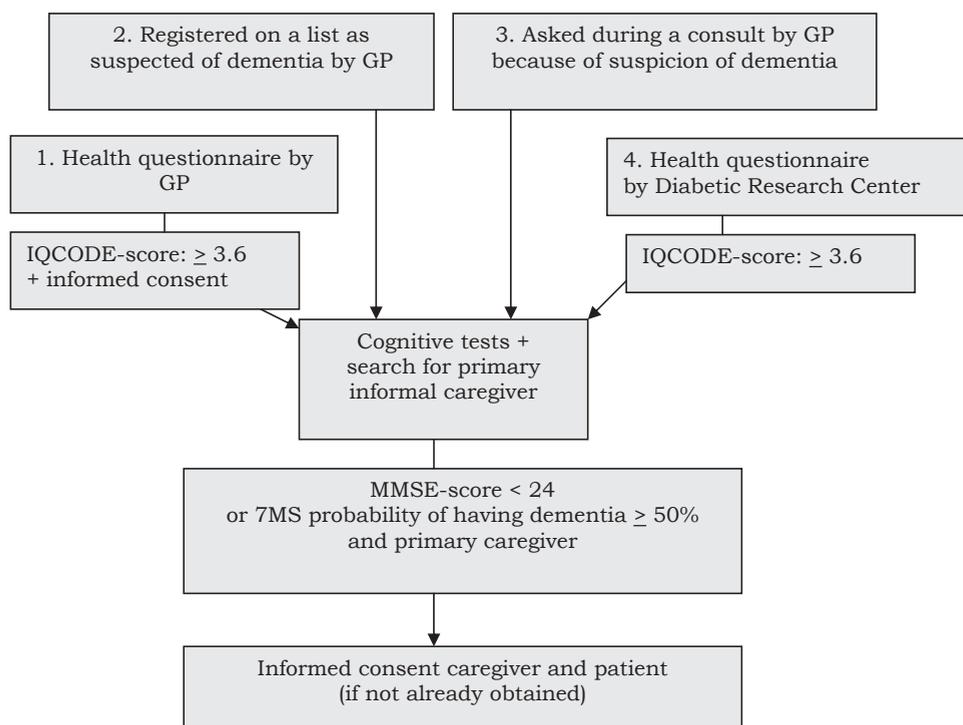
The design is a RCT with assignment to either usual care or case management by district nurses among patients with dementia symptoms and their primary informal caregivers. Figure 1 shows the design of the study. Participants are only allowed to enter the study after signed informed consent. Representatives give informed consent of incompetent patients. The Medical Ethics Committee of the VU University medical center in Amsterdam approved the study.



**Figure 1** Design

### **Participants**

Detection of patients and subsequent recruitment of their informal caregivers takes place among GP patients in West-Friesland, the Netherlands. Patients are potentially eligible for trial entry if they are 65 years or over, live outside of institutional settings, and suffer from dementia symptoms. Patients with dementia symptoms have multiple cognitive impairments (i.e. memory impairments, aphasia, apraxia, agnosia, and impairment in executive functioning). These symptoms lead to significant limitations in social functioning and progressive decline in general functioning. Two sources are used to detect patients; 1) Caseload of co-operating GPs. 2) The primary care Diabetic Research Center in which all GPs of West-Friesland participate. Detection of patients takes place in four ways, as shown in Figure 2.



**Figure 2** Recruitment of the Study Population

GP= general practitioner; IQCODE= Informant Questionnaire on Cognitive Decline in the Elderly; MMSE= Mini Mental State Examination; 7MS= seven Minute Screen

1) GPs who are willing to co-operate, provide a list of addresses of all their patients, aged 75 or over and living at home. All patients receive a postal health questionnaire in order to identify older adults with cognitive decline, as assessed with a self-report version of the short Informant Questionnaire on Cognitive Decline (IQCODE).<sup>36</sup> 2) Co-operating GPs mark patients who they suspect of dementia on the list of addresses they provide. 3) All GPs in West-Friesland invite patients suspected of dementia after consultation, for a cognitive assessment. 4) The primary care Diabetic Research Center provides addresses of their community-dwelling diabetic patients aged 65 or over and not approached formerly. Older patients with diabetes mellitus are more at risk of dementia and cognitive decline than those with normal glucose tolerance.<sup>37</sup> Diabetic patients also receive an IQCODE. Patients with an IQCODE score of 3.6 or over (strongly suggesting cognitive decline), and patients suspected of dementia by their GP, are assessed

at home with the 7 minute screen (7MS)<sup>38</sup> and the Mini Mental State Examination (MMSE).<sup>39</sup> Patients who score less than 24 on the MMSE or who have a probability of having dementia of 50% or more according to the 7MS are considered eligible for trial entry. If an eligible patient has more than one informal caregiver, the primary caregiver is the one who spends most hours on caregiver tasks and who coordinates the caring process. Exclusion criteria for patients applied at baseline are: assistance by an outpatient geriatric team for cognitive problems, terminal illness, insufficient command of the Dutch language, participation in other research projects, and institutionalisation. Exclusion criteria for caregivers are: terminal illness and insufficient command of the Dutch language. Recruitment commenced in spring 2003 and ended in summer 2005.

### **Randomisation**

Randomisation takes place after baseline measurement. An external independent person establishes the random order using random number tables. Blocking by practice (blocks of four) is used to ensure that comparison groups are of approximately the same size per practice.

### **Intervention**

During one year, three district nurses who are specialized in geriatric care, act as case manager of both patient and informal caregiver. Case management entails assessment, planning, coordination, collaboration, and monitoring of care. Nurses provide practical, informational and socio-emotional support. Multiple support strategies (e.g. support groups, respite care) are offered to informal caregivers and patients. The nurses start the intervention with a home-visit in which they administer a patient assessment; the Resident Assessment Instrument Home Care (RAI-HC). The RAI-HC is a computerised multidimensional instrument that consists of a Minimum Data Set (MDS), which assesses general functioning of the patient, and Client Assessment Protocols (CAPS), providing protocols for the management of 30 potential and actual problem areas.<sup>40</sup> Together with the participants, the nurses order the identified problems of the RAI into a hierarchy, and formulate a care-plan for these problems. Subsequently, they leave behind a form to register care received and appointments with health professionals. In the second home-visit, nurses explore the caregiver's situation with a capacity and burden questionnaire<sup>41</sup> and hand a guide to caregivers holding available

social services and welfare professionals. The nurses formulate a care plan for the informal caregiver based on the capacity and burden questionnaire. After these two visits, the nurses and participants decide how they want to proceed with the intervention. When more visits are not necessary, the nurses contact the participants at least every 3 months to monitor their situation. The nurses leave a dossier at the patient's house. This dossier contains the care plan, identified problems by RAI assessment and notes of planned and undertaken activities. Other visiting health professionals may take notice of the dossier and add their own notes. The nurses contact the GPs to inform them about the situation. Apart from these compulsory activities, the intervention holds some tailor-made activities. When necessary, nurses refer to other health professionals, including diagnostic services and monitor the anticipated effect. In addition, the nurses may organise family-meetings to educate relatives, improve social support and relieve the caregiver.<sup>4</sup> Nurses were trained in working with the computerised RAI-HC, and in organizing family-meetings. They also received seminars on how to deal with dementia patients and their patients. They meet monthly to discuss innovations and geriatric cases while supervised by a staff member. Nurses provide care according to a National Guideline on dementia for district nurses.<sup>42</sup>

### **Usual care**

Patients and informal caregivers in the control group receive usual care. In the Netherlands, all people are registered in a primary care practice. General practitioners, as well as a regional indication institution act as gatekeepers of the Dutch health care system. GPs provide care according to the Guideline on dementia of the Dutch College of General Practitioners. They aim to diagnose and inform dementia patients and their relatives preferably at an early stage.<sup>43</sup> However, guideline recommendations in general, are followed in on average 67% of the decisions.<sup>44</sup> Co-operating GPs are unaware of patients allocated to usual care, unless participants reveal their allocation. Participants of the usual care group have no access to most of the structured and tailor-made activities of the intervention (e.g. family meetings, RAI-HC assessment, guide for informal caregivers). In the region of research, suspected patients are referred to mental health professionals, never to district nurses. All participants of the usual care group are offered the intervention after the one-year follow-up.

## Measurements

Table 1 provides an overview of all effect and economic measurements. At baseline (T0), and after 6 (T1) and 12 months (T2) trained interviewers visit participants.

**Table 1** Measurement Scheme

Outcomes	Instrument	T0	T1	T2
<i>Effect evaluation: primary outcome</i>				
a. Sense of competence	SCQ	X	X	X
<i>Effect evaluation: secondary outcomes</i>				
b. Quality of life of the caregiver	SF-36 EQ 5-D	X X	X X	X X
c. Psychological well-being of the caregiver	CES-D	X	X	X
d. Caregiver's burden	SPPIC	X	X	X
e. Days until institutionalisation of the patient	GP	continuous registration		
f. Quality of life of the patient	DQOL EQ 5-D	X X	X X	X X
g. Days until death of the patient	GP	continuous registration		
h. Hospital days of the patient	Cost diaries	continuous registration		
<i>Economic evaluation</i>				
i. Direct and indirect costs	Cost diaries and home-care organisation	continuous registration		

SCQ= Sense of Competence Questionnaire; SF-36= the MOS 36-item Short-Form Health Survey; EQ 5-D= the EuroQoL instrument; CES-D= Center for Epidemiologic Studies Depression Scale; SPPIC= Self-Perceived Pressure by Informal Care questionnaire; GP= general practitioner; DQoL= Dementia Quality of Life Instrument

At baseline and after 6 months, interviewers leave cost diaries for patients and caregivers to register medical consumption during the successive 6 months. These cost diaries also provide the possibility to visualize delivery of the intervention and usual care. When patients are unable to fill out a questionnaire, their informal caregiver is allowed to fill it out or to provide assistance.

*Effect evaluation*

Primary outcome is:

1. Caregiver's sense of competence as measured with the Sense of Competence Questionnaire (SCQ).<sup>45</sup>

The SCQ consists of three domains, identified by factor analysis: consequences of involvement in care for the personal life of the caregiver, satisfaction with one's own performance as a caregiver and satisfaction with the impaired person as a recipient of care. The questionnaire was based on Zarit's Burden Inventory<sup>46</sup> and Bengtson and Kuypers' family crisis model.<sup>47</sup>

Secondary outcomes are:

2. Caregiver's quality of life by means of the MOS 36-item short-form health survey (SF-36);<sup>48</sup>
3. Caregiver's psychological well-being as determined with the Center for Epidemiologic Studies Depression Scale (CES-D);<sup>49</sup>
4. Caregiver's burden by means of the Self-Perceived Pressure by Informal Care (SPPIC);<sup>50</sup>
5. Days until institutionalisation of the patient as checked with GP records;
6. Patient's quality of life as measured with the Dementia Quality of Life Instrument (DQOL);<sup>51</sup>
7. Days until death of the patient as checked with GP records;
8. Hospital days of the patient by means of cost diaries.

Apart from these outcomes, we assess the following potential confounding variables on the level of the caregiver: socio-demographic characteristics, disabilities in activities of daily living (ADL) functioning and instrumental activities of daily living (IADL) functioning by means of the Groningen Activity Restriction Scale (GARS),<sup>52</sup> presence of chronic diseases, locus of control (Mastery),<sup>53</sup> and social support (social support list).<sup>54</sup> On patient level we assess socio-demographic characteristics, cognitive functioning (MMSE, 7MS, IQCODE), presence of chronic diseases, ADL and IADL disability with the Interview for Deterioration in Daily living activities in Dementia (IDDD),<sup>55</sup> behavioural problems and mood by means of the Neuropsychiatric Inventory (NPI-Q),<sup>56</sup> and incontinence.

### *Economic evaluation*

The economic evaluation is performed from a societal perspective. The evaluation is a combination of a cost-effectiveness analysis on caregiver's sense of competence (SCQ) and two cost-utility analyses on caregivers and patients separately. Utilities are based on the EQ-5D.<sup>57</sup> Quality Adjusted Life Years (QALY) are calculated by multiplying the utility with the amount of time a patient spends in this particular health state.<sup>58</sup> Incremental costs per QALY gained are calculated. In all analyses, direct costs inside and outside health care are considered. Besides, indirect costs of productivity loss of caregivers and indirect costs of the intervention are estimated. Direct costs inside health care (e.g. costs of consulting the GP, hospitalisations, and use of medication), direct costs outside health care (e.g. costs of travelling, costs of informal care, and costs of consulting alternative health professionals), and productivity loss are assessed by means of cost diaries for caregivers and patients, in which subjects register the amount of healthcare they use. Indirect costs of the intervention, such as nurses' trainings, are calculated using the bottom-up method, by measuring all resources and multiplying these by associated cost prices. Dutch guidelines for economic evaluations in health care are followed to estimate costs.<sup>59</sup>

### **Sample size calculation**

Sample size calculations were based on scores reported for groups similarly to our target group on the main outcome measure of the RCT, namely sense of competence (mean 17.9 SD 5.2, range 4-27).<sup>60</sup> Calculations are based on  $\alpha=0.05$  and a desired power of 0.80. For an anticipated effect of 15% difference in final scores between intervention group and usual care group, and with improved scores in the intervention group and stable scores in the control group, 37 persons per group are required. As we expect a drop out rate of about 25% during the one-year follow-up, this means a total of 100 patients and caregivers to be included in the study.

### **Blinding**

Interviewers are kept blind from the randomisation status of participants. GPs can be unaware of patients allocated to the usual care group, but they will be aware of patients in the intervention group as nurses contact the GP about these patients. Participants are not blinded.

## **Analysis**

### *Effect evaluation*

Data are primary analysed according to the intention-to-treat principle. Additionally, data are analysed according to the on-treatment (i.e. per protocol) principle in order to examine whether protocol deviations have caused bias. General Linear Models are used to analyse differences between the intervention and usual care group on caregiver's sense of competence, caregiver's quality of life and caregiver's psychological well-being. Potential baseline differences are accounted for by covariates. Differences in days until institutionalisation and death between patients of the two groups are tested with survival analyses (Cox-proportional hazard modelling). Differences on patient's hospitalisation days and patient's quality of life are tested by a chi-square test and student t-test, respectively. Potential confounding is checked, including the effect of different interviewers and nurses.

### *Economic evaluation*

The economic evaluation involves calculating cost-effectiveness and cost-utility ratios. In the pair wise comparison of the mean groups, bootstrapping is used to calculate confidence intervals around the mean difference in costs and ratios. Incremental costs and benefits of the intervention compared to usual care are presented in cost-effectiveness planes and acceptability curves. Substitution of costs is analysed by describing volumes of healthcare use and associated costs in both groups.

## **DISCUSSION**

In this paper we described the study protocol of an innovative RCT that evaluates case management by district nurses to primary informal caregivers of men and woman aged 65 or over with dementia symptoms who live at home, and the older men and women who receive informal care. This is one of the first trials on case management that includes an economic evaluation. Moreover, it concerns a tailor-made intervention in early-detected patients with dementia symptoms and their caregivers. In addition, the detection method of patients with dementia symptoms preceding recruitment of these patients and their informal caregivers is unique. A large general practice

population of older patients was approached by mailed questionnaires. Particular strengths of our study protocol are the randomisation approach, in which allocation concealment involves an external independent person, and methods used to enhance the quality of measurements such as assessors who are blinded to group assignment and training of assessors. Another strength is the possibility to visualize delivery of the intervention and usual care by cost diaries. Cost diaries might also provide insight in factors related to the intervention process that may influence the effectiveness of case management.

Below, we describe design features that address potential threats to reliability and validity. Firstly, selection of participants may limit generalization of the results of this study as selective non-response of older adults, selective refusal of caregivers, and selective dropout are possible. Non-responding older adults in other studies have been observed to have higher rates of functional and cognitive impairment.<sup>61;62</sup> To limit this potential selection bias we will send personalized invitation letters by GPs and provide reminders to initial non-responders. This strategy has shown to be effective.<sup>63</sup> Furthermore, we anticipate that caregivers check mail of cognitively impaired individuals and provide help with filling out as inhabitants are informed about the project by a newspaper article. Selective refusal of caregivers to participate might be assumed as some caregivers will label cognitive impairment as an accepted aspect of normal ageing, or do not experience adverse consequences of caregiving. Possibly, they will refuse more often than other caregivers. The same might be assumed about severely burdened caregivers who could be afraid to become even more burdened with participating in the project's measurements. To limit such selective refusal, interviewers will contact potential participating caregivers after screening to inform them about the project before sending personalized invitation letters to them. To prevent selective drop-out of severely burdened caregivers and severely disabled patients, appointments for measurements are made by one fixed interviewer on times and locations suitable for the participants.

Secondly, two situations may cause information bias. Firstly, bias may occur as cognitively impaired subjects without insight may fill out questionnaires. However, as we assume that detected patients suffer mainly from mild or moderate dementia symptoms, and insight is mainly preserved in these subjects, this bias probably will be limited. Secondly, in

the economic evaluation, caregivers are allowed to provide assistance or to fill out the EQ-5D when patients are unable to fill out this questionnaire. This may lead to information bias as it is known that agreement on the EQ-5D between patients' and caregivers' is poor.<sup>64</sup> However, this bias probably will be limited as well, as we assume that detected patients suffer mainly from mild or moderate dementia symptoms, and most patients will fill out the questionnaire themselves.

Thirdly, contamination could bias results of this study as we choose to perform randomisation on patient level. However, influence of contamination on results is unlikely as participants of the usual care group have no access to particular activities of the intervention (e.g. family meetings, RAI-HC assessment, guide for informal caregivers). Nevertheless, it is possible that participating GPs are encouraged by the project to give more attention to patients with dementia symptoms and their informal caregivers participating in the usual care group.

Lastly, we expect heterogeneity in study subjects because response to interventions may be different depending on caregiver circumstances. In combination with the relatively small sample size of approximately 100 participants, this heterogeneity may make it hard to interpret the outcomes. However, increasing the sample size is not feasible. Therefore, we will visualize distribution of characterizes over comparison groups to estimate the influence of this heterogeneity on outcome measures. Moreover, cost diaries will detect heterogeneity in received care within the usual care group as well as in the case management group.

The results of this RCT will provide valuable information for health professionals and policy makers on effectiveness and cost-effectiveness of timely tailor-made case management for patients and their informal caregivers. Moreover, positive effects will challenge current health care systems to move to more pro-active approaches for this group. In case of proven effectiveness and cost-effectiveness, we recommend implementing this case management intervention into usual healthcare. The results of this study will be available in autumn 2006.

## REFERENCES

1. Wimo A, Ljunggren G, Winblad B. Costs of dementia and dementia care: a review. *Int. J Geriatr.Psychiatry* 1997;12:841-56.
2. Hofman A, Rocca WA, Brayne C, Breteler MM, Clarke M, Cooper B *et al.* The prevalence of dementia in Europe: a collaborative study of 1980-1990 findings. Eurodem Prevalence Research Group. *Int.J.Epidemiol.* 1991;20:736-48.
3. Wimo A, Winblad B, Aguero-Torres H, von Strauss E. The magnitude of dementia occurrence in the world. *Alzheimer Dis.Assoc.Disord.* 2003;17:63-7.
4. Mittelman M, Epstein C, Pierzchala A. Counseling the Alzheimer's Caregiver: a Resource for Health Care Professionals. Chicago: AMA Press, 2003.
5. Huckle PL. Review: families and dementia. *Int.J.Geriatr.Psychiat.* 1994;9:735-41.
6. Schulz R, O'Brien AT, Bookwala J, Fleissner K. Psychiatric and physical morbidity effects of dementia caregiving: prevalence, correlates, and causes. *Gerontologist* 1995;35:771-91.
7. Schulz R, Beach SR. Caregiving as a risk factor for mortality: the Caregiver Health Effects Study. *JAMA* 1999;282:2215-9.
8. O'Connor DW, Pollitt PA, Brook CP, Reiss BB, Roth M. Does early intervention reduce the number of elderly people with dementia admitted to institutions for long term care? *BMJ* 1991;302:871-5.
9. O'Connor DW, Pollitt PA, Hyde JB, Brook CP, Reiss BB, Roth M. Do general practitioners miss dementia in elderly patients? *BMJ* 1988;297:1107-10.
10. van Hout H. Studies on recognition of dementia by primary care physicians are inconsistent. *Arch.Intern.Med.* 2001;161:1238-9.
11. Vernooij-Dassen MJ, Moniz-Cook ED, Woods RT, De Lepeleire J, Leuschner A, Zanetti O *et al.* Factors affecting timely recognition and diagnosis of dementia across Europe: from awareness to stigma. *Int.J Geriatr.Psychiatry* 2005;20:377-86.
12. Iliffe S, Manthorpe J, Eden A. Sooner or later? Issues in the early diagnosis of dementia in general practice: a qualitative study. *Fam.Pract.* 2003;20:376-81.
13. van Hout H, Vernooij-Dassen M, Bakker K, Blom M, Grol R. General practitioners on dementia: tasks, practices and obstacles. *Patient.Educ.Couns.* 2000;39:219-25.
14. Acton GJ, Kang J. Interventions to reduce the burden of caregiving for an adult with dementia: a meta-analysis. *Res.Nurs.Health* 2001;24:349-60.
15. Bourgeois MS, Schulz R, Burgio L. Interventions for caregivers of patients with Alzheimer's disease: a review and analysis of content, process, and outcomes. *Int.J Aging Hum.Dev.* 1996;43:35-92.
16. Pusey H, Richards D. A systematic review of the effectiveness of psychosocial interventions for carers of people with dementia. *Aging Ment.Health* 2001;5:107-19.
17. Schulz R, Burgio L, Burns R, Eisdorfer C, Gallagher-Thompson D, Gitlin LN *et al.* Resources for Enhancing Alzheimer's Caregiver Health (REACH): overview, site-specific outcomes, and future directions. *Gerontologist* 2003;43:514-20.

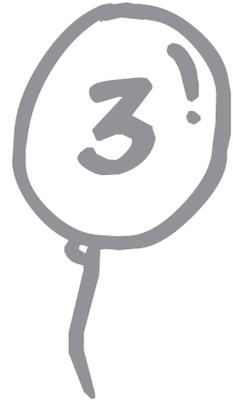
## Chapter 2

18. Sorensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist* 2002;42:356-72.
19. Dröes RM, Breebaart E, Meiland FJ, Van Tilburg W, Mellenbergh GJ. Effect of Meeting Centres Support Program on feelings of competence of family carers and delay of institutionalization of people with dementia. *Aging Ment.Health* 2004;8:201-11.
20. Vernooij-Dassen M, Huygen F, Felling A, Persoon J. Home care for dementia patients. *J.Am.Geriatr.Soc.* 1995;43:456-7.
21. Newcomer R, Yordi C, DuNah R, Fox P, Wilkinson A. Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. *Health Serv. Res.* 1999;34:669-89.
22. Sutcliffe C, Larner S. Counselling carers of the elderly at home: a preliminary study. *Br.J.Clin.Psychol.* 1988;27 (Pt 2):177-8.
23. Mittelman MS, Roth DL, Coon DW, Haley WE. Sustained benefit of supportive intervention for depressive symptoms in caregivers of patients with Alzheimer's disease. *Am.J Psychiatry* 2004;161:850-6.
24. Mittelman MS, Roth DL, Haley WE, Zarit SH. Effects of a caregiver intervention on negative caregiver appraisals of behavior problems in patients with Alzheimer's disease: results of a randomized trial. *J Gerontol.B Psychol.Sci.Soc.Sci.* 2004;59:27-34.
25. Brodaty H, Gresham M. Effect of a training programme to reduce stress in carers of patients with dementia. *BMJ* 1989;299:1375-9.
26. Brodaty H, Gresham M, Luscombe G. The Prince Henry Hospital dementia caregivers' training programme. *Int.J.Geriatr.Psychiatry* 1997;12:183-92.
27. Eloniemi-Sulkava U, Notkola IL, Hentinen M, Kivela SL, Sivenius J, Sulkava R. Effects of supporting community-living demented patients and their caregivers: a randomized trial. *J Am.Geriatr.Soc.* 2001;49:1282-7.
28. Mittelman MS, Ferris SH, Shulman E, Steinberg G, Levin B. A family intervention to delay nursing home placement of patients with Alzheimer disease. A randomized controlled trial. *JAMA* 1996;276:1725-31.
29. Peacock SC, Forbes DA. Interventions for caregivers of persons with dementia: a systematic review. *Can.J Nurs.Res* 2003;35:88-107.
30. Zarit SH, Gaugler JE, Jarrott SE. Useful services for families: research findings and directions. *Int.J Geriatr.Psychiatry* 1999;14:165-77.
31. Miller R, Newcomer R, Fox P. Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. *Health Serv.Res* 1999;34:691-714.
32. Drummond MF, Mohide EA, Tew M, Streiner DL, Pringle DM, Gilbert JR. Economic evaluation of a support program for caregivers of demented elderly. *Int.J Technol. Assess.Health Care* 1991;7:209-19.
33. Gaugler JE, Zarit SH, Townsend A, Stephens MA, Greene R. Evaluating community-based programs of dementia caregivers: the cost-implications of adult day services. *J Appl.Gerontol.* 2003;22:118-33.
34. Wimo A, Wallin JO, Lundgren K, Ronnback E, Asplund K, Mattsson B *et al.* Impact of day care on dementia patients: costs, well-being and relatives' views. *Fam.Pract.* 1990;7:279-87.

35. Martikainen J, Valtonen H, Pirttila T. Potential cost-effectiveness of a family-based program in mild Alzheimer's disease patients. *Eur.J.Health Econ.* 2004;5:136-42.
36. Jorm AF, Jacomb PA. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): socio-demographic correlates, reliability, validity and some norms. *Psychol.Med.* 1989;19:1015-22.
37. Awad N, Gagnon M, Messier C. The relationship between impaired glucose tolerance, type 2 diabetes, and cognitive function. *J.Clin.Exp.Neuropsychol.* 2004;26:1044-80.
38. Solomon PR, Hirschhoff A, Kelly B, Relin M, Brush M, DeVeaux RD *et al.* A 7 minute neurocognitive screening battery highly sensitive to Alzheimer's disease. *Arch.Neurol.* 1998;55:349-55.
39. Folstein M, Folstein S, McHugh P. "Mini-Mental" State: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.
40. Landi F, Tua E, Onder G, Carrara B, Sgadari A, Rinaldi C *et al.* Minimum data set for home care: a valid instrument to assess frail older people living in the community. *Med.Care* 2000;38:1184-90.
41. KITTZ. [Capacity and burden questionnaire for primary caregivers]. Groningen: Gorcum & Comp, 1997.
42. KITTZ. [Guideline on dementia for district nurses]. Groningen: KITTZ, 2003.
43. Boomsma LJ, Boukes FS, Wind AW, Assendelft WJ. [Summary of the practice guideline 'Dementia' (second revision) from the Dutch College of General Practitioners]. *Ned. Tijdschr.Geneeskd.* 2004;148:1191-7.
44. Grol R. Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Med.Care* 2001;39:II46-54.
45. Vernooij-Dassen MJ, Felling AJ, Brummelkamp E, Dauzenberg MG, van den Bos GA, Grol R. Assessment of caregiver's competence in dealing with the burden of caregiving for a dementia patient: a Short Sense of Competence Questionnaire (SSCQ) suitable for clinical practice. *J Am.Geriatr.Soc.* 1999;47:256-7.
46. Zarit SH, Todd PA, Zarit JM. Subjective burden of husbands and wives as caregivers: a longitudinal study. *Gerontologist* 1986;26:260-6.
47. Bengtson VL, Kuypers J. The family support cycle: psychosocial issues in the aging family. In Munnichs JMA, Olbrich E, Mussen P, Coleman PG, eds. *Life-span and change in a gerontological perspective*, pp 257-73. New York: Academic Press, 1985.
48. McHorney CA, Ware JE Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med.Care* 1993;31:247-63.
49. Radloff LS. The CES-D Scale: a Self-Report Depression Scale for Research in the General Population. *Appl.Psych.Meas.* 1977;1:385-401.
50. Pot AM, van Dyck R, Deeg DJ. [Perceived stress caused by informal caregiving. Construction of a scale]. *Tijdschr.Gerontol.Geriatr.* 1995;26:214-9.
51. Brod M, Steward AL, Sands L, Walton P. Conceptualization and Measurement of Quality of Life in Dementia: the Dementia Quality of Life Instrument (DQoL). *Gerontologist* 1999;39:25-35.

## Chapter 2

52. Kempen GI, Miedema I, Ormel J, Molenaar W. The assessment of disability with the Groningen Activity Restriction Scale. Conceptual framework and psychometric properties. *Soc.Sci.Med.* 1996;43:1601-10.
53. Pearlin LI, Schooler C. The structure of coping. *J Health Soc.Behav.* 1978;19:2-21.
54. Bridges KR, Sanderman R, Van Sonderen E. An English language version of the social support list: preliminary reliability. *Psychol.Rep.* 2002;90:1055-8.
55. Teunisse S, Derix MM. [Measurement of activities of daily living in patients with dementia living at home: development of a questionnaire]. *Tijdschr.Gerontol.Geriatr.* 1991;22:53-9.
56. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T *et al.* Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin.Neurosci.* 2000;12:233-9.
57. Kind P. The EuroQol instrument: an index of health related quality of life. In Spilker B, ed. *Quality of life and pharmacoeconomics in clinical trials*, pp 191-201. Philadelphia: Lippincott-Raven Publishers, 1996.
58. Dolan P. Modeling valuations for EuroQol health states. *Med.Care* 1997;35:1095-108.
59. Oostenbrink JB, Koopmanschap MA, Rutten FF. Standardisation of costs: the Dutch Manual for Costing in economic evaluations. *Pharmacoeconomics.* 2002;20:443-54.
60. Vernooij-Dassen, M. [Dementia and home-care. PhD thesis]. Amsterdam/Lisse: Swets & Zeitlinger B.V., 1993.
61. Bowns I, Challis D, Tong MS. Case finding in elderly people: validation of a postal questionnaire. *Br.J Gen.Pract.* 1991;41:100-4.
62. Hebert R, Bravo G, Korner-Bitensky N, Voyer L. Refusal and information bias associated with postal questionnaires and face-to-face interviews in very elderly subjects. *J Clin. Epidemiol.* 1996;49:373-81.
63. Edwards P, Roberts I, Clarke M, DiGuseppi C, Pratap S, Wentz R *et al.* Increasing response rates to postal questionnaires: systematic review. *BMJ* 2002;324:1183.
64. Ankri J, Beaufils B, Novella JL, Morrone I, Guillemin F, Jolly D *et al.* Use of the EQ-5D among patients suffering from dementia. *J Clin.Epidemiol.* 2003;56:1055-63.



**Effectiveness of case management among  
older adults with dementia symptoms and  
their primary informal caregivers:**

*a randomised clinical trial*

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## ABSTRACT

**Objectives** To compare the effects of case management and usual care among community-dwelling older adults with dementia symptoms and their primary informal caregivers.

**Design** Randomised clinical trial with measurements at baseline and after 6 and 12 months.

**Setting** Primary care in West-Friesland, the Netherlands.

**Participants** 99 pairs of community-dwelling older patients with dementia symptoms, recruited by screening and cognitive testing on indication of primary care physicians, and their primary informal caregivers.

**Interventions** 12 months of case management by district nurses for both patients and informal caregivers, versus usual care.

**Measurements** Primary outcome: caregiver's sense of competence. Secondary outcomes: caregiver's quality of life, psychological well-being, and burden, and patient's quality of life, days of temporary institutionalisation, days until permanent institutionalisation, and days until death.

**Results** Linear mixed model analyses showed no statistically significant differences over time between the groups on caregiver's sense of competence, quality of life, psychological well-being and burden, and on patient's quality of life. Survival analyses showed no statistically significant differences between the patient groups with respect to days until death and days until permanent institutionalisation. Logistic regression analysis showed no statistically significant differences between the patient groups on days of temporary institutionalisation. Clinically relevant differences were absent on all outcomes as well.

**Conclusion** This study provides no reason to recommend case management in primary care above usual care for persons with dementia symptoms and their primary informal caregivers.

**Trial registration** ISCRTN83135728

## **INTRODUCTION**

About two-third of the demented older adults live at home.<sup>1</sup> Informal caregivers take care of the majority of them. The experience of providing care may provide emotional benefits, but for many caregivers it also has adverse financial, physical, social, and psychological consequences, for example psychiatric morbidity.<sup>2</sup> Even in patients with dementia symptoms (i.e. cognitive impairment, pre-diagnostic dementia or dementia in its early stages), providing care may have a major impact on informal caregivers because of its chronic progressive and depersonalising nature.<sup>3-5</sup> However, there is evidence that vulnerable informal caregivers remain unnoticed by health care professionals until they are at a point of crisis,<sup>6</sup> while primary care physicians (PCPs) are frequently unaware of the presence of cognitive impairment and dementia in their older patients.<sup>7-11</sup> By identifying patients with dementia symptoms and their caregivers before they are in a crisis, managed care interventions may be offered to prevent adverse consequences of care giving for both the caregiver and the patient.

In co-operation with PCPs and district nurses in West-Friesland, a region in the north-western part of the Netherlands, we developed an early and pro-active case management intervention aimed at both the care recipients with dementia symptoms and their primary informal caregivers. The rationale of this case management intervention that was derived from Lazarus and Folkman's Stress process model<sup>12</sup> is to create buffers against the burden of stressors in caregiving in order to prevent negative health outcomes in caregivers (i.e. poor psychological well-being and quality of life). Caregivers commonly face numerous types of stressors, e.g. problematic patient behaviour, memory impairments and impairments in instrumental activities of daily living (IADL), and problems with providing assistance with patient self-care. The effect of these stressors on health is mediated by the caregiver's appraisal of stressors and adaptive capacities (i.e. sense of competence).<sup>13;14</sup> Furthermore, buffers to prevent negative health outcomes can be created by improving mastery, coping responses, and social support. Negative outcomes in patients (i.e. poor quality of life, institutionalisation and death) may be prevented or postponed because the case management intervention aims to optimise and prolong the care given at home both by supporting the informal caregivers and bringing in formal caregivers if necessary and to tackle actual and potential health problems in patients.

Previous studies have evaluated similar interventions, such as home visits for older adults, family-counselling, collaborative care in primary care, case management and support by home-helpers for older adults with dementia and/or their informal caregivers. The results of studies evaluating the effects of home visits for older adults are inconclusive. However, reviews using pooled analyses reported that home visits can reduce nursing home admission and mortality,<sup>15;16</sup> provided that they are targeted at persons who are at lower risk of death (elderly < 80 years), and that they are based on a multi-dimensional geriatric assessment and include multiple follow-up home visits.<sup>16</sup> In caregiver research, multi-component interventions that provide caregivers with diverse services and individually tailored interventions were found to be the most effective programmes.<sup>17-20</sup> Trials showed increased caregivers' sense of competence,<sup>21;22</sup> stabilized well-being of caregivers<sup>23</sup> to a benefit in reducing depressive symptoms of caregivers,<sup>24;25</sup> improvements in distress,<sup>24</sup> decreased burden,<sup>21</sup> and prevention of increased burden.<sup>26</sup> Furthermore, even though some trials found a delay in institutionalisation<sup>21;22;27;28</sup> overall, no reductions were found on rates of institutionalisation<sup>24;27;29</sup> and death.<sup>24</sup> There is a lack of studies in a regular care setting and among persons with dementia symptoms instead of diagnosed dementia. Therefore, in our study, we chose to investigate the effectiveness of case management among older adults with dementia symptoms and their primary informal caregivers in a regular care setting.

We hypothesized that during a period of one year:

- Informal caregivers in the case management group would improve on sense of competence, quality of life, psychological well-being, and perceived burden, while informal caregivers in the usual care group would remain stable or decline on these outcomes;
- Care recipients in the case management group would improve on quality of life, while care recipients in the usual care group would be stable or decline on this outcome;
- Patients in the case management group would spend fewer days in institutions than patients in the usual care group;
- Time until permanent institutionalisation and death of patients would be prolonged among patients in the case management group as compared to patients in the usual care group.

## **METHODS**

### **Design**

A randomised clinical trial was conducted with random assignment of older adults with dementia symptoms and their primary informal caregivers to either case management by district nurses or usual care. The trial was executed after a screening for dementia symptoms and cognitive testing on indication of the PCPs among older general practice patients. Researchers asked potential participants to participate by means of an information letter and informed consent form. In case people were incompetent their representatives were asked to give informed consent. The Medical Ethics Committee of the VU University medical center in Amsterdam approved the study protocol. Details of the study protocol have been described elsewhere.<sup>30</sup>

### **Participants**

Recruitment of persons with dementia symptoms and their informal caregivers took place among 6303 older general practice patients in West-Friesland, the Netherlands. In the Netherlands, all people are registered in a general practice. Firstly, 55 PCPs sent a health questionnaire, including the Informant Questionnaire on Cognitive Decline (IQCODE)<sup>31</sup> to 4823 older adults, who were 75 years of age or older and living in the community. 44 PCPs also identified persons suspected of dementia among the persons they had approached. Secondly, a primary care Diabetic Research Center sent a health questionnaire, including the IQCODE, to 1480 older diabetic adults, who were 65 years of age or older and living in the community, and who had not been approached by their GP. Persons with an IQCODE score of 3.6 and over (strongly suggesting cognitive decline) or who were suspected of dementia by their PCP underwent two cognitive tests: the Mini Mental State Examination (MMSE)<sup>32</sup> and the seven Minute Screen (7MS).<sup>33</sup> Patients were eligible for trial entry if they had scores on the MMSE<sup>32</sup> below 24 or a risk of dementia of 50% or more according to the 7MS,<sup>33</sup> and if a primary caregiver was present. When an eligible patient had more than one informal caregiver, the primary caregiver was defined as the person who spent most hours on caregiving tasks and/or who co-ordinated the caring process. Exclusion criteria for patients applied at baseline were: assistance from an outpatient geriatric or psychiatric team for cognitive problems, terminal

illness, insufficient command of the Dutch language, participation in other research projects, and institutionalisation. Exclusion criteria for caregivers were: terminal illness, providing less than one hour of care a week, and insufficient command of the Dutch language.

### **Randomisation and blinding**

Randomisation took place after the baseline measurements. An external independent person established the random order using random number tables. Participants knew that two different interventions were studied and they were informed about group assignment. However, PCPs and interviewers were blinded to group assignment unless participants revealed their allocation. Researchers were blinded until they finished analysing data.

### **Interventions**

#### *Case management*

Three district nurses who were specialized in geriatric care, acted as case manager of dyads of informal caregivers and their care recipients during one year. The case manager had mainly a co-coordinating function consisting of assessment, giving advice and information, planning, co-ordination, organizing collaboration, and monitoring of care. The case managers provided practical, informational and socio-emotional support.

They started their intervention with a home-visit in which they administered the Resident Assessment Instrument Home Care (RAI-HC).<sup>34</sup> The RAI-HC is a computerised multidimensional instrument that consists of a Minimum Data Set (MDS), which assesses the general functioning of the patient, and Client Assessment Protocols (CAPs), providing protocols for the management of 30 potential and actual problem areas. Together with the participants, the case managers ordered the identified problems of the RAI into a hierarchy of importance, and they formulated a care-plan for these problems. Subsequently, they left behind a form to register the care patients received and the agreements made with health care professionals.

In the second home-visit, the case managers explored the caregiver's situation with a capacity and burden questionnaire<sup>35</sup> and handed a guide to caregivers holding available social and welfare services. Based on the capacity and burden questionnaire, the case managers formulated a care

plan for the informal caregiver.

After these two visits, the case managers and participants decided how to proceed with the intervention. When more visits were not considered necessary at that moment, the case managers contacted the participants at least every 3 months by telephone to monitor their situation. In addition, the case managers were available for consultation by telephone. The case managers visited the PCPs to inform them about the patient's and caregiver's situation by discussing the problems that were identified with the RAI-HC.

Apart from these standard activities, the intervention held some tailor-made activities. For instance, the case managers referred patients and informal caregivers to other health care professionals, including diagnostic services, if necessary, and they monitored the anticipated effect. In addition, the case managers could organise family-meetings aimed at educating relatives, improving social support and relieving the primary caregiver.<sup>36</sup>

Before the intervention started, the case managers were trained in working with the computerised RAI-HC and in organising family-meetings. They also received two seminars on how to deal with dementia patients and their informal caregivers. They met monthly to discuss innovations and geriatric cases while supervised by a staff member of their home care organisation.

#### *Usual care*

In the usual care group, the participants could receive care depending on their own initiative. Usual care comprehends a diversity of health care and welfare services and can differ across participants. However, the participants had no access to family meetings, nor received an assessment with the RAI-HC and they only had limited access to the guide for caregivers, because these supportive activities were not offered regularly. Co-operating PCPs were unaware of patients allocated to usual care, unless participants revealed their allocation.

#### **Measurements**

We assessed outcomes independently by means of interviews and caregiver-completed questionnaires at baseline and after 6 and 12 months. Primary outcome was caregiver's sense of competence measured with a subscale of the Sense of Competence Questionnaire (SCQ):<sup>37</sup> Consequences of involvement in care for the personal life of the caregiver (scores ranging from: 8-40).

Secondary outcomes were caregiver's quality of life measured with both the mental component summary score (0-100) and physical component summary score (0-100) of the MOS 36-item Short-Form health survey (SF-36),<sup>38</sup> caregiver's psychological well-being determined with the Center for Epidemiologic Studies Depression Scale (CES-D) (0-60),<sup>39</sup> caregiver's burden measured with the Self-Perceived Pressure by Informal Care (SPPIC) (0-9),<sup>40</sup> patient's quality of life measured with the subscales self-esteem, positive affect, negative affect, feelings of belonging, sense of aesthetics, and overall perception on quality of life of the Dementia Quality of Life Instrument (DQOL) (1-5),<sup>41</sup> patient's days of temporary institutionalisation (e.g. non-permanent admission to nursing homes, homes for the elderly, hospitals, psychiatric units, and rehabilitation units) by means of cost diaries, patient's days until permanent institutionalisation and days until death as checked with the PCP and the informal caregiver.

Apart from these outcomes, we assessed the following variables of the caregiver at baseline: socio-demographic characteristics (age, gender, educational level, relation with the care recipient, (not) living together with the care recipient), months spent on caring, hours spent on caring a week, help from other persons, functioning in activities of daily living (ADL) and instrumental activities of daily living (IADL) measured with the Groningen Activity Restriction Scale (GARS) (scores ranging from: 18-72),<sup>42</sup> presence of chronic diseases, mastery over one's life measured with the Mastery Scale (7-35),<sup>43</sup> caregiver's distress due to patient's behavioural problems measured with the distress-subscale of the Neuropsychiatric Inventory (NPI-Q) (0-60),<sup>44</sup> and social support measured with the social support list (SSL-I, subscale positive interactions) (34-136).<sup>45</sup> On patient level at baseline we assessed socio-demographic characteristics (age, gender, last job level), cognitive functioning measured with the MMSE (0-30),<sup>32</sup> the 7MS (0-100),<sup>33</sup> and the Informant Questionnaire on Cognitive Decline (IQCODE) (1-5),<sup>31</sup> presence of chronic diseases, patient's initiative to perform self-care (0-36) and patient's actual performance of self-care (0-44) measured with the Interview for Deterioration in Daily living activities in Dementia (IDDD),<sup>46</sup> behavioural problems measured with the Neuropsychiatric Inventory (NPI-Q) (0-36),<sup>44</sup> and urinary incontinence.

### **Sample size calculation**

Sample size calculations were based on dichotomised sum-scores on the SCQ reported for informal caregivers of patients with diagnosed dementia (mean 17.9 SD 5.2, range 4-27).<sup>47</sup> Calculations were based on  $\alpha=0.05$  and a desired power of 0.80. For an anticipated effect of 15% difference in final scores of sense of competence after 12 months between the case management group and usual care group, and with improved scores in the case management group and stable scores in the usual care group, 37 persons per group were required. We expected a drop out rate of about 25% during the one-year follow-up, resulting in a total of 100 patients and caregivers to be included in the study (Statpower software).

### **Analysis**

Firstly, we studied baseline similarity. Secondly, we compared baseline characteristics of dropouts and completers by using logistic regression analysis. Thirdly, we investigated differences in outcomes between the case management and usual care group. To investigate the intervention effect, data were primarily analysed according to the intention-to-treat principle. Additionally, data were analysed according to the intensity of the intervention across three groups. Participants in the case management group were divided into groups with more or less than 10 hours of case management as a proxy intensity measure. Those who did not receive the case management intervention at all were excluded from these intensity analyses.

Linear Mixed Models (SPSS version 12.0.2) with an unstructured covariance type were used to analyse differences over time between the case management and usual care group on caregiver's sense of competence, caregiver's quality of life, caregiver's psychological well-being, and patient's quality of life. Linear mixed models have become the standard tool to analyse longitudinal data and permit the inclusion of participants with missing data.<sup>48</sup> The analysis yields restricted maximum likelihood estimates for the effects of time, treatment group and the time\*treatment group interaction. The effectiveness of treatment is flagged by a statistically significant time\*treatment group interaction: the two groups have different patterns of change in outcome measurements over time. At baseline, no differences are expected because of the randomisation, but after 6 or 12 months the two groups will differ if usual care and case management differ in effectiveness. A significant time effect alone means that the 2 groups have similar patterns

of change in outcomes over time, and hence that there is no differential effect of the treatment.

Differences in days until permanent institutionalisation of patients and death of patients between the two groups were tested with Kaplan-Meier survival analyses, whereas differences in patient's days of temporary institutionalisation were tested by Mann-Whitney U tests and logistic regression analysis (SPSS version 12.0.2). Days in institutions were dichotomised into 1 (no days) and 2 ( $\geq 1$  day in institutions) to perform logistic regression analysis.

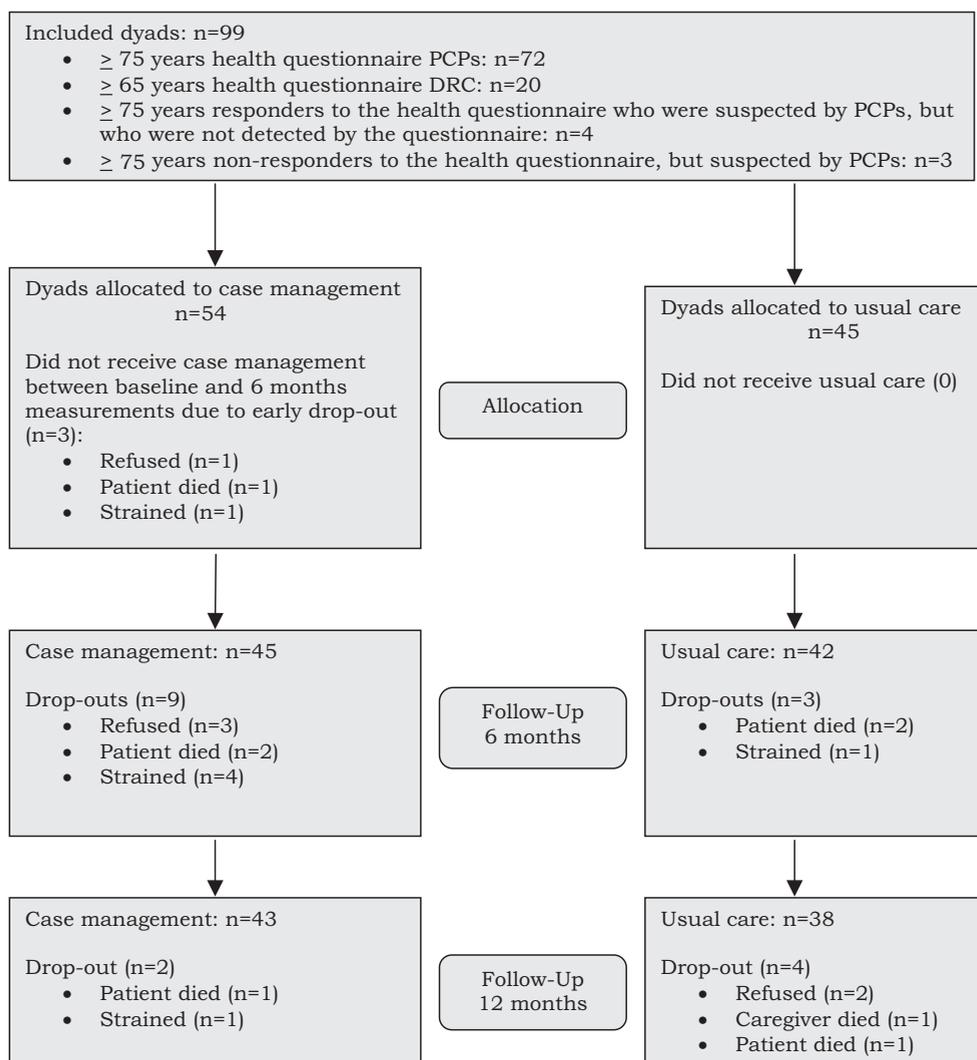
Potential confounding due to baseline differences was checked by adding these variables as covariates in the analyses. Apart from the analyses with the two treatment groups we performed analyses using four groups (i.e. usual care, nurse 1, nurse 2, and nurse 3). Furthermore, we did three subgroup analyses for being a spouse of the care-recipient (yes/no), for living with the care recipient (yes/no) and for caregiver's gender.

## **RESULTS**

### **Participants**

Between February 2004 and June 2005, 99 pairs of informal caregivers and care recipients were enrolled in the study in three ways:

- 1) 72 care recipients, aged 75 years or older, were identified by means of a health questionnaire sent by their PCP and subsequent cognitive testing with the MMSE and 7MS;
- 2) 7 care recipients, aged 75 years or older, were suspected of dementia by their PCP and identified by subsequent cognitive testing. They had not responded to the health questionnaire or they were not suspected of early dementia symptoms according to the questionnaire;
- 3) 20 care recipients, aged 65 years or older, were identified by means of a health questionnaire sent by a primary care Diabetic Research Center (DRC) and subsequent cognitive testing.



**Figure 1** Flow-chart of the study

PCPs= Primary Care Physicians; DRC= primary care Diabetic Research Center

Figure 1 presents a flow-chart of the study. During follow-up, 8 pairs in the case management group and 3 pairs in the usual care group withdrew from the study. Furthermore, 3 patients died in both groups whereas 1 caregiver died in the usual care group. Finally, 81 participating pairs were retained in the trial at 12 months. No differences appeared between the proportion of withdrawals in the case management group (8/54) and in

the usual care group (3/45); difference in risk: 0.08, 95% CI [-0.63, 0.79]. Spousal pairs were more likely to withdraw than other pairs (OR=4.5, 95% CI: 1.11-18.2). Among the 81 pairs that completed all measurements, 70 pairs completed the two 6 months-cost diaries with data on received care and days of temporary institutionalisation. Spousal informal caregivers less likely failed to complete cost diaries than non-spousal informal caregivers (OR=0.92, 95% CI: 0.86-0.98).

Table 1 shows the baseline characteristics of participants. The characteristics were largely similar for the two groups except for caregiver's perceived social support ( $t=2.483$ ;  $P = .015$ ), and the number of months with cognitive symptoms according to the caregiver (Mann-Whitney  $U=353.00$ ;  $P = .003$ ). Participating informal caregivers reported relatively good sense of competence, and little distress due to patients' behavioural problems, as well as low severity of behavioural problems in patients.

### **Effectiveness of case management**

#### *Intention-to-treat analyses*

Linear mixed model analyses among the 99 participating pairs revealed no differences in the course over time between the two groups on caregiver's sense of competence, caregiver's quality of life, caregiver's psychological well-being, caregiver's burden and patient's quality of life. Table 2 shows that all outcomes were stable over time in both groups, with the exception of patient's sense of aesthetics (DQoL) and Consequences of involvement in care for the personal life of the caregiver (SCQ), which declined over time in both groups. Completers-only analyses ( $n=81$ ) revealed no other effects.

Among completers of cost-diaries ( $n=70$  out of  $n=81$ ), the care recipients of the case management group did not report statistically significant more days of temporary institutionalisation than those of the usual care group ( $P = .117$ ). The case management group spent a mean of 13.4 days in institutions (range 0-176;  $n=38$ ), whereas the usual care groups spent a mean time of 0.8 days (range 0-9;  $n=32$ ). The higher mean time in the case management group was due to outliers.

No confounding due to baseline differences appeared. Furthermore, no other effects revealed when we repeated the same analyses with four groups (usual care, nurse 1, nurse 2, and nurse 3) and when we performed the three subgroup analyses.

In the case management group, 2 persons were institutionalised during the study period, whereas 1 person was institutionalised in the usual care group. Kaplan-Meier survival analyses revealed no differences between the two groups in days until permanent institutionalisation ( $\chi^2=0.23$ ;  $df=1$ ;  $P = .633$ ) and days until death ( $\chi^2=0.24$ ;  $df=1$ ;  $P = .843$ ).

The outcomes of the intensity-analyses were similar to those of the intention-to-treat analyses.

**Table 1** Baseline Characteristics of Participating Informal Caregivers and Persons with Dementia Symptoms

Characteristics	Unit of size	Case management	Usual care
<b>Informal caregivers</b>			
<i>Demographic characteristics</i>			
Age	mean (SD)	63.6 (13.8)	61.6 (15.2)
Gender	female (%)	67	73
Relation with the care recipient			
Spouse	(%)	42	41
Child		49	50
Child in law		2	7
Other		7	2
Living together with the care recipient	(%)	50	43
Months spent on caring, median	median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	24.0 (15.0, 36.0)	33.0 (23.0, 48.0)
Hours spent on caring a week	median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	7.0 (3.4, 67.5)	10.0 (3.0, 20.0)
Help from other persons	(%)	60	63
Social support (SSL-I, subscale positive interactions: 34-136)*	mean (SD)	65.5 (12.0)	73.2 (16.7)
Educational level			
primary school or no education	(%)	14	17
secondary		72	64
college, university		14	19
<i>General (health) functioning</i>			
Self reported health	(very) good or excellent (%)	69	71
Chronic disease	≥ 1 chronic diseases (%)	72	60
Mastery (mastery, 7-35)	mean (SD)	25.1 (4.9)	25.3 (4.8)
(I)ADL functioning (GARS, 18-72)	mean (SD)	22.1 (6.0)	22.3 (8.7)
Caregiver's distress associated with patient's neuropsychiatric symptoms (NPI-Q distress, 0-60)	mean (SD)	7.4 (7.6)	7.4 (8.9)
<i>Primary outcome measure</i>			
Caregiver's sense of competence (SCQ)			
Subscale 'Consequences of involvement in care for the personal life of the caregiver' (8-40)	mean (SD)	28.4 (5.8)	28.8 (6.8)

<i>Secondary outcome measures</i>			
quality of life (SF-36)	mean (SD)	51.0 (9.1)	47.6 (9.9)
1. Mental component summary (0-100)	mean (SD)	44.6 (10.1)	48.0 (11.6)
2. Physical component summary (0-100)	mean (SD)	10.6 (5.9)	11.5 (7.8)
psychological well-being (CES-D, 0-60)	mean (SD)	3.9 (2.7)	3.3 (2.6)
burden (SPPIC, 0-9)			
<b>Care recipients</b>			
<i>Demographic characteristics</i>			
Age	mean (SD)	82.1 (5.7)	81.0 (6.5)
Gender	female (%)	70	58
Cognitive functioning (MMSE, 0-30)	mean (SD)	22.0 (4.2)	22.7 (3.8)
Cognitive functioning (7MS, 0-100)	median (5 <sup>th</sup> , 10 <sup>th</sup> percentile)	100 (64, 83)	100 (0, 64)
Cognitive functioning (IQCODE by caregiver, 1-5)	mean (SD)	4.1 (0.6)	4.1 (0.6)
Months with cognitive symptoms*	median (25 <sup>th</sup> , 75 <sup>th</sup> percentile)	24.0 (16.3, 36.0)	36.0 (24.0, 60.0)
Severity of neuropsychiatric symptoms (NPI-Q severity, 0-36)	mean (SD)	6.2 (5.0)	6.2 (6.2)
Initiative in daily living functioning (IDDD, 0-36)	mean (SD)	12.3 (8.8)	11.4 (8.2)
Actual performance in daily living functioning (IDDD, 0-44)	mean (SD)	14.1 (10.0)	13.2 (9.3)
Chronic disease	≥ 1 chronic diseases (%)	82	71
Urinary incontinence	(%)	38	28
(Last) job level (not housewife)	frequency		
Unskilled jobs		1/26	-
Semi-skilled jobs		15/26	13/29
Skilled jobs		10/26	11/29
Higher professional jobs		-	1/29
Highly specialized jobs		-	3/29
<i>Secondary outcome measures</i>			
Quality of life (DQoL)	mean (SD)	3.2 (0.7)	3.3 (0.7)
1. self-esteem (1-5)	mean (SD)	3.4 (0.7)	3.5 (0.6)
2. positive affect (1-5)	mean (SD)	2.5 (0.7)	2.2 (0.7)
3. negative affect (1-5)	mean (SD)	3.4 (0.7)	3.5 (0.7)
4. feelings of belonging (1-5)	mean (SD)	3.6 (0.9)	3.7 (0.8)
5. sense of aesthetics (1-5)	mean (SD)	2.7 (1.0)	2.9 (1.0)
6. overall perception on quality of life (1-5)	mean (SD)		

SD= Standard Deviation; SSL-I= Social Support List- Interactions; (I)ADL functioning= functioning in activities of daily living and instrumental activities of daily living; GARS= Groningen Activity Restriction Scale; NPI-Q= Neuropsychiatric Inventory - Questionnaire; SCQ= Sense of Competence Questionnaire; SF-36= MOS 36-item Short-Form health survey; CES-D= Center for Epidemiologic Studies Depression Scale; SPPIC= Self-Perceived Pressure by Informal Care; MMSE= Mini Mental State Examination; 7MS= 7 Minute Screen; IQCODE= Informant Questionnaire on Cognitive Decline in the elderly; NPI-Q= Neuropsychiatric Inventory-Questionnaire; IDDD= Interview for Deterioration in Daily living activities in Dementia; DQoL= Dementia Quality of Life instrument; \*statistically significant difference between the two groups at baseline

**Table 2** Effects of Case management and Usual Care at Baseline, at 6 Months and at 12 Months

Outcome measures	Case management n=54 (mean)	Usual care n=45 (mean)	Linear Mixed Model
<i>Primary outcome measure</i>			
Caregiver's sense of competence (SCQ):			
Consequences of involvement in care (8-40)			
baseline	28.1	28.8	decline over time in both groups T: F=4.74; P = .013
6 months	28.0	29.6	G: F=0.68; P = .460
12 months	27.1	27.7	T*G: F=0.55; P = .494
<i>Secondary outcome measures</i>			
Caregiver's quality of life (SF-36)			
1. Mental component summary (0-100)			
baseline	51.0	48.0	stable over time in both groups T: F=1.38; P = .257
6 months	48.7	49.1	G: F=0.33; P = .568
12 months	48.2	47.7	T*G: F=1.37; P = .260
2. Physical component summary (0-100)			
baseline	44.5	48.0	stable over time in both groups T: F=0.41; P = .667
6 months	45.5	46.5	G: F=1.11; P = .294
12 months	46.0	47.5	T*G: F=1.06; P = .353
Caregiver's psychological well-being (CES-D, 0-60)			
baseline	10.6	11.2	stable over time in both groups T: F=0.14; P = .867
6 months	11.9	9.7	G: F=0.18; P = .669
12 months	11.2	11.2	T*G: F=1.80; P = .172
Caregiver's burden (SPPIC, 0-9)			
baseline	3.9	3.3	stable over time in both groups T: F=3.05; P = .053
6 months	3.8	2.7	G: F=2.89; P = .092

12 months	4.2	3.3	T*G: F=0.72; P = .492
Care recipient's Quality of life (DQoL)			
1. self-esteem (1-5)			stable over time in both groups
baseline	3.3	3.3	T: F=1.50; P = .230
6 months	3.2	3.3	G: F=0.01; P = .981
12 months	3.4	3.3	T*G: F=0.45; P = .638
2. positive affect (1-5)			stable over time in both groups
baseline	3.4	3.4	T: F=0.17; P = .845
6 months	3.4	3.5	G: F=0.02; P = .894
12 months	3.5	3.4	T*G: F=2.53; P = .087
3. negative affect (1-5)			stable over time in both groups
baseline	2.5	2.2	T: F=1.20; P = .309
6 months	2.5	2.2	G: F=3.40; P = .069
12 months	2.3	2.2	T*G: F=0.29; P = .747
4. sense of aesthetics(1-5)			decline over time in both groups
baseline	3.6	3.7	T: F=3.32; P = .042
6 months	3.3	3.5	G: F=0.16; P = .690
12 months	3.4	3.3	T*G: F=0.48; P = .621
5. feelings of belonging (1-5)			stable over time in both groups
baseline	3.4	3.4	T: F=0.31; P = .735
6 months	3.3	3.4	G: F=0.13; P = .715
12 months	3.4	3.3	T*G: F=0.75; P = .476
6. overall perception on quality of life (1-5)			stable over time in both groups
baseline	2.7	2.9	T: F=1.45; P = .241
6 months	2.8	3.0	G: F=0.14; P = .710
12 months	2.8	2.6	T*G: F=0.96; P = .387

SCQ= Sense of Competence Questionnaire; SF-36= MOS 36-item Short-Form health survey; CES-D= Center for Epidemiologic Studies Depression Scale; SPPIC= Self-Perceived Pressure by Informal Care; DQoL= Dementia Quality of Life instrument; \*statistically significant difference between the two groups at baseline

### **Care received in the case management group and usual care group**

The three case managers spent a mean time of 10.8 hours a year per patient-caregiver dyad on the case management intervention (range 0.75-28 hours). The case managers differed in mean time spent on the intervention per dyad; case manager 1 spent 8.8 hours (range 2-26), case manager 2 spent 5.5 hours (range 0.75-15), and case manager 3 spent 15.2 hours (range 9.6-28);  $F=9.811$ ,  $P < .001$ .

During the 12 months, apart from the case management intervention by district nurses, no other relevant differences were found in care consumption between the case management group and usual care group (see Table 3).

## **DISCUSSION**

Case management by district nurses showed no statistically significant and relevant benefits compared to usual care among community-dwelling older adults with early dementia symptoms and their primary informal caregivers. No differences were found with regard to caregiver's sense of competence, quality of life, psychological well-being, burden, and patient's quality of life, days spent in institutions, and days until permanent institutionalisation and death. Our finding may be influenced by the content of the case management intervention, the delivery of the intervention by the care providers, the participants, and the methodological characteristics of this study.

### **Content of the case management intervention**

The case management intervention may have lacked sufficient intensity and duration to establish a change in outcomes measures. However, even in the group with the highest intensity of case management, no change in outcomes was established. Furthermore, the case management intervention is a complex intervention that combines different elements and that covers many potential 'active ingredients'. It is difficult to unravel the contribution of each element to our findings. We tried to find out the intervention fidelity and contribution of elements by asking participating caregivers to specify the elements of the intervention they received. Unfortunately, only a small group ( $n=24$ ) of the 43 completers answered the questions on this topic and we were not able to use these data to unravel the contribution of elements of the intervention to our findings.

**Table 3** Care Received by the Informal Caregivers and by the Care Recipients in the Case management Group and the Usual Care Group

Care Received	Case management n=36 (out of n=43) mean, median (range)	Case management n=38 (out of n=38) mean, median (range)
<i>Informal caregivers</i>		
Primary care physician (number of consults by telephone, home-visits, and at practice)	3.9, 3.0 (0-16)	3.9, 3.0 (0-20)
Home care (hours a week)	2.7, 0 (0-50)	0.9, 0 (0-9)
Outpatient geriatric/psychiatric team (number of consults)	0.03, 0 (0-1)	0.8, 0 (0-18)
Dinner service (number of days)	4.8, 0 (0-156)	6.1, 0 (0-182)
Medical specialist (number of consults)	1.8, 0 (0-23)	1.7, 0 (0-8)
Dutch support center for informal caregivers (number of consults)	never	never
Information by phone for informal caregivers (number of consults)	0.3, 0 (0-10)	never
Respite care (number of days)	0.06, 0 (0-2)	never
Temporary institutionalisations (number of days)	2.3, 0 (0-56)	0.2, 0 (0-7)
Physiotherapist (number of consults)	3.9, 0 (0-35)	2.2, 0 (0-23)
Homeopath (number of consults)	never	0.3, 0 (0-9)
Psychologist (number of consults)	never	0.3, 0 (0-11)
Social worker (number of consults)	0.1, 0 (0-3)	never
<i>Care Recipients</i>		
	Case management n=37 (out of n=43) mean, median (range)	Case management n=33 (out of n=38) mean, median (range)
Primary care physician (number of consults by telephone, home-visits, and at practice)	8.3, 5.0 (0-58)	6.6, 4.0 (0-40)
Home care (hours a week)	6.0, 3.0 (0-52.0)	4.0, 2.2 (0-21.5)
Outpatient geriatric/psychiatric team/diagnostic service (number of consults)	0.5, 0 (0-6)	0.2, 0 (0-5)
Day care (number of days)	19.4, 0 (0-182)	15.0, 0 (0-364)
Dinner service (number of days)	33.5, 0 (0-362)	62.1, 0 (0-364)
Medical specialist (number of consults)	2.7, 1.0 (0-19)	3.3, 2.0 (0-14)
Physiotherapist (number of consults)	6.2, 0 (0-52)	6.2, 0 (0-100)
Homeopath (number of consults)	never	0.03, 0 (0-1)
Psychologist (number of consults)	never	0.03, 0 (0-1)
Social worker (number of consults)	0.05, 0 (0-2)	0.03, 0 (0-1)

### **Delivery of the intervention**

The intervention will only be successful if the case manager's role is adequately explained and understood both within and among different health care professionals and agreed upon. This role may not have been accepted or understood clearly by the involved health care professionals. Another explanation for the fact that we found no effect may be that the district nurses did not deliver the case management intervention appropriately.

### **Participants**

The preventive intervention may not be effective at the short time and/or relevant yet for this target group that reports relatively good sense of competence, little distress and low severity of behavioural problems in patients. In addition, not all participants received a diagnosis of dementia yet. This may have hampered providing a good rationale for the delivery of case management. However, a randomised trial is suitable to draw conclusions on group level, but less to draw conclusions for individuals. The heterogeneity of the study subjects does not rule out the possibility that some individuals may have experienced benefit of the intervention.

### **Methodological characteristics**

It is unlikely that our overall findings can be attributed to methodological problems because many requirements for a high quality trial were met. Furthermore both groups were largely similar at baseline, dropout rates were low for this vulnerable target group (18%), and contamination was unlikely. However, the combination of a relatively small sample size and heterogeneity of participants in our study may not be sufficient to establish subgroup effects.

### **Previous research**

Although we have implemented the most effective elements of home visits (i.e. a multi-dimensional geriatric assessment and multiple follow-up home visits)<sup>16</sup> and of interventions among dementia patients and their informal caregivers (i.e. multi-component and individually tailored)<sup>17-20</sup> in our case management program, we found no benefits of case management over usual care. However, this study had a different target group than previous studies. The preventive intervention may not be relevant yet, or effects of case management will only be visible at the long term for this target group.

A previous study showed that those individuals who utilized inhome help services earlier in their dementia caregiving careers were more likely to delay institutionalisation over a 3-year period.<sup>49</sup> Furthermore, this study was an effectiveness study (in a regular care setting) mirroring clinical practices as much as possible, in contrast with many of the previous studies that were closer to efficacy studies (in more 'ideal' research settings). Positive results in an efficacy study do not guarantee that a similar intervention will show positive results in a regular care setting.

In conclusion, this study provides no reason to recommend case management in primary care above usual care for patients with (early) dementia symptoms and their primary informal caregivers.

## **REFERENCES**

1. U.S.Congress Office of Technology Assessment. *Losing a Million Minds: Confronting the Tragedy of Alzheimer's Disease and Other Dementias*. p. 14. U.S. Government Printing Office, 1987.
2. Beach SR, Schulz R, Yee JL, Jackson S. Negative and positive health effects of caring for a disabled spouse: longitudinal findings from the caregiver health effects study. *Psychol.Aging* 2000;15:259-71.
3. Braekhus A, Oksengard AR, Engedal K, Laake K. Social and depressive stress suffered by spouses of patients with mild dementia. *Scand.J.Prim.Health Care* 1998;16:242-6.
4. Garand L, Dew MA, Eazor LR, DeKosky ST, Reynolds III CF. Caregiving burden and psychiatric morbidity in spouses of persons with mild cognitive impairment. *Int. J.Geriatr.Psychiatry* 2005;20:512-22.
5. Thommessen B, Aarsland D, Braekhus A, Oksengaard AR, Engedal K, Laake K. The psychosocial burden on spouses of the elderly with stroke, dementia and Parkinson's disease. *Int.J.Geriatr.Psychiatry* 2002;17:78-84.
6. Butler SS, Turner W, Kaye LW, Ruffin L, Downey R. Depression and caregiver burden among rural elder caregivers. *J.Gerontol.Soc.Work* 2005;46:47-63.
7. Chodosh J, Petitti DB, Elliott M, Hays RD, Crooks VC, Reuben DB *et al*. Physician recognition of cognitive impairment: evaluating the need for improvement. *JAm.Geriatr.Soc.* 2004;52:1051-9.
8. Eefsting JA, Boersma F, Van den Brink W, Van Tilburg W. Differences in prevalence of dementia based on community survey and general practitioner recognition. *Psychol. Med.* 1996;26:1223-30.
9. O'Connor DW, Pollitt PA, Hyde JB, Brook CP, Reiss BB, Roth M. Do general practitioners miss dementia in elderly patients? *BMJ* 1988;297:1107-10.

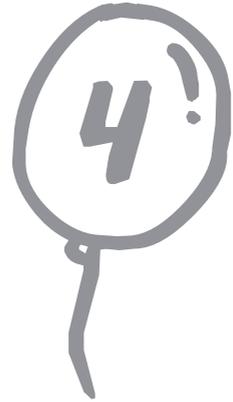
### Chapter 3

10. Valcour VG, Masaki KH, Curb JD, Blanchette PL. The detection of dementia in the primary care setting. *Arch.Intern.Med.* 2000;160:2964-8.
11. van Hout H. Studies on recognition of dementia by primary care physicians are inconsistent. *Arch.Intern.Med.* 2001;161:1238-9.
12. Lazarus RS, Folkman S. Stress, appraisal, and coping. New York: Springer Publishing Company, 1984.
13. Pot AM, Deeg DJ, van Dyck R, Jonker C. Psychological distress of caregivers: the mediator effect of caregiving appraisal. *Patient.Educ.Couns.* 1998;34:43-51.
14. Roth DL, Mittelman MS, Clay OJ, Madan A, Haley WE. Changes in social support as mediators of the impact of a psychosocial intervention for spouse caregivers of persons with Alzheimer's disease. *Psychol.Aging* 2005;20:634-44.
15. Elkan R, Kendrick D, Dewey M, Hewitt M, Robinson J, Blair M *et al.* Effectiveness of home based support for older people: systematic review and meta-analysis. *BMJ* 2001;323:719-25.
16. Stuck AE, Egger M, Hammer A, Minder CE, Beck JC. Home visits to prevent nursing home admission and functional decline in elderly people: systematic review and meta-regression analysis. *JAMA* 2002;287:1022-8.
17. Acton GJ, Kang J. Interventions to reduce the burden of caregiving for an adult with dementia: a meta-analysis. *Res.Nurs.Health* 2001;24:349-60.
18. Brodaty H, Green A, Koschera A. Meta-analysis of psychosocial interventions for caregivers of people with dementia. *J.Am.Geriatr.Soc.* 2003;51:657-64.
19. Pusey H, Richards D. A systematic review of the effectiveness of psychosocial interventions for carers of people with dementia. *Aging Ment.Health* 2001;5:107-19.
20. Sorensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist* 2002;42:356-72.
21. Dröes RM, Breebaart E, Meiland FJ, Van Tilburg W, Mellenbergh GJ. Effect of Meeting Centres Support Program on feelings of competence of family carers and delay of institutionalization of people with dementia. *Aging Ment.Health* 2004;8:201-11.
22. Vernooij-Dassen M, Huygen F, Felling A, Persoon J. Home care for dementia patients. *J.Am.Geriatr.Soc.* 1995;43:456-7.
23. Newcomer R, Yordi C, DuNah R, Fox P, Wilkinson A. Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. *Health Serv. Res.* 1999;34:669-89.
24. Callahan CM, Boustani MA, Unverzagt FW, Austrom MG, Damush TM, Perkins AJ *et al.* Effectiveness of collaborative care for older adults with Alzheimer disease in primary care: a randomized controlled trial. *JAMA* 2006;295:2148-57.
25. Mittelman MS, Roth DL, Coon DW, Haley WE. Sustained benefit of supportive intervention for depressive symptoms in caregivers of patients with Alzheimer's disease. *Am.J Psychiatry* 2004;161:850-6.
26. Weuve JL, Boult C, Morishita L. The effects of outpatient geriatric evaluation and management on caregiver burden. *Gerontologist* 2000;40:429-36.

27. Eloniemi-Sulkava U, Notkola IL, Hentinen M, Kivela SL, Sivenius J, Sulkava R. Effects of supporting community-living demented patients and their caregivers: a randomized trial. *J Am.Geriatr.Soc.* 2001;49:1282-7.
28. Mittelman MS, Ferris SH, Shulman E, Steinberg G, Levin B. A family intervention to delay nursing home placement of patients with Alzheimer disease. A randomized controlled trial. *JAMA* 1996;276:1725-31.
29. Miller R, Newcomer R, Fox P. Effects of the Medicare Alzheimer's Disease Demonstration on nursing home entry. *Health Serv.Res* 1999;34:691-714.
30. Jansen AP, van Hout HP, van Marwijk HW, Nijpels G, de Bruijne MC, Bosmans JE *et al.* (Cost)-effectiveness of case-management by district nurses among primary informal caregivers of older adults with dementia symptoms and the older adults who receive informal care: design of a randomized controlled trial [ISCRTN83135728]. *BMC.Public Health* 2005;5:133.
31. Jorm AF, Jacomb PA. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): socio-demographic correlates, reliability, validity and some norms. *Psychol.Med.* 1989;19:1015-22.
32. Folstein M, Folstein S, McHugh P. "Mini-Mental" State: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.
33. Solomon PR, Hirschhoff A, Kelly B, Relin M, Brush M, DeVaux RD *et al.* A 7 minute neurocognitive screening battery highly sensitive to Alzheimer's disease. *Arch.Neurol.* 1998;55:349-55.
34. Landi F, Tua E, Onder G, Carrara B, Sgadari A, Rinaldi C *et al.* Minimum data set for home care: a valid instrument to assess frail older people living in the community. *Med.Care* 2000;38:1184-90.
35. KITTZ. [Capacity and burden questionnaire for primary caregivers]. Groningen: Gorcum & Comp, 1997.
36. Mittelman M, Epstein C, Pierzchala A. Counseling the Alzheimer's Caregiver: a Resource for Health Care Professionals. Chicago: AMA Press, 2003.
37. Vernooij-Dassen MJ, Felling AJ, Brummelkamp E, Dauzenberg MG, van den Bos GA, Grol R. Assessment of caregiver's competence in dealing with the burden of caregiving for a dementia patient: a Short Sense of Competence Questionnaire (SSCQ) suitable for clinical practice. *J Am.Geriatr.Soc.* 1999;47:256-7.
38. McHorney CA, Ware JE Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med.Care* 1993;31:247-63.
39. Radloff LS. The CES-D Scale: a Self-Report Depression Scale for Research in the General Population. *Appl.Psych.Meas.* 1977;1:385-401.
40. Pot AM, van Dyck R, Deeg DJ. [Perceived stress caused by informal caregiving. Construction of a scale]. *Tijdschr.Gerontol.Geriatr.* 1995;26:214-9.
41. Brod M, Steward AL, Sands L, Walton P. Conceptualization and Measurement of Quality of Life in Dementia: the Dementia Quality of Life Instrument (DQoL). *Gerontologist* 1999;39:25-35.
42. Kempen GI, Miedema I, Ormel J, Molenaar W. The assessment of disability with the Groningen Activity Restriction Scale. Conceptual framework and psychometric properties. *Soc.Sci.Med.* 1996;43:1601-10.

### Chapter 3

43. Pearlin LI, Schooler C. The structure of coping. *J Health Soc.Behav.* 1978;19:2-21.
44. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T *et al.* Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin.Neurosci.* 2000;12:233-9.
45. Bridges KR, Sanderman R, Van Sonderen E. An English language version of the social support list: preliminary reliability. *Psychol.Rep.* 2002;90:1055-8.
46. Teunisse S, Derix MM. [Measurement of activities of daily living in patients with dementia living at home: development of a questionnaire]. *Tijdschr.Gerontol.Geriatr.* 1991;22:53-9.
47. Vernooij-Dassen, M. [Dementia and home-care. PhD thesis]. Amsterdam/Lisse: Swets & Zeitlinger B.V., 1993.
48. Fitzmaurice GM, Laird NM, Ware JH. Applied longitudinal analysis. John Wiley & Sons, 2004.
49. Gaugler JE, Kane RL, Kane RA, Newcomer R. Early community-based service utilization and its effects on institutionalization in dementia caregiving. *Gerontologist* 2005;45:177-85.



**Why is case management in persons with  
dementia symptoms and their informal  
caregivers ineffective?**

*An evaluation of the delivery of the  
case management intervention*

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## ABSTRACT

**Background** Even in its early and pre-diagnostic stages, dementia as well as cognitive impairment may have a major impact on informal caregivers. Among community-dwelling older adults with diagnosed dementia and their primary informal caregivers, some studies on case management and home visits showed promising effects. Therefore, case management was expected to be effective among older adults with early dementia symptoms (i.e. cognitive impairment, pre-diagnostic dementia or dementia in its early stages) and their informal caregivers. However, in a recently completed randomised clinical trial we found no evidence of effectiveness of case management by district nurses compared to usual care. To get insight into the possible causes of this absence of effectiveness, we explored whether the case management intervention was delivered appropriately.

**Methods** 99 pairs of informal caregivers and older adults with early dementia symptoms were enrolled in the study and 54 pairs were allocated to the case management group. Three nurses acted as case manager during one year. Delivery of the intervention was revealed with four assessments: 1. Time between date of assignment and the first home visit (nurses were instructed to visit participating pairs within one month after randomisation); 2. Intervention fidelity (i.e. whether or not participants received the intervention as designed) of nurses according to the informal caregivers by means of marking the elements received out of a list with elements of the intervention; 3. Intervention fidelity reported by the nurses in semi-structured qualitative interviews, as well as nurses' opinion about the intervention; 4. Hours spent on case management by the nurses; 5. Satisfaction with the quality of care received.

**Results** Nurses seldom started in time with their first home visit. They spent a mean time of 10.8 hours per dyad during 1 year. Intervention fidelity according to the participating informal caregivers was poor, as well as intervention fidelity reported by the nurses.

**Conclusion** This study shows that incomplete implementation of a case management intervention delivered by district nurses in a randomised clinical trial is one plausible reason for not finding any surplus value of case management above usual care. The nurses often did not appraise case management as necessary yet for the included participants. This may have contributed to the fact that the case management intervention was not delivered as designed. Therefore, we recommend paying attention to

the realisation of the planned activities during the implementation of case management interventions.

**Trial registration** ISCRTN83135728

## **BACKGROUND**

Even in its early and pre-diagnostic stages, dementia as well as cognitive impairment may have a major impact on informal caregivers.<sup>1-3</sup> Among community-dwelling older adults with diagnosed dementia and their primary informal caregivers, some studies showed promising effects of case management programmes and home visits on caregivers' sense of competence,<sup>4;5</sup> well-being and burden,<sup>6;7</sup> and on institutionalisation rate and mortality of older adults.<sup>8-13</sup> Therefore, we expected that case management would also be effective among older adults with early dementia symptoms (i.e dementia in its early stages, pre-diagnostic dementia or severe cognitive impairment) and their informal caregivers. However, in a recently completed randomised clinical trial we found no evidence of benefits of case management by district nurses over usual care in this target group.<sup>14</sup> For that reason, we investigated whether the delivery of the case management intervention was appropriate. An incomplete delivery of the intervention could be one of the possible explanations for the absence of a beneficial effect.

## **METHODS**

### **Description of the intervention**

#### *Organisation and collaboration*

Three district nurses who were specialised in geriatric care, acted as case manager of pairs of informal caregivers and their care recipients during one year. In implementing the intervention, the home care organisation co-operated with the majority of general practitioners in the region, the majority of homes for the elderly and nursing homes, and the organisation that offers the outpatient geriatric and psychiatric services as well as the diagnostic psychiatric services. To tune activities to the diagnostic psychiatric services a memo regarding the content of the collaboration was drawn up.

*Content of the intervention: case management protocol*

The case management intervention entailed assessment, planning, co-ordination, collaboration, and monitoring of care. The nurses provided practical, informational and socio-emotional support. The content of the intervention is briefly summarized in Box 1.

**Box 1** Case management protocol

<p><b>Standard activities</b></p> <p><i>First home visit (within one month after randomisation):</i></p> <ul style="list-style-type: none"><li>• Patient assessment with the Resident Assessment Instrument-HomeCare</li><li>• Ranking the identified patient problems into a hierarchy</li><li>• Discussing the patient problems</li><li>• Choosing together problems of focus in the patient</li><li>• Making a care plan</li><li>• Leaving a dossier at the patient's home</li><li>• Leaving a visiting card and telephone number</li><li>• Leaving behind a form to register care received and appointments with health care professionals</li></ul> <p><i>Second home visit:</i></p> <ul style="list-style-type: none"><li>• Exploring the caregiver situation with a capacity and burden questionnaire</li><li>• Discussing the caregiver's situation</li><li>• Making a care plan</li><li>• Leaving a guide for informal caregivers</li></ul> <p><i>After two visits:</i></p> <ul style="list-style-type: none"><li>• Discussing how to proceed with the intervention</li><li>• Visiting the patient's general practitioner to inform him/her about the caregiver's situation and patient's situation by means of the problems identified with the Resident Assessment Instrument-HomeCare</li><li>• Monitoring the situation every three months</li></ul> <p><b>Tailor-made activities</b></p> <ul style="list-style-type: none"><li>• Referring to other health care professionals, including diagnostic services, and monitoring the anticipated effect</li><li>• Organising family-meetings</li></ul>
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**Standard activities**

*1. First home visit*

The nurses were instructed to visit the participating pairs within one month after assignment to the case management intervention. They started the intervention with a home-visit in which they administered a patient assessment: the Resident Assessment Instrument Home Care (RAI-HC). The RAI-HC is a computerised multidimensional instrument that consists of a Minimum Data Set (MDS), which assesses general functioning of the patient, and Client Assessment Protocols (CAPs), providing protocols for the management of 30 potential and actual problem areas.<sup>15</sup> The nurses were

instructed to rank, together with the participants, the identified problems into a hierarchy of importance and to choose problems to focus on. Next, they had to formulate a care-plan for these problems. The nurses left a dossier at the patient's home. This dossier contained the care plan, identified problems by the RAI assessment and notes of planned and undertaken activities. Other visiting health care professionals could take notice of the dossier and add their own notes. Subsequently, they left behind a form to register care received and appointments with health care professionals.

### *2. Second home visit*

In the second home-visit, nurses were instructed to explore the caregiver's situation with a capacity and burden questionnaire<sup>16</sup> and to hand a guide to caregivers holding available social and welfare services. Based on the results of the capacity and burden questionnaire, the nurses had to formulate a care plan for the informal caregiver.

### *3. After two visits*

After two visits, the nurses and participants had to decide how to proceed with the intervention. When more visits were not considered necessary, the nurses were instructed to contact the participants at least every 3 months to monitor their situation. In addition, the nurses were told to be available for consultation by telephone. Furthermore, the nurses were instructed to visit the general practitioners of their clients to inform them about the patient's and caregiver's situation by discussing the identified problems with the RAI-HC.

### **Tailor-made activities**

Apart from these standard activities, the case management intervention held some tailor-made activities. For instance, nurses referred patients and informal caregivers to other health care professionals, including diagnostic services, if necessary, and they monitored the anticipated effect. In addition, if necessary, the nurses organised family-meetings to educate relatives, improve social support and relieve the caregiver.<sup>17</sup>

### *Training of the nurses*

All nurses had a bachelor degree in nursing. The nurses met monthly to discuss innovations and geriatric cases while supervised by a staff

member of their home care organisation. Moreover, they discussed the case management protocol and they were given instructions. Besides the case management intervention, the nurses had a caseload among other target groups in their own district. The nurses already had expertise in providing care for older adults, including demented older adults and their informal caregivers.

Before the start of the intervention, the nurses received a manual to work with the RAI-HC and were trained in working with the computerised RAI-HC and in organising family-meetings. Moreover, working with the RAI-HC was piloted and got much emphasize because the nurses were not skilled in working with laptops. Furthermore, the nurses also received two seminars on how to deal with persons with dementia and their caregivers and on how to support them in coping with the consequences of dementia in their daily life. The nurses indicated that they appraised the seminars and trainings as useful.

### **Trial, measures, data collection and analysis**

#### *Randomised clinical trial*

Details of the randomised clinical trial we conducted have been described elsewhere.<sup>18</sup> In short, 99 pairs of informal caregivers and older adults with early dementia symptoms were enrolled in the study: 54 pairs were allocated to the case management group. Finally, 43 of these pairs retained in the trial during the 1-year follow-up: 8 pairs withdrew from the study and 3 older adults died during follow-up.

### **Measures**

#### *Delivery of the intervention*

The actual execution of the case management protocol was revealed with four assessments. Firstly, we checked whether the nurses visited the participating pairs to administer the RAI-HC within one month after they were assigned to the case management intervention. Time between date of administration of the RAI-HC and date of assignment was calculated and differences between the three nurses were analysed using Analysis of Variance (ANOVA).

Secondly, we assessed intervention fidelity according to the participants. Intervention fidelity means whether or not participants received

the intervention as designed.<sup>19</sup> Twelve months after baseline researchers asked the informal caregivers to complete a questionnaire, i.e. to mark the elements of the case management intervention they had received in the past year on a list with 13 obligatory and 3 tailor-made elements. We surveyed per element whether participants indicated that they had received it. Furthermore, we calculated a sum score of the obligatory elements received according to the participants (possible range: 0-13). Differences in intervention fidelity across the nurses were analysed using Kruskal Wallis test.

Thirdly, we assessed intervention fidelity of the nurses and their opinion about elements of the intervention by means of semi-structured qualitative interviews with the three nurses. Based on these interviews, a scheme was made with elements of the case management intervention (not) executed as designed by the three nurses.

Semi-structured interviews with the three nurses were carried out with a topic guide and were conducted by one researcher (AJ) at the end of 2005 and the beginning of 2006. The three nurses were still executing the case management intervention when they were interviewed. Each interview covered the following topics: 1. Opinion about the elements of the case management intervention, 2. Delivery of the case management intervention. AJ wrote down the themes mentioned by the nurses on notes in order that the nurses were able to overlook the themes they mentioned during the interview. This made it easier for the nurses to name all important aspects. Interviews were audio taped and lasted approximately one hour. Following the interview AJ wrote memos about the nurse and the interview. After each interview AJ evaluated whether the topic guide needed adjustments. Transcription was carried out by AJ to a level that included words and speech particles. Firstly, open coding was applied to each transcribed interview. Two researchers (AJ and HH) independently read each transcription. Based on the interviews, both researchers made a scheme with elements of the case management intervention that were and were not executed by the three nurses, as well as a scheme with the nurses' opinion about the elements of the intervention.

Lastly, the actual execution of the case management protocol was assessed with the hours spent on case management by the three district nurses based on registrations of the home care organisation. Differences between

the three nurses were analysed using ANOVA. Furthermore, multiple linear regression analysis was used to investigate the determinants of the time spent on case management.

*Quality of the intervention through the participants' eyes*

At the post-intervention measurement, 12 months after baseline, caregivers in the case management group were asked to complete questions about their satisfaction with the care arranged for both the caregiver and care recipient by the district nurse (very satisfied, satisfied, unsatisfied, very unsatisfied), as well as their overall judgement of this district nurse (positive, neutral, negative).

Caregivers' satisfaction with the quality of the case management intervention was further measured with a part of the QUality Of Care Through the patients' Eyes (QUOTE-elderly) questionnaire.<sup>20</sup> With this questionnaire we compared the conditions for care as valued important by informal caregivers and care as delivered by the three nurses. We asked caregivers about the importance of aspects of care (not important, fairly important, important, extremely important) and whether the nurses satisfied on these aspects (no, not really, on the whole yes, yes). The QUOTE-elderly covers 1. An importance index, the mean importance score per aspect on a scale ranging from 1 (not important) to 4 (extremely important), 2. A performance index, the proportion of caregivers not (really) satisfied with the nurse on an aspect of care, and 3. A quality impact index, the importance score multiplied by the performance score. The quality impact index indicates quality aspects that can be improved.

## **RESULTS**

In the trial 54 pairs were allocated to the case management group and 43 of these pairs retained in the trial during the 1-year follow-up. The 43 informal caregivers who retained were invited to complete questions on intervention fidelity and satisfaction with care. Furthermore, the three nurses who executed the case management intervention participated in interviews.

## **Delivery of the intervention**

### *Timely RAI-HC assessment*

Almost none of the participants received the RAI-HC assessment within one month after randomisation. The mean time between randomisation and the assessment was 3.2 months (range: 0.5-8.1 months). The nurses did not differ in mean time between randomisation and assessment; the mean “waiting” time for nurse 1 was 3.4 months (range 1.4-8.2), 2.4 months for nurse 2 (range 0.7-5.3), and 3.5 months for nurse 3 (range 0.7-7.8);  $F=0.687$ ,  $p=0.508$ . Furthermore, three pairs dropped out before an assessment had taken place (1 refused, 1 was strained, and 1 patient died).

### *Intervention fidelity according to the participating informal caregivers*

Table 1 shows 16 elements of the case management intervention and the compliance to these elements by nurses according to participating informal caregivers. The compliance questions were answered poorly and 8 completers of the study did not answer the compliance questions at all. Two of these caregivers explained that a nurse had never visited or contacted him/her (despite the administration of the RAI-HC), and another caregiver was never contacted after the RAI-HC assessment. Note that the interviewers who visited participants to obtain questionnaires noticed that the informal caregivers often did not understand to whom the questions about fidelity and satisfaction referred. Moreover, even after giving the names of the case managers some caregivers did not remember the person. Finally, 24 participating informal caregivers completed all items of the questions about compliance. According to these persons, nurses implemented on average 11 out of the 13 obligatory elements in compliance with the protocol (range 4-13;  $n=24$  out of 43). The nurses did not differ in the number of elements implemented ( $\chi^2=2.914$ ,  $df=2$ ,  $p=0.233$ ). Nurse 1 implemented on average 10 elements (range 4-12;  $n=7$  out of  $n=15$ ), nurse 2 implemented on average 10 elements (range 7-13;  $n=6$  out of  $n=9$ ), and nurse 3 implemented on average 11 elements (range 9 -13;  $n=11$  out of  $n=19$ ). According to the participants intervention fidelity of the nurses with regard to the following three elements could be improved:

- Contacting the general practitioner;
- Leaving behind a form to register care received and appointments with health care professionals;
- Leaving behind a guide for informal caregivers.

**Table 1** Compliance per element of the case management intervention according to participating informal caregivers

<b>Element</b>	<b>Executed according to the informal caregivers/Number of informal caregivers that answered the question</b>
<i>Obligatory elements</i>	
Administration of Resident Assessment Instrument-HomeCare	34/34
Discussion about problems	31/34
Ranking the identified problems into a hierarchy	29/32
Choosing together problems of focus in the patient	32/33
Exploring the caregiver situation during the second home visit	30/33
Discussion the care plan with the caregiver	27/31
Leaving a dossier at the patient's home	28/30
Leaving a visiting card and telephone number	27/30
Being informed about illness of the nurse and her replacement	21/31
Leaving a guide for informal caregivers	17/29
Leaving behind a form to register care received and appointments with health care professionals	15/29
After two visits: discussing how to proceed with the intervention	25/31
The nurse contacted the general practitioner to inform her/him about the situation	13/32
<i>Tailor-made elements</i>	
Organising a family-meeting	2/33
Referring to other health care professionals	13/33
Referring to diagnostic services	9/33

*Intervention fidelity reported by nurses*

Intervention fidelity was rather poor according to the nurses themselves. Table 2 shows elements of the case management intervention (not) executed by the three nurses. Box 2 presents nurses' opinion about some elements of the case management intervention. The nurses were united in their opinion

about the RAI-HC, but they had different experiences and opinions about most other elements. The delivery of some elements stands out:

1. Not every nurse monitored the situation every 3 months, even in case of little problems, especially not if the patient's situation was stable. Moreover, it seems that in case of a stable situation of the patient, the informal caregiver was sometimes not contacted in monitoring;
2. Contacting the general practitioner to inform her/him about the situation was not always possible. GPs' reactions varied: some were enthusiastic and others were not in for it. Moreover, two nurses indicated that the collaboration with the GPs has not improved by means of the project;
3. Family-meetings were seldom organised. According to the nurses, they were mostly not necessary in this group with mild symptoms. In addition, beforehand, nurses thought that it would be very difficult to lead such meetings. However, at the end of the trial the two nurses who organised a family meeting regarded a meeting as very valuable;
4. (Collaborating) health care professionals made it hard to monitor the anticipated effect of referrals to them: all nurses indicated that other health care professionals often did not give feedback about the patient after referral;
5. Two nurses left behind a form to register care received and appointments made with health care professionals. The third nurse only left a form when she had the forms with her, which was not always the case. One nurse noticed that appointments with other health care professionals were not registered on the form, while the other nurses did not always examine the forms during the visits.

Nurses did not always see the necessity for home visits among the included participants who had fewer health problems than they had expected. Informal caregivers reported little distress and older adults suffered from mild cognitive impairments and few health problems. The nurses indicated that only a minority of the participating patients had health problems. The intervention was often not appraised as necessary yet for the participants and the nurses thought that the intervention would have been more appropriate for dependent older adults with more severe dementia symptoms and their informal caregivers.

**Table 2** Elements of the case management intervention (not) executed by the three nurses.

Elements	Nurse 1	Nurse 2	Nurse 3
<i>Obligatory elements</i>			
Administration of RAI-HC	Yes	Yes	Yes
Discussion about problems	Yes	Probably*	Probably*
Ranking the identified problems into a hierarchy	Probably*	Probably*	Probably*
Exploring the caregiver situation during the second home visit	Yes	Yes	Yes
Leaving a dossier at the patient's home	Only if more-long-lasting care was necessary	Yes	Yes
Leaving a visiting card and telephone number	Yes	Yes	Yes
Leaving a guide for informal caregivers	Yes, if she had the guides with her	Yes	Yes
Leaving behind a form to register care received and appointments with health care professionals	Only if she had the forms with her	Yes	Yes
After two visits: discussing how to proceed with the intervention	How to proceed depended on the care needs	How to proceed depended on the care needs	How to proceed depended on the care needs
Monitoring the situation every 3 months (even in case of little problems on the RAI-HC)	No	Yes	Possibly, the situation of the informal caregiver was not monitored if the patient's situation was stable*
The nurse contacted the general practitioner to inform her/him about the situation	Seldom, general practitioners were not in for it	Yes, but not all general practitioners were in for it	Yes and all the general practitioners were in for it
<i>Tailor-made elements</i>			
Organising a family-meeting	Never	Yes, in 1 participant	Yes, in 1 participant
Referring to other health care professionals and monitoring the anticipated effect	After referring she did not actively check the anticipated effect	Yes	Yes
Referring to diagnostic services and monitoring the anticipated effect	Yes	Yes	Yes

RAI-HC= Resident Assessment Instrument-HomeCare \* The nurses did not explicitly tell this, but we abstracted this out of their interview

## **Box 2** Overview of nurses' experiences and opinions about the elements of the intervention

### **Resident Assessment Instrument-HomeCare (Rai-HC)**

The following adjustments of the RAI-HC are necessary because now the instrument is very time-consuming: it should leave space to indicate the client's precise situation because choosing out of fixed options does not always satisfy, it should be more suitable to map the specific situation of persons with cognitive problems, it should cover more items about the caregiver's situation to clearly map the caregiver's situation, the order of questions could be made more fluently because now the RAI-HC jumps from one question to another.

### **Form to register care received and appointments with other health care professionals**

'People often already have a medicine chart, a national health card and a general practice card, and one from the specialist, so yes, I wondered whether it would be any use to them'

### **Capacity and burden questionnaire**

'Well, that list really concerned people who are overworked, which not all of them were'

### **Guide for informal caregivers**

'That was very good - they were all pleased to have it - now that they could look up where to go, for instance a service centre, and all those well-being organisations in a row'

'And I was also happy to give it to them - with everything in it, they'll find it useful.'

### **Contact with the general practitioner**

'I also phoned the GP and wanted to make an appointment with him, but he didn't think it was necessary at all. That could all be done by telephone, surely - he didn't think it was necessary, I could feel that.'

'Some were more enthusiastic than others'

'Sometimes it has to be clear to the GP why that contact is so important, because when I phone a GP I get different reactions. Some GPs are very enthusiastic and are willing to talk, and if I ask them to ring me back they do so, but others just don't understand what it's all about, don't think it's important, or just say OK, and don't want you to come and see them. So how do you stimulate such GPs to get involved? I think that we need to learn this - what is your aim when you go to a GP and how do you start the conversation. If you come with a real problem they will listen to you, because then they think that something must be done about it, OK.'

### **Monitoring**

'If the family, the informal caregiver says there's no problem, we have it all under control, and when I come I see someone who is really still very independent, then I think there's no need. You can have a conversation every time, but what is there to talk about? So, I think it's OK if it's necessary.'

'With others I think that perhaps I should have asked the informal caregiver more often how things were going, but if the situation was stable I didn't always involve them, but of course they might have had something to say'

'I keep in contact just to see how they are, yes, that's how I do it.'

### **Family meeting**

'I would think that's very difficult'

'Well, perhaps you ought not to do that on your own, or in other words, for instance, that you should do it together with a social worker'

'I found it very enlightening'

'Well, in particular, I think that people have to be open about it, because otherwise I think that you begin something, but not much comes out, and then it doesn't work.'

'People must talk about it - if they keep on thinking they can manage, then you can't do it - you can't have a family-meeting'

### **Dossier**

'If I think that no more interventions are needed and everything is going well, then I don't think that a care file is necessary - it only just lies there in the cupboard'

*Time spent on case management*

The nurses spent a mean time of 10.8 hours a year per dyad on the case management intervention (range 0.75-28 hours). The nurses differed in mean time per dyad spent on the intervention; nurse 1 spent 8.8 hours (range 2-26), nurse 2 spent 5.5 hours (range 0.75-15), and nurse 3 spent 15.2 hours (range 9.6-28);  $F=9.811$ ,  $p<0.001$ . However, this difference did not lead to differences in outcomes of the intervention across the three nurses.

Furthermore, with aging of the care recipient nurses spent more time on case management. Additional determinants of more time spent on case management were a low score on the Mini Mental State Examination (MMSE) at baseline and being a spousal caregiver.

**Quality of the intervention through the participants' eyes**

34 participating informal caregivers completed the questions about satisfaction and overall judgement of the nurse. No differences were found in satisfaction of the clients across the three nurses. Overall, 9 persons were very satisfied, 23 satisfied, 1 unsatisfied and 1 very unsatisfied about the care offered. The unsatisfied caregiver explained that the nurse asked questions that confronted the care recipient too much with reality, whereas the very unsatisfied caregiver explained that no nurse had contacted or visited him/her. We noticed that some caregivers were satisfied although they indicated that they hardly received care. Two satisfied caregivers reported that they received no assistance from a nurse, whereas another reported that he/she needed no assistance from a nurse. Lastly, a very satisfied caregiver reported that the tasks of the several health care professionals involved are unclear.

Furthermore, no differences were found in overall judgement of the nurse of the clients across the three nurses. No participating caregiver had an overall negative judgement about the case manager: 25 participating caregivers were positive and 9 were neutral. Again, we noticed that some caregivers judged positive or neutral although they indicated that they hardly received care. Of the caregivers who had a neutral judgement, one explained that he/she had no idea who the nurse was, one explained that he/she had not noticed the extra care, whereas another explained that he/she had not needed assistance from a nurse. Of the caregivers who had a positive

judgement, one explained that they received no assistance from a nurse, one explained that she was not present at the patient's home when the nurse visited the care recipient and another explained that the nurse had arranged some care.

Overall, nurses performed satisfactorily on aspects of care valued as important by caregivers. Table 3 shows a view on the importance of aspects of care, and on whether the nurses performed satisfactory on these aspects and on the quality index. The QUOTE scores indicate that the following aspects of care could be improved: care co-ordination, spending more time on consultations, trying to understand the patient's problems, discussing problems, and organising a replacement when the regular help is absent.

**Table 3** QUOTE (N=38 out of 43 completers)

Aspects of care	Nurses		
	Importance (sd) <sup>a</sup>	Performance <sup>*</sup>	Quality <sup>#</sup>
Understanding of patients' problems	2.7 (0.7)	0.07	0.19
Work efficiently	3.1 (0.6)	0	0
Patient decides about treatment/help	3.0 (0.7)	0	0
Take patient seriously	3.2 (0.7)	0	0
Keep appointments punctually	2.9 (0.6)	0	0
Good care co-ordination	3.0 (0.6)	0.12	0.36
Friendly attitude	3.0 (0.7)	0	0
Enough time during consultations	2.6 (0.6)	0.08	0.21
Cover when my regular help is absent	2.5 (0.8)	0.04	0.10
Discuss problems/mistakes	3.0 (0.6)	0.04	0.12
Home help for as many hours needed	2.5 (0.7)	0	0

sd=standard deviation

<sup>a</sup> Importance index=mean score on a scale ranging from 1 (not important) to 4 (extremely important)

<sup>\*</sup> Performance index= proportion of caregivers not (really) satisfied with the performance of the nurse

<sup>#</sup> Quality impact index=importance score multiplied by the performance score. This index indicates quality aspects that can be improved

## **DISCUSSION**

We wanted to know why in our intervention study we did not find any surplus value of case management by district nurses above usual care to community-dwelling older adults with early dementia symptoms and their primary informal caregivers in our intervention study. For that reason, we

investigated one of the possible explanations of ineffectiveness: the degree of delivery of the case management intervention.

We found convincing evidence for incomplete implementation of the case management intervention. The main failures were a lack of co-ordination and monitoring. Due to the incomplete implementation some of the elements of the case management intervention had little chance of success. The nurses did often not appraise the intervention as necessary yet for the participants: they thought that the intervention would have been more appropriate for dependent older adults with more severe dementia symptoms and their informal caregivers. This may have contributed to the fact that the case management intervention was not delivered as designed. Thus, one can conclude that incomplete implementation of the case management intervention in the intervention study we conducted is one plausible reason for not finding a surplus value of case management by district nurses above usual care.

### **Delivery of the intervention**

The nurses did not seem aware of the importance of their role and tasks, especially when there were no active problems yet or when the burden of caregivers was low. However, our training sessions and meetings might not have been focused enough on discovering nurses' attitude towards the intervention and prejudices against elements of the intervention and on subsequently tackling these attitudes and prejudices. Or, our training was focused too much on more severely impaired patients and burdened caregivers.

It appeared that the nurses focused on the person with dementia symptoms and that they sometimes forgot to monitor the caregiver's situation. Moreover, it appears that some caregivers were hardly or not at all involved because they were unaware of the nurse's visits to the care recipient. Overall, the monitoring task appeared to fade away when the person with dementia symptoms' situation was relatively uncomplicated at the start of the intervention. Co-ordination did not live up to its promise. Despite agreements with committed organisations, they neglected to give feedback about referred clients. Meanwhile, nurses did not actively monitor the anticipated effects of referrals, and the co-ordination was hindered as not all nurses used the form to register received care and appointments with health care professionals as intended. Nevertheless, we think that a

time-investment of 10.8 hours per dyad per year suffices to deliver the case management intervention adequately.

### **Quality of the intervention through the participants' eyes**

Satisfaction is strongly associated with receiving care according to the participants' expectations.<sup>21</sup> Overall, participants were satisfied with the nurses and the overall judgement of the nurses was positive or neutral whether or not care was received or nurses' names were known.

### **Study limitations**

An important limitation of the present report is that we were not able to assess the exact delivery of each element of the intervention and to relate the delivery of each element to our findings. We tried to find out the intervention fidelity by asking participating caregivers to specify the elements of the intervention they received. Unfortunately, only a small group (n=24) of the 43 completers answered the questions on this topic.

Another limitation of this study is the risk of subjectivity in the analysis of the qualitative interviews. Moreover, social desirability may have biased the answers of the nurses during the interviews and, as a consequence, the reported intervention fidelity and the attitude of the nurses towards elements of the intervention in reality may have overestimated.

Lastly, social desirability may have biased the answers of the participating informal caregivers as well and, as a consequence intervention fidelity and satisfaction with care may have been overestimated as well. On the other hand, fidelity and satisfaction may have been underestimated as recall-bias may have played a part in this process evaluation because participating informal caregivers had to think retrospectively about the questions. As a consequence they may have been less aware of the case manager's support than they would have been during the project.

### **Recommendations**

We recommend researchers planning a randomised clinical trial that evaluates a complex multi-component intervention to assess the delivery of the elements of the intervention during the whole study, as well as the experiences of the care providers and care recipients. This process evaluation helps to explore why the intervention did (not) work: was it attributable to the level of implementation? Thus, researchers should monitor interventions

very closely during trials. Others have also pointed out this issue.<sup>22</sup>

The training and monitoring of the care providers needs specific attention. Researchers should monitor whether professionals execute the protocol in a more or less uniform way before and during the trial. Before starting the trial, researchers should be aware of case managers' attitude towards the intervention and possible prejudices against elements of the intervention and on subsequently tackling of negative attitudes and unrealistic prejudices. They should manage in a similar way with the attitudes of collaborative health care professionals towards the role of the case manager. If necessary, before starting the trial, they can adapt the intervention to the experiences of the case managers. Moreover, researchers should involve the executing health care professionals in the development of their interventions. Furthermore, in planning implementation of case management interventions attention should be paid to the realisation of the planned activities.

## **CONCLUSION**

This study shows that incomplete implementation of a case management intervention delivered by district nurses in a randomised clinical trial is one plausible reason for not finding any surplus value of case management above usual care. The intervention was often not appraised as necessary yet for the included participants. This may have contributed to the fact that the case management intervention was not delivered completely as designed. Therefore, we recommend paying attention to the realisation of the planned activities during the implementation of case management interventions.

## REFERENCES

1. Braekhus A, Oksengard AR, Engedal K, Laake K. Social and depressive stress suffered by spouses of patients with mild dementia. *Scand.J.Prim.Health Care* 1998;16:242-6.
2. Garand L, Dew MA, Eazor LR, DeKosky ST, Reynolds III CF. Caregiving burden and psychiatric morbidity in spouses of persons with mild cognitive impairment. *Int. J.Geriatr.Psychiatry* 2005;20:512-22.
3. Thommessen B, Aarsland D, Braekhus A, Oksengaard AR, Engedal K, Laake K. The psychosocial burden on spouses of the elderly with stroke, dementia and Parkinson's disease. *Int.J.Geriatr.Psychiatry* 2002;17:78-84.
4. Dröes RM, Breebaart E, Meiland FJ, Van Tilburg W, Mellenbergh GJ. Effect of Meeting Centres Support Program on feelings of competence of family carers and delay of institutionalization of people with dementia. *Aging Ment.Health* 2004;8:201-11.
5. Vernooij-Dassen M, Huygen F, Felling A, Persoon J. Home care for dementia patients. *J.Am.Geriatr.Soc.* 1995;43:456-7.
6. Newcomer R, Yordi C, DuNah R, Fox P, Wilkinson A. Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. *Health Serv. Res.* 1999;34:669-89.
7. Weuve JL, Boult C, Morishita L. The effects of outpatient geriatric evaluation and management on caregiver burden. *Gerontologist* 2000;40:429-36.
8. Dröes RM, Meiland FJ, Schmitz MJ, Van Tilburg W. Effect of the Meeting Centres Support Program on informal carers of people with dementia: results from a multi-centre study. *Aging Ment.Health* 2006;10:112-24.
9. Elkan R, Kendrick D, Dewey M, Hewitt M, Robinson J, Blair M *et al.* Effectiveness of home based support for older people: systematic review and meta-analysis. *BMJ* 2001;323:719-25.
10. Eloniemi-Sulkava U, Notkola IL, Hentinen M, Kivela SL, Sivenius J, Sulkava R. Effects of supporting community-living demented patients and their caregivers: a randomized trial. *J Am.Geriatr.Soc.* 2001;49:1282-7.
11. Gaugler JE, Kane RL, Kane RA, Newcomer R. Early community-based service utilization and its effects on institutionalization in dementia caregiving. *Gerontologist* 2005;45:177-85.
12. Mittelman MS, Ferris SH, Shulman E, Steinberg G, Levin B. A family intervention to delay nursing home placement of patients with Alzheimer disease. A randomized controlled trial. *JAMA* 1996;276:1725-31.
13. Stuck AE, Egger M, Hammer A, Minder CE, Beck JC. Home visits to prevent nursing home admission and functional decline in elderly people: systematic review and meta-regression analysis. *JAMA* 2002;287:1022-8.
14. Jansen APD, van Hout HPJ, Nijpels G, Rijmen F, Dröes RM, Pot AM *et al.* Effectiveness of case management among older adults with dementia symptoms and their primary informal caregivers: a randomised clinical trial. *unpublished* 2007.
15. Landi F, Tua E, Onder G, Carrara B, Sgadari A, Rinaldi C *et al.* Minimum data set for home care: a valid instrument to assess frail older people living in the community. *Med.Care* 2000;38:1184-90.

## Chapter 4

16. KITZ. [Capacity and burden questionnaire for primary caregivers]. Groningen: Gorcum &Comp, 1997.
17. Mittelman M, Epstein C, Pierzchala A. Counseling the Alzheimer's Caregiver: a Resource for Health Care Professionals. Chicago: AMA Press, 2003.
18. Jansen AP, van Hout HP, van Marwijk HW, Nijpels G, de Bruijne MC, Bosmans JE *et al.* (Cost)-effectiveness of case-management by district nurses among primary informal caregivers of older adults with dementia symptoms and the older adults who receive informal care: design of a randomized controlled trial [ISCRTN83135728]. *BMC.Public Health* 2005;5:133.
19. Perrin KM, Burke SG, O'connor D, Walby G, Shippey C, Pitt S *et al.* Factors contributing to intervention fidelity in a multi-site chronic disease self-management program. *Implement.Sci.* 2006;1:26.
20. Sixma HJ, van Campen C, Kerssens JJ, Peters L. Quality of care from the perspective of elderly people: the QUOTE-elderly instrument. *Age Ageing* 2000;29:173-8.
21. McKinley RK, Stevenson K, Adams S, Manku-Scott TK. Meeting patient expectations of care: the major determinant of satisfaction with out-of-hours primary medical care? *Fam.Pract.* 2002;19:333-8.
22. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ* 2006;332:413-6.



**Sense of Competence Questionnaire  
among informal caregivers  
of older adults with dementia symptoms:**

***a psychometric evaluation***

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## ABSTRACT

**Background** The Sense of Competence Questionnaire (SCQ) was originally developed for informal caregivers of patients with diagnosed dementia. In order to study the validity and usefulness of the SCQ when applied to informal caregivers of older adults with dementia symptoms, we investigated the construct validity, feasibility, subscales, homogeneity, and floor and ceiling effects in this new target population.

**Methods** A psychometric evaluation was performed among 99 informal caregivers. To investigate construct validity, hypotheses were tested, concerning the association between sense of competence and burden, mental quality of life, depressive symptoms, and mastery. To investigate feasibility, response rate and the proportion of missing data were explored for each item. An exploratory principal component analysis was used to investigate whether the SCQ comprises the three subscales established in previous studies. Homogeneity was assessed for each subscale with Cronbach's  $\alpha$  and item-total correlations. Floor and ceiling effects were explored.

**Results** Most hypotheses on construct validity were rejected. Only the subscale 'Consequences of involvement in care' was found to be partly valid. Feasibility: 93 out of 99 persons completed the SCQ. The proportion of unanswered items per item ranged from 0-3%. Subscales: the SCQ comprises the three expected subscales. Homogeneity: Cronbach's alpha and item-total correlations of the three subscales were satisfactory. A ceiling effect occurred on the subscale 'Satisfaction with the care recipient'.

**Conclusions** The three subscales of the SCQ showed good homogeneity and feasibility, but their validity is insufficient: only the subscale 'Consequences of involvement in care' was found to be partly valid. The two other subscales might not be relevant yet for the new target population, since many of the items on these scales refer to problem behaviour and problematic interactions. Our message to clinicians and researchers is to use only the subscale 'Consequences of involvement in care' in the new target group.

## **BACKGROUND**

Even in its early stages, dementia may have a major impact on informal caregivers because of its chronic progressive and depersonalising nature. Informal caregivers are persons who provide unpaid assistance to relatives and friends who have health problems or functional needs. They play an essential role in the provision of long-term care to community-dwelling older adults with cognitive impairment and with dementia.<sup>1,2</sup> Caregiving is generally unplanned and most informal caregivers gradually adopt their role because of the insidious nature of cognitive impairment and dementia.<sup>3</sup> Furthermore, caregiving may be a physically and emotionally demanding daily task that often lasts for years. The caregiving experience may provide emotional benefits to the caregiver, but it may also have adverse psychological, physical, social, and financial consequences.<sup>1,2</sup>

Valid tools to measure the effects of care in informal caregivers of older adults with dementia symptoms (i.e. cognitive impairment, pre-diagnostic dementia or dementia in its early stages) are necessary. An important concept in the evaluation of effects of care is 'sense of competence'. This concept denotes the caregiver's feeling of being capable to care for the care recipient. The Sense of Competence Questionnaire (SCQ) measures this concept. The SCQ was originally developed for informal caregivers of patients with diagnosed dementia. It consists of three domains, identified by principal-components analysis in the original target population:

1. Satisfaction with the care recipient,
2. Satisfaction with one's own performance, and
3. Consequences of involvement in care for the personal life of the caregiver.

The SCQ has been validated among informal caregivers of older adults with diagnosed dementia and, later, in stroke caregivers. In both populations, it was found to be a valid instrument.<sup>4,5</sup> Content validity among informal caregivers of patients with diagnosed dementia was evaluated on the basis of classifications of the items made by a panel of experts, including professional caregivers and clinical researchers. The three dimensions of the SCQ were shown to have a high degree of correspondence with classifications made by this panel. Construct validity was checked with a principal-components analysis that revealed the three subscales.<sup>5</sup>

However, the SCQ has never been used for informal caregivers of older adults with dementia symptoms. Therefore, we wanted to know whether the SCQ is a useful and valid questionnaire for this new target

population. We gathered information on how this specific group performs on the SCQ because this may be different from informal caregivers of patients with diagnosed dementia. Informal caregivers of older adults with dementia symptoms may experience less distress due to behavioural problems of their care recipient than informal caregivers of patients with a diagnosis of dementia. Moreover, they may experience less adverse consequences of caregiving for their personal life. Therefore, we examined psychometric properties (construct validity, feasibility, subscales, homogeneity, and floor and ceiling effects) of the SCQ in informal caregivers of older adults with dementia symptoms.

## **METHODS**

### **Design**

This study is a psychometric evaluation of the SCQ alongside a randomised clinical trial among primary informal caregivers of community-dwelling older adults with dementia symptoms. Baseline measurements of the trial were used. Caregivers entered the study after completing and returning an informed consent form. The Medical Ethics Committee of the VU University medical center in Amsterdam approved the study.

### **Participants**

99 pairs of informal caregivers and their care recipients participated in the trial. Care recipients were 65 years and older and lived at home in West-Friesland, a region in the northern part of the Netherlands. They received no assistance from outpatient geriatric services or outpatient diagnostic services and they had scores on the Mini Mental State Examination (MMSE)<sup>6</sup> below 24 or they had a risk of dementia of 50% or more according to the seven Minute Screen (7MS).<sup>7</sup> Details on recruitment of participants have been described elsewhere.<sup>8</sup> In short, informal caregivers were recruited after screening for older adults with dementia symptoms in a large general practice population. Only primary informal caregivers were included. They were friends or relatives who were responsible for the informal care and who provided at least one hour of care a week. Exclusion criteria for patients were: terminal illness, insufficient command of the Dutch language, and participation in other research projects. Exclusion criteria for caregivers

were: terminal illness and insufficient command of the Dutch language.

## **Instruments**

### *SCQ*

The SCQ comprises 27 items that are rated on a 5-point scale: 1 'yes, completely agrees', 2 'yes, agrees', 3 'on the one hand agrees but on the other hand disagrees', 4 'no, disagrees', 5 'no, completely disagrees'.<sup>5</sup> When caregivers do not know an answer they can indicate this. The SCQ was found to consist of three subscales: 1. Satisfaction with the care recipient (7 items; range 7-35; Cronbach's alpha=0.55); 2. Satisfaction with one's own performance as a caregiver (12 items; range 12-60; Cronbach's alpha=0.63); and 3. Consequences of involvement in care for the personal life of the caregiver (8 items; range 8-40; Cronbach's alpha=0.50). Two items were recoded in the opposite direction and item-scores were summed subsequently. Higher scores indicate better sense of competence. Overall sum-scores were calculated in previous studies.<sup>5,9</sup> These scores ranged from 27-135. Next to sum-scores based on raw item-scores, sum-scores based on dichotomised item-scores ( $\leq 3$  versus  $> 3$ ) were calculated in previous research.<sup>5</sup>

Apart from caregivers' sense of competence, the following caregiver variables were covered: age, gender, educational level, living situation, marital status, months spent on caring, hours spent on caring a week, help from other persons, time spent on caring a week, self-reported health, chronic diseases, level of caregiver's distress due to patient's behavioural problems measured with the distress scale of the Neuropsychiatric Inventory-Questionnaire (NPI-Q)<sup>10</sup>, caregiver's burden measured with the Self-Perceived Pressure by Informal Care questionnaire (SPPIC),<sup>11</sup> caregiver's mental quality of life as determined with the mental component summary score of the MOS 36-item short-form health survey (SF-36),<sup>12</sup> mastery (i.e. the extent to which one regards one's life chances as being under one's own control in contrast to being fatalistically ruled) as measured with the Mastery scale,<sup>13</sup> and, depressive symptoms measured with the Center for Epidemiologic Studies Depression Scale (CES-D).<sup>14</sup> Furthermore, we collected the following care recipient characteristics: cognitive functioning measured with the Mini Mental State Examination (MMSE),<sup>6</sup> patients' initiative to perform self-care and patients' actual performance of self-care measured with the Interview

## Chapter 5

for Deterioration in Daily life in Dementia (IDDD),<sup>15</sup> severity of behavioural problems measured with the severity scale of the Neuropsychiatric Inventory-Questionnaire (NPI-Q),<sup>10</sup> and, duration of cognitive problems in months.

Trained interviewers visited participating caregivers to obtain the SCQ and IDDD. Moreover, they picked up a caregiver-completed questionnaire. This postal questionnaire covered all remaining variables, described above, with the exception of cognitive functioning (MMSE). Cognitive functioning of care recipients was measured before baseline measurements of the trial.

To investigate construct validity, the SCQ was compared with measurements of caregiver's burden, caregiver's mental quality of life, depressive symptoms, and mastery. These measurements are described in more detail below.

### *SPPIC*

The SPPIC is a 9-item self-report Rasch scale that measures self-perceived pressure from informal care. Items are scored on a 5-point scale: 1 'no!', 2 'no', 3 'more or less', 4 'yes', 5 'yes!'. To score the SPPIC, item-scores are dichotomised and summed subsequently.<sup>11</sup> Scores 1 and 2 are recoded into 0 (i.e. not perceiving pressure) and scores 3, 4 and 5 are recoded into 1 (i.e. perceiving pressure). Scores range from 0 to 9 with higher scores indicating more pressure.<sup>11</sup>

### *SF-36*

The SF-36 is composed of 36 questions and standardized response choices, organised into eight multi-item scales. Besides, two summary scales, the Physical Component Summary (PCS) measure and the Mental Component Summary (MCS) measure can be calculated. Only the MCS is used for this study. Raw scale scores are linearly converted to a 0 to 100 scale, with higher scores indicating higher levels of functioning or well-being.<sup>12</sup>

### *CES-D*

The CES-D is a 20-item self-report scale for assessing depressive symptoms. It asks subjects to describe how often they had depressive symptoms over the past week. Items are rated on a 4-point scale from 0 'rarely or none of the time' to 3 'most or all of the time'. Scores range from 0 to 60, with scores over 15 indicating possible depression.<sup>14</sup>

### *Mastery*

The mastery scale is composed of 7 items. Items are rated on a 5 point scale: 1 'yes, completely agrees', 2 'yes, agrees', 3 'on the one hand agrees but on the other hand disagrees', 4 'no, disagrees', 5 'no, completely disagrees'. Two items were recoded in the opposite direction. Subsequently, item-scores were summed and divided by the number of items. No missing items were allowed. Scores ranged from 7 to 35, with higher scores indicating better mastery.<sup>13</sup>

### **Analysis**

#### *Feasibility*

Response rate and the percentage of missing values per item were calculated.

#### *Subscales of the SCQ*

First, we ran an exploratory principal component analysis (PCA) to check whether the SCQ measured the three domains established before.<sup>5</sup> As a consequence of the small sample size, performing a confirmatory analysis was not considered appropriate. We selected factors on the basis of the Scree test,<sup>16</sup> i.e. we looked for a break between the factors with relatively large eigenvalues and those with smaller eigenvalues. Factors that appeared before the break were assumed to be potentially useful. Then, we conducted a forced three-factor analysis with oblique rotation (direct oblimin), similar to the study among informal caregivers of demented care recipients,<sup>5</sup> to check and compare factor structure and loadings with those in the study among caregivers of demented care recipients.

#### *Homogeneity*

Homogeneity was assessed per subscale of the questionnaire. It was checked with Cronbach's  $\alpha$  and the item-total correlations, both in raw and imputed data for which missing values were replaced with series means. Cronbach's  $\alpha$  between 0.70 and 0.90 is considered to be adequate.<sup>17</sup> Items should correlate with the total score between 0.20 and 0.80.<sup>17</sup>

#### *Floor and ceiling effects*

We explored the presence of floor and ceiling effects by examining the

frequency of highest and lowest possible scores at baseline SCQ-domain scores. Floor effects were considered present if more than 15% of participants had a minimal score at baseline, ceiling effect were considered present if more than 15% of participants had a maximum baseline score.<sup>18</sup> If ceiling or floor effects are present, a scale is unable to detect an improvement or decline in sense of competence in a considerable part of the target population.

### *Construct validity*

Based on an underlying theory of what sense of competence is, one can hypothesize how the concept 'sense of competence' correlates with other concepts. If many of the hypotheses will be confirmed in the new target population, construct validity is good. We hypothesized a priori:

1. A moderate to strong negative association ( $r_s = [-0.40, -0.80]$ ) between caregivers' sense of competence and self-perceived burden. It is plausible that these two concepts influence each other because burden, referring to the consequences of the impaired person's restrictions for the caregiver, decreases the sense of competence referring to the caregiver's capability in caring for the impaired person.<sup>9</sup>
2. A moderate to strong positive association ( $r_s = [0.40, 0.80]$ ) between caregivers' sense of competence and mental quality of life, because it is plausible that mental quality of life influences sense of competence and the other way around.
3. A moderate to strong negative association  $r_s = [-0.40, -0.80]$  between caregivers' sense of competence and depressive symptoms, because it is plausible that depressive symptoms influences sense of competence and the other way around.
4. A moderate to strong positive association  $r_s = [0.40, 0.80]$  between caregivers' sense of competence and mastery, because it is plausible that the extent to which one regards one's life chances as being under one's own control (i.e. sense of competence in general) influences sense of competence in caring, and the other way around.

We examined per subscale of the SCQ associations between the SCQ and caregiver's burden (SPPIC), caregiver's mental quality of life (MCS of the SF-36), caregiver's depression (CES-D) and mastery (Mastery) by calculating Pearson's correlation coefficients and their 95% confidence intervals. Correlations in the range 0.40 to 0.80 were regarded as moderate to strong

associations.<sup>17</sup> Besides, we checked whether caregivers with low burden, with a high reported mental quality of life, without clinical relevant depressive symptoms and with a high reported mastery reported higher mean SCQ scores than the remaining caregivers. Therefore, we recoded burden, mental quality of life, depression and mastery scores in two ways: into three categories with equal distances and into quartiles, i.e. four categories with equal numbers of caregivers. Furthermore, we dichotomised CES-D scores into clinical relevant depressive symptoms (i.e. CES-D  $\geq$  16) and no clinical relevant depressive symptoms (i.e. CES-D < 16).<sup>19</sup>

## **RESULTS**

Ninety-three informal caregivers out of 99 participating informal caregivers completed the SCQ. Five caregivers completed the postal questionnaire, but not the interview due to logistic problems. Furthermore, the research-team did not receive the SCQ and postal questionnaire of one caregiver due to problems with the Post Office. Table 1 presents the characteristics of the 93 participants who completed the SCQ, and their care recipients.

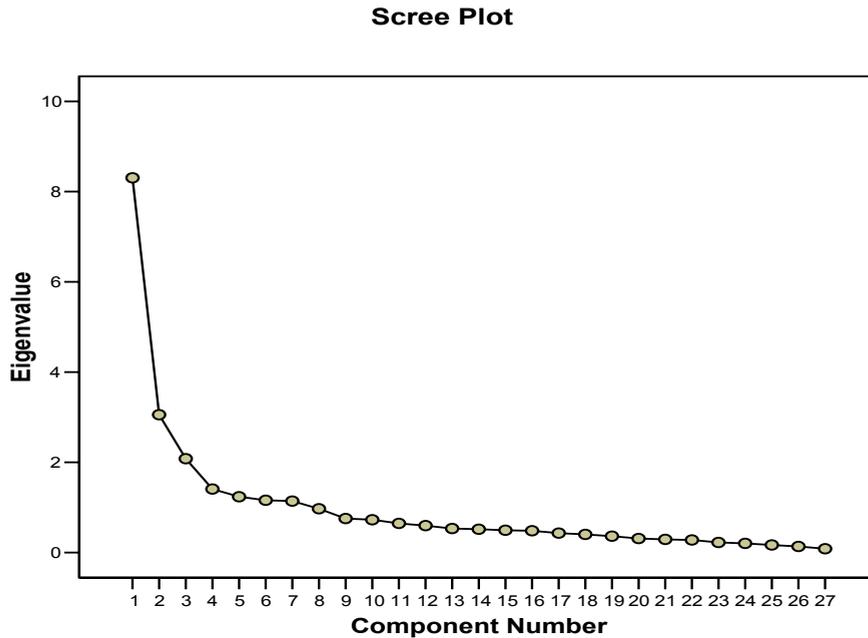
Participating informal caregivers of older adults with dementia symptoms reported better sense of competence than informal caregivers of older adults with diagnosed dementia (mean dichotomised score in dementia caregivers: 17.9; sd: 5.2;<sup>5</sup> mean dichotomised score in our participants: 21.3; sd: 4.4). Furthermore, our participants reported little distress associated with patients' behavioural problems, as well as low severity of behavioural problems in patients.

### **Feasibility**

A completed SCQ of 93 out of the 99 participating caregivers (94%) was received. Among those who completed the SCQ, the percentage of missing values per item ranged from 0% to 3%. On 18 items no missing values occurred.

### **Subscales of the SCQ**

Exploratory principal component analyses showed that the SCQ measured three distinct constructs, as was expected. The Scree plot in Figure 1 shows a distinct break before factor four, suggesting that only the first three factors were potentially useful enough to be retained.



**Figure 1** Scree plot of Eigenvalues of the SCQ

A forced three-factor analysis with an oblique rotation (direct oblimin) revealed that variables loading on the three factors were similar to those in the original questionnaire.<sup>5</sup> Factor loadings in our study population, as well as those in the original study among informal caregivers of patients with diagnosed dementia, are shown in Table 2. Items that loaded high on the first factor were those related to satisfaction with the care recipient. Moreover, items that loaded high on the second factor were related to consequences of involvement in care for the personal life of the caregiver, and items that loaded high on the third factor were related to satisfaction with one's own performance. However, only the items of the subscale 'consequences of involvement in care' all showed simple structure and they were associated well to the factors that they were grouped together with in the original questionnaire. Likewise, in the original questionnaire only the items of the subscale 'consequences of involvement in care' all showed simple structure. In our study, items 1, 2, 3, 5, 10, 11, 18, and 19 did not demonstrate simple structure, and the items 1, 2, 10, 11, 18, and 19 were not associated well to the factors that they were grouped with in the original questionnaire.

Furthermore, factor 1 correlated weakly with factor 2 and 3 (0.28 and 0.32, respectively). Factor 2 correlated weakly with factor 3 (0.20).

**Table 1** Characteristics of participating caregivers and their care recipients (n=93)

Characteristics	Value	N <sup>a</sup>
<i>Caregivers' socio-demographics</i>		
Age, mean ± SD (range)	62.9 ± 14.4 (32.5-91.2)	87
Gender, female (%)	71	93
Relation with the care recipient		92
Spouse	41%	
Child	50%	
Child in law	4%	
Other (friend, other member of the family)	5%	
Married (%)	83	86
Widowed (%)	1	
Living together with the care recipient (%)	47	93
Months spent on caring, median (25th percentile, 75th percentile)	24.0 (16.0, 48.0)	63
Hours spent on caring a week, median (25th percentile, 75th percentile)	7.0 (3.0, 41.0)	65
Help from other persons/shared care (%)	61	83
Educational level, primary school or no education (%)	15	88
<i>Caregivers' sense of competence</i>		
Overall SCQ, mean ± SD (range)	107.7 ± 13.7 (65.9-132.0)	93
Subscale 1. Satisfaction with one's own performance as a caregiver, mean ± SD (range)	49.2 ± 6.5 (29.0-60.0)	93
Subscale 2. Consequences of involvement in care for the personal life of the caregiver, mean ± SD (range)	28.6 ± 6.2 (13.0-40.0)	93
Subscale 3. Satisfaction with the care recipient, mean ± SD (range)	29.9 ± 4.2 (16.0-35.0)	93
<i>Caregivers' general (health) functioning</i>		
Self reported health, good, very good or excellent health (%)	69	88
Chronic disease, one or more chronic diseases (%)	67	88
Caregiver's burden, SPPIC, mean ± SD (range)	3.5 ± 2.6 (0-9.0)	82
Mastery, mastery, mean ± SD (range)	25.3 ± 4.9 (16.0-35.0)	85
Depressive symptoms, CES-D, mean ± SD (range)	10.9 ± 6.9 (0-35.0)	88
Mental quality of life, MCS of the SF-36, mean ± SD (range)	49.5 ± 9.8 (23.6-68.1)	88
Caregiver's distress associated with patient's neuropsychiatric symptoms, NPI-Q distress, mean ± SD (range)	7.7 ± 8.3 (0-38.0)	84
<i>Patients</i>		
Cognitive functioning, MMSE-score, mean ± SD (range)	22.4 ± 4.0 (8-28)	90
Months with symptoms, median (25th percentile, 75th percentile)	26.0 (19.0, 48.0)	65
Severity of neuropsychiatric symptoms, NPI-Q, mean ± SD (range)	6.3 ± 5.6 (0-27.0)	84
Initiative to perform self-care, IDDD, mean ± SD (range)	11.9 ± 8.5 (0-32.0)	82
Actual performance of self-care, IDDD, mean ± SD (range)	13.7 ± 9.7 (0-40.0)	84

N<sup>a</sup>= number of completed questionnaires; SD= Standard Deviation; SCQ= Sense of Competence Questionnaire; SPPIC= Self-Perceived Pressure of Informal Care questionnaire; CES-D= Center for Epidemiologic Studies Depression Scale; MCS= Mental Component Summary; SF-36= MOS 36-item Short-Form health survey; NPI-Q= Neuropsychiatric Inventory-Questionnaire; MMSE= Mini Mental State Examination; IDDD= Interview for Deterioration in Daily life in Dementia

**Table 2** Principal Component Analysis: eigenvalues and factor loadings after oblique (direct oblimin) rotation

Item	Factor 1. Satisfaction with the care recipient		Factor 2. Consequences of involvement in care for the personal life of the caregiver		Factor 3. Satisfaction with one's own performance	
	Our study	Original questionnaire	Our study	Original questionnaire	Our study	Original questionnaire
<i>Satisfaction with the care recipient</i>						
1. I feel pleased about my interactions with my ....	.44	.20	-.24	-.40	<b>.20</b>	-.79
2. I don't feel capable to care for my ....	-.04	-.09	.04	-.18	<b>.27</b>	.63
3. I wish that my .... and I had a better relationship.	.35	.06	-.07	.05	<b>.53</b>	.56
4. I feel guilty about my interactions with my ....	-.02	.01	-.15	-.10	<b>.68</b>	.50
5. I feel strained in my interactions with my ....	.38	.14	-.21	.29	<b>.48</b>	.50
6. I feel that in the past, I haven't done as much for my .... as I could have or should have.	-.07	-.08	.09	-.14	<b>.72</b>	.49
7. It is not clear to me how much care I should give to my ....	-.05	-.15	.10	-.00	<b>.74</b>	.40
8. I feel that my .... doesn't benefit from what I do for him/her.	.00	.08	-.04	-.03	<b>.77</b>	.37
9. I feel nervous or depressed about my interactions with my ....	-.03	.17	-.32	.30	<b>.44</b>	.34
10. I feel angry about my interactions with my ....	.39	.28	-.33	.04	<b>.33</b>	.32
11. I feel that I don't do as much for my .... as I should do.	.41	-.04	-.24	-.16	<b>.25</b>	.31
12. I feel useful in my interactions with my ....	.14	-.02	.12	-.04	<b>.32</b>	-.28
<i>Satisfaction with the care recipient</i>						
13. I feel that my .... behaves the way s/he does to have her/his own way.	<b>.82</b>	.89	-.06	.02	-.04	-.13
14. I feel that my .... behaves the way s/he does to annoy me.	<b>.83</b>	.72	.09	-.11	-.02	.04

15. I feel that may .... tries to manipulate me.	<b>.90</b>	.68	.13	.09	-.15	-.18
16. My .... appreciates my constant care less than the care others give him/her.	<b>.61</b>	.60	.05	-.06	.26	.20
17. I feel that my .... makes requests, which I perceive to be over and above what s/he needs.	<b>.50</b>	.59	-.39	.11	-.09	-.14
18. I feel resentful about my interactions with my ....	<b>.35</b>	.49	-.35	-.03	.35	.32
19. I feel embarrassed over my .... behaviour.	<b>.24</b>	.40	-.31	-.14	.37	.36
<i>Consequences of involvement in care</i>						
20. I feel that my present situation with my .... doesn't allow me as much privacy as I'd like.	.08	.01	<b>-.68</b>	.67	-.05	-.03
21. Because of my involvement with my .... I don't have enough time for myself.	-.02	-.00	<b>-.85</b>	.69	-.07	-.19
22. I feel that my social life has suffered because of my involvement with my ....	.13	-.02	<b>-.76</b>	.57	.04	.05
23. I feel that I cannot leave my .... alone, he/she needs me continuously.	.10	-.04	<b>-.70</b>	.52	-.08	-.08
24. I feel stressed between trying to give up my .... as well as to other family responsibilities, job etc.	-.03	.03	<b>-.63</b>	.49	-.05	.18
25. I feel that my health has suffered because of my involvement with my ....	-.06	-.03	<b>-.66</b>	.46	.19	.20
26. I worry all the time about my ....	-.30	-.029	<b>-.71</b>	.44	.06	.27
27. I feel that my .... Seems to expect me to take care of him/her as if I were only one s/he could depend on.	.12	.17	<b>-.66</b>	.37	-.16	-.16
Unrotated:						
Eigenvalue	8.39	-	3.03	-	2.02	-
Variance explained	31%	-	11%	-	7%	-

### **Homogeneity**

The following figures on homogeneity were found on the subscales:

- satisfaction with the care recipient: Cronbach's  $\alpha=0.83$  and range of item-total correlations: 0.50-0.68;
- satisfaction with one's own performance as a caregiver: Cronbach's  $\alpha=0.83$  and range of item-total correlations: 0.16-0.70;
- consequences of involvement in care for the personal life of the caregiver: Cronbach's  $\alpha=0.85$  and range of item-total correlations: 0.50-0.76.

The results were similar for imputed and raw data.

### **Floor and ceiling effects**

Floor and ceiling effects were not present with the exception of the subscale 'satisfaction with the care recipient'. Here, a ceiling effect occurred: 18% of the participants had a maximum score.

### **Construct validity**

The hypothesized outcomes and realized outcomes of the 4 hypotheses are summarized per subscale of the SCQ: 'satisfaction with one's own performance as a caregiver' in Table 3, 'consequences of involvement in care' in Table 4, and 'satisfaction with the care recipient' in Table 5. On the subscales 'satisfaction with one's own performance' and 'satisfaction with the care recipient' none of the four hypotheses was accepted. Only on the subscale 'consequences of involvement in care' the expected associations with burden and mental quality of life were found, but not with depression and mastery.

**Table 3** Tested hypotheses on construct validity: Satisfaction with one's own performance as a caregiver

We expected:	Value outcome found	Hypothesis accepted?*
<i>Burden</i>		
A moderate to strong negative association with measures of caregivers' burden.	1. Association with caregivers' burden: r = -0.21, 95% Confidence Interval (CI): [-0.43, 0.01]; n=82.	-
	2. Categories of burden: -equal distances: 49.5 (SPPIC 0-3, n=45), 48.6 (3-6, n=25), to 46.7 (6-9, n=12); -equal observations: 49.9 (1, n=21), 49.4 (2, n=18), 49.6 (3, n=23), 46.2 (4, n=20).	-
<i>Mental quality of life</i>		
A moderate to strong positive association with measures of caregivers' mental quality of life.	1. Association with caregivers' mental quality of life: r =0.24, 95% CI: [0.03, 0.46]; n=88.	-
	2. Categories of mental quality of life: -equal distances: 46.1 (MCS 0-33.3, n=8), 48.3 (33.3-49.9, n=27), to 50.0 (49.9-100.0, n=53); F=1.535, p=0.221; -equal observations: 47.3 (1, n=22), 48.2 (2, n=22), 50.1 (3, n=22), 50.8 (4, n=22); F=1.434, p=0.239.	-
<i>Depressive symptoms</i>		
A moderate to strong negative association with depressive symptoms.	1. Association with caregivers' depressive symptoms: r = -0.21, 95% CI: [-0.42, 0.004]; n=88.	-
	2. Categories of depressive symptoms: -dichotomised: 47.4 (CES-D $\geq$ 16.0, n=18), 49.5 (CES-D < 16, n=70), student's t-test: p=0.212.	-
<i>Mastery</i>		
A moderate to strong positive association with mastery.	1. Association with caregivers' mastery: r = 0.19, 95% CI: [-0.02, 0.41]; n=85.	-
	2. Categories of mastery: -equal distances: 46.8 (mastery 16-21, n=18), 49.3 (mastery 21-28, n=45), to 50.7 (mastery 28-35, n=21); -equal observations: 47.2 (1, n=23), 50.5 (2, n=20), 48.3 (3, n=20), 50.7 (4, n=22).	-

\* hypothesis accepted:  
+ accepted  
- rejected

**Table 4** Tested hypotheses on construct validity: Consequences of involvement in care

We expected:	Value outcome found	Hypothesis accepted?*
<i>Burden</i>		
A moderate to strong negative association with measures of caregivers' burden.	1. Association with caregivers' burden: $r = -0.69$ , 95% Confidence Interval (CI): $[-1.00, 0.62]$ ; $n=82$ .	+
	2. Categories of burden : -equal distances: 31.4 (SPPIC 0-3, $n=45$ ), 26.7 (SPPIC 3-6, $n=25$ ), to 19.4 (SPPIC 6-9, $n=12$ ); $F=38.850$ , $p < 0.001$ ; -equal observations: 32.0 (1, $n=21$ ), 31.0 (2, $n=18$ ), 28.8 (3, $n=23$ ), 21.1 (4, $n=20$ ); $F=24.452$ , $p < 0.001$ .	+
<i>Mental quality of life</i>		
A moderate to strong positive association with measures of caregivers' mental quality of life.	1. Association with caregivers' depressive symptoms: $r = 0.44$ , 95% CI: $[0.14, 0.57]$ ; $n=88$	+
	2. Categories of mental quality of life: -equal distances: 23.5 (MCS 0-33.3, $n=8$ ), 26.0 (MCS 33.3-49.9, $n=27$ ), to 30.1 (MCS 49.9-100.0, $n=53$ ); $F=7.615$ , $p=0.001$ ; -equal observations: 24.6 (1, $n=22$ ), 28.1 (2, $n=22$ ), 28.1 (3, $n=22$ ), 32.2 (4, $n=22$ ); $F=6.462$ , $p=0.001$ .	+
<i>Depressive symptoms</i>		
A moderate to strong negative association with depressive symptoms.	1. Association with caregivers' depressive symptoms: $r = -0.27$ , 95% CI: $[-0.49, -0.06]$ ; $n=88$	-
	2. Categories of depressive symptoms: -dichotomised: 27.7 (CES-D $\geq 16.0$ , $n=18$ ), 28.3 (CES-D $< 16$ , $n=68$ ), student's t-test: $p=0.716$ .	-
<i>Mastery</i>		
A moderate to strong positive association with mastery.	1. Association with caregivers' mastery: $r = 0.34$ , 95% CI: $[0.14, 0.57]$ ; $n=85$	-
	2. Categories of mastery: -equal distances: 24.9 (mastery 16-21, $n=18$ ), 28.5 (mastery 21-28, $n=45$ ), to 30.9 (mastery 28-35, $n=21$ ); -equal observations: 25.9 (1, $n=23$ ), 28.5 (2, $n=21$ ), 28.2 (3, $n=19$ ), 30.9 (4, $n=21$ ).	-

\* hypothesis accepted:  
+ accepted  
- rejected

**Table 5** Tested hypotheses on construct validity: Satisfaction with the care recipient

We expected:	Value outcome found	Hypothesis accepted?*
<i>Burden</i>		
A moderate to strong negative association with measures of caregivers' burden.	1. Association with caregivers' burden: r = -0.23, 95% CI: [-0.46, -0.02]; n=82.	-
	2. Categories of burden: -equal distances: 30.4 (SPPIC 0-3, n=45), 30.2 (3-6, n=25), to 27.1(6-9, n=12); -equal observations: 30.7 (1, n=21), 30.1 (2, n=18), 30.7 (3, n=23), 27.9 (4, n=20).	-
<i>Mental quality of life</i>		
A moderate to strong positive association with measures of caregivers' mental quality of life.	1. Association with caregivers' mental quality of life: r = 0.16, 95% CI: [-0.05, 0.38]; n=88	-
	2. Categories of mental quality of life: -equal distances: 29.4 (MCS 0-33.3, n=8), 29.0 (33.3-49.9, n=27), to 30.3 (49.9-100.0, n=53); -equal distances: 28.4 (1, n=22), 30.3 (2, n=22), 30.0 (3, n=22), 30.7 (4, n=22).	-
<i>Depressive symptoms</i>		
A moderate to strong negative association with depressive symptoms.	1. Association with caregivers' depressive symptoms: r = -0.05, 95% CI: [-0.26, 0.16]; n=88.	-
	2. Categories of depressive symptoms: -dichotomised: 30.0 (CES-D $\geq$ 16.0, n=18), 29.8 (CES-D < 16, n=70), student's t-test: p=0.830.	-
<i>Mastery</i>		
A moderate to strong positive association with mastery.	1. Association with caregivers' mastery: r = 0.15, 95% CI: [-0.06, 0.37]; n=85	-
	2. Categories of mastery: -equal distances: 28.9 (mastery 16-21, n=18), 29.8 (mastery 21-28, n=45), to 30.7 (mastery 28-35, n=22); -equal observations: 28.9 (1, n=23), 30.2 (2, n=20), 29.8 (3, n=20), 30.7 (4, n=22).	-

\* hypothesis accepted:  
+ accepted  
- rejected

## **DISCUSSION**

The SCQ has been used for informal caregivers of older adults with diagnosed dementia, but has never been used for informal caregivers of older adults with dementia symptoms. This new target population performed differently on the SCQ than informal caregivers of patients with diagnosed dementia. Unsurprisingly, participating informal caregivers of older adults with dementia symptoms reported better sense of competence than informal caregivers of older adults with diagnosed dementia.

### **Feasibility**

Feasibility was satisfactory as the proportion of unanswered items on the SCQ was very low.

### **Subscales of the SCQ**

Exploratory principal component analyses showed that the SCQ measured three constructs similar to those found in the study among caregivers of older adults with dementia.<sup>5</sup> However, only the items of the subscale 'consequences of involvement in care' all showed simple structure, just as on the original questionnaire.

### **Homogeneity**

Cronbach's alphas of the three subscales satisfied and were more adequate than those found in the source population in which the SCQ was validated.<sup>5</sup>

### **Floor and ceiling effects**

Floor effects were absent. However, on the subscale 'satisfaction with the care recipient' a ceiling effect occurred. This means that it is impossible to detect an improvement on this subscale in a considerable part of the target population. Furthermore, the subscale 'satisfaction with the care recipient' seems to be less relevant for our study population. The reason may be that the items of this subscale refer to problem behaviour. Probably, caregivers of persons with dementia symptoms are not yet familiar nor do encounter problems with problem behaviour, since participants reported low distress associated with patients' behavioural problems, as well as low severity of behavioural problems in patients.

### **Construct validity**

Most hypotheses were rejected. Only the subscale ‘consequences of involvement in care for the personal life of the caregiver’ was found to be partly valid. However, we do not know how the SCQ performs with regard to comparison questionnaires among informal caregivers of patients with diagnosed dementia, because no previous research has focused on this subject and in the original questionnaire, construct validity was determined by means of a principal component analysis.

The strength of this study is that we were able to compare sense of competence with several other related constructs in a new target population. However, this study has some limitations. Firstly, comparison questionnaires were chosen based on the overall construct sense of competence. Our perception of this construct equalled the subscale ‘consequences of involvement in care’, but corresponded less well with the two other subscales ‘satisfaction with one’s own performance’ and ‘satisfaction with the care recipient’. However, that only partly explains the weakness of the correlations with the comparison questionnaires and these subscales. A more important explanation for the weak correlations might be that the two subscales are not very relevant yet for the new target population, since many items on these scales refer to problem behaviour and problematic interactions. Another explanation might be that the constructs are not related in the way we think “plausible”.

Secondly, the study population may not be representative for all informal caregivers of older adults with cognitive impairment and dementia in its early stages, since the study population was recruited after screening for older adults with dementia symptoms in a large general practice population. Informal caregivers of non-respondents to the screening were not recruited, while these non-respondents were found to have higher rates of functional and cognitive impairment in other studies.<sup>20;21</sup> Thus, informal caregivers of more severely impaired older adults with dementia symptoms may be under-represented.

Thirdly, the comparison questionnaires used in examining the construct validity suffered from missing values on the sum-scores of the SPPIC, CES-D and SF-36. However, the influence of this small number of missing values on construct validity is limited as there is no reason to assume that the persons with missing values differed from the persons without such values since missing values were at random.

## CONCLUSIONS

In conclusion, among informal caregivers of older adults with dementia symptoms, the subscales of the SCQ showed good homogeneity and feasibility, but their validity is insufficient: only the subscale 'Consequences of involvement in care for the personal life of the caregiver' was found to be partly valid. The two other subscales are not yet very relevant for the new target population, since many of the items on these scales refer to problem behaviour and problematic interactions while participants reported low distress associated with patients' behavioural problems, as well as low severity of behavioural problems in patients. Our message to clinicians is not to use the subscales 'Satisfaction with one's own performance' and 'satisfaction with the care recipient' in informal caregivers of older adults with dementia symptoms who do not have behavioural problems or problematic interactions with their caregiver. Furthermore, the subscale 'Satisfaction with the care recipient' is unable to detect an improvement in a considerable part of informal caregivers of older adults with dementia symptoms. Therefore, we advise caution when using the subscale 'Satisfaction with the care recipient' to detect changes in levels of functioning among informal caregivers of persons with dementia symptoms.

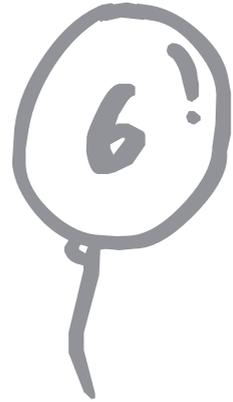
## REFERENCES

1. Beach SR, Schulz R, Yee JL, Jackson S. Negative and positive health effects of caring for a disabled spouse: longitudinal findings from the caregiver health effects study. *Psychol.Aging* 2000;15:259-71.
2. Huckle PL. Review: families and dementia. *Int.J.Geriatr.Psychiat.* 1994;9:735-41.
3. Mittelman M, Epstein C, Pierzchala A. Counseling the Alzheimer's Caregiver: A Resource for Health Care Professionals. Chicago: AMA Press, 2003.
4. Scholte op Reimer WJ, de Haan RJ, Pijnenborg JM, Limburg M, van den Bos GA. Assessment of burden in partners of stroke patients with the sense of competence questionnaire. *Stroke* 1998;29:373-9.
5. Vernooij-Dassen, M. [Dementia and home-care. PhD thesis]. Amsterdam/Lisse: Swets & Zeitlinger B.V., 1993.
6. Folstein M, Folstein S, McHugh P. "Mini-Mental" State: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.
7. Solomon PR, Pendlebury WW. Recognition of Alzheimer's disease: the 7 Minute Screen. *Fam.Med.* 1998;30:265-71.

### *A psychometric evaluation of the Sense of Competence Questionnaire*

8. Jansen AP, van Hout HP, van Marwijk HW, Nijpels G, de Bruijne MC, Bosmans JE *et al.* (Cost)-effectiveness of case-management by district nurses among primary informal caregivers of older adults with dementia symptoms and the older adults who receive informal care: design of a randomized controlled trial [ISCRTN83135728]. *BMC.Public Health* 2005;5:133.
9. Vernooij-Dassen MJ, Persoon JM, Felling AJ. Predictors of sense of competence in caregivers of demented persons. *Soc.Sci.Med.* 1996;43:41-9.
10. Kaufer DI, Cummings JL, Ketchel P, Smith V, MacMillan A, Shelley T *et al.* Validation of the NPI-Q, a brief clinical form of the Neuropsychiatric Inventory. *J Neuropsychiatry Clin.Neurosci.* 2000;12:233-9.
11. Pot AM, van Dyck R, Deeg DJ. [Perceived stress caused by informal caregiving. Construction of a scale]. *Tijdschr.Gerontol.Geriatr.* 1995;26:214-9.
12. McHorney CA, Ware JE Jr, Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Med.Care* 1993;31:247-63.
13. Pearlin LI, Schooler C. The structure of coping. *J Health Soc.Behav.* 1978;19:2-21.
14. Radloff LS. The CES-D Scale: a Self-Report Depression Scale for Research in the General Population. *Appl.Psych.Meas.* 1977;1:385-401.
15. Teunisse S, Derix MM. [Measurement of activities of daily living in patients with dementia living at home: development of a questionnaire]. *Tijdschr.Gerontol.Geriatr.* 1991;22:53-9.
16. Streiner DL. Figuring out factors: the use and misuse of factor analysis. *Can.J Psychiatry* 1994;39:135-40.
17. Streiner DL, Norman G. Health Measurement Scales: a practical guide to their development and use. Oxford: Oxford University Press, 2003.
18. McHorney CA, Tarlov AR. Individual-patient monitoring in clinical practice: are available health status surveys adequate? *Qual.Life Res* 1995;4:293-307.
19. Comstock GW, Helsing KJ. Symptoms of depression in two communities. *Psychol. Med.* 2006;6:551.
20. Bowns I, Challis D, Tong MS. Case finding in elderly people: validation of a postal questionnaire. *Br.J Gen.Pract.* 1991;41:100-4.
21. Hebert R, Bravo G, Korner-Bitensky N, Voyer L. Refusal and information bias associated with postal questionnaires and face-to-face interviews in very elderly subjects. *J Clin. Epidemiol.* 1996;49:373-81.





**Self-reports on the IQCODE in older adults:  
*a psychometric evaluation***

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## ABSTRACT

**Background** The Informant Questionnaire on Cognitive Decline (IQCODE) has been successful in identifying demented persons in a general population. We used this questionnaire as a self-report screening for dementia symptoms.

**Objective** To investigate the feasibility, homogeneity and construct validity of self-reports on the IQCODE.

**Methods** 4823 community-dwelling older adults received an IQCODE-SR. Feasibility was assessed on the basis of response rate, the proportion of missing data for each item, and the number of persons who received help in completing the questionnaire. Homogeneity was checked with Cronbach's  $\alpha$ . To investigate construct validity, hypotheses on performance of the IQCODE-SR were tested.

**Results** a) Feasibility was acceptable, with a response rate of 58.9%. Missing answers per item ranged from 2.5-7.3%, and 915 out of 2841 participants received help in completing the questionnaire. b) Homogeneity was good, with Cronbach's  $\alpha=0.94$ . c) The majority of hypotheses on construct validity were confirmed.

**Conclusion** The IQCODE-SR meets the basic requirements of a good measurement instrument.

## **INTRODUCTION**

In Europe, the estimated prevalence rate of dementia among older adults, 65-95 years of age, is 6.6%. Dementia is age-related, and the prevalence rates range from 1.4% in persons aged 65-69 years to 32% in persons aged 90-94 years.<sup>1</sup> The timely detection of dementia is therefore important for society, for patients and for their informal caregivers, because it benefits care support and the planning of future care.<sup>2</sup> In the advanced stages of dementia it is more difficult to discuss preferences for care with patients. However, dementia tends to be under-diagnosed in primary care,<sup>3-7</sup> and diagnosis often occurs late in the disease process.<sup>8</sup> An important patient-related barrier to timely recognition is the absence of a request for help. This can be attributed to denial, labelling cognitive impairment as normal ageing, lack of insight, and the idea that nothing can be done.<sup>9;10</sup> If primary care physicians wait for obvious symptoms of dementia before taking action, the diagnosis is delayed, often by several years, and this can cause delays in the initiation of support for patients and their caregivers.<sup>11</sup> Early detection by means of screening might prevent such delays in this vulnerable group of patients who do not easily request help. However, it is feared and reported that after diagnosis these patients may suffer from feelings of shock, anger, fear and negative effects on their self-esteem.<sup>12</sup> On the other hand, the vast majority of patients with mild dementia wish to be fully informed.<sup>13</sup> Furthermore, it was initially feared that these patients would become depressed after diagnosis, but most of them do not.<sup>14</sup> Although there is still insufficient evidence to recommend or disapprove of screening for dementia and cognitive impairment in asymptomatic persons, it is worthwhile continuing with research on new screening methods.<sup>11;15;16</sup>

We developed a pro-active screening method to improve the identification of patients with dementia in general practice. In a large general practice population of older people, we decided that it would be most efficient and practical to identify persons who are at high risk of dementia with a postal self-report questionnaire that could be completed either with or without assistance, followed by targeted cognitive assessments of those with a high risk. It can be expected that such an approach will be most successful in the early stages of dementia, when insight is more preserved.<sup>17</sup> We searched for a postal self-report instruments to screen for dementia in community-dwelling older adults, containing questions about cognitive decline and

functioning in the instrumental activities of daily living (IADL), because cognitive impairment is strongly associated with IADL functioning.<sup>18;19</sup> Although several methods of screening for cognitive status were found,<sup>20-22</sup> no postal method of screening, containing questions about cognitive decline and IADL functioning was found. However, one questionnaire, the Informant Questionnaire on Cognitive Decline (IQCODE) is available. It was found to be successful in identifying demented people from a sample of the general population, based on differences in mean scores and separated frequency distributions.<sup>23</sup> Moreover, it covered IADL items such as handling money for shopping and managing financial matters. Therefore, we administered this IQCODE in a different way: we used self-reports (with or without help from a proxy) instead of proxy reports.

Self-reports on the IQCODE constitute a new method of administration, which enabled us to investigate psychometric properties.

The IQCODE contains questions about cognitive changes over the previous ten years, and higher scores on the IQCODE indicate more cognitive decline. Principal component analysis has shown that the questionnaire measures one general factor of cognitive decline.<sup>23;24</sup> Reported internal-consistency figures were uniformly high, ranging from 0.93-0.97.<sup>24</sup> The original questionnaire contained 26 items, but after eliminating items with lower reliability and validity or a substantial influence of education, 16 items remained on the short form.<sup>25</sup>

The 16 item self-report IQCODE (IQCODE-SR) was used to identify older adults with a high risk of dementia in the community. We expected that the self-report version would have similar psychometric properties as the informant version of the questionnaire, so we examined its feasibility, homogeneity and construct validity. Construct validity can be described as an underlying theory on how the IQCODE-SR is expected to perform as a screening instrument for patients with a high risk of dementia in the community.<sup>26</sup> We hypothesized a priori:

1. A negative association  $r_s$   $-(0.30$  to  $0.70)$  with measures of current cognitive functioning (in tests with higher scores indicating better functioning), as on the informant version: correlations with the Mini Mental State Examination were in the range of  $-0.37$  to  $-0.78$ .<sup>24</sup>
2. Higher mean and median IQCODE-SR scores in patients with suspected dementia, according to their general practitioner (GP), than in other patients.

3. A moderate, positive association  $r_s$  (0.40 to 0.60) with ratings of disabilities in performing the activities of daily living (ADL) and the instrumental activities of daily living (IADL), because cognitive decline in the initial stages of dementia is associated with a decline in IADL and, in the later stages, also with a decline in ADL functioning.<sup>19;27</sup>
4. Higher mean and median IQCODE-SR scores in the oldest persons than in the youngest, because dementia is age-related.<sup>1</sup>
5. Similar mean and median IQCODE-SR scores for men and women.
6. A negligible association  $r_s$  (-0.10 to 0.10) with level of education and last job level, because previous studies reported a negligible correlation with education on the informant version.<sup>24</sup>
7. A small positive association  $r_s$  (0.20 to 0.45) with depression, just as on the informant version,<sup>24</sup> because depression affects cognitive functioning,<sup>28</sup> but simultaneously it would be undesirable if depression strongly affected the scores on the IQCODE-SR.
8. Higher mean and median IQCODE-SR scores in persons who completed the questionnaire with help than in those who completed the questionnaire independently, because we assumed that there would be more cognitively impaired persons in the first group.

## **METHODS**

### **Design**

This was a study of the psychometric properties (feasibility, homogeneity, and construct validity) of self-reports on the 16-item IQCODE. The self-reports were used to screen for dementia symptoms alongside a randomised clinical trial. A postal health questionnaire, including an IQCODE-SR, was sent to 4823 older adults by their GP. Independently, the GPs were asked to identify dementia cases among the persons they had approached. Participants with an IQCODE-SR score of 3.6 and over (strongly suggesting cognitive decline on informant reports) underwent cognitive tests, as well as a random sample of 200 participants with an IQCODE-SR score of less than 3.6. The Medical Ethics Committee of the VU University Medical Center in Amsterdam approved the study protocol.

## **Participants**

The source population consisted of 4823 patients of 55 GPs in West-Friesland, in the Netherlands. The patients were 75 years of age and older and lived at home. Written informed consent was obtained from the participants or, in the case of those who were incompetent, from their representatives. Scores on the IQCODE and the results of the cognitive tests were used as criteria for inclusion in a randomised clinical trial among cognitive impaired patients and their primary informal caregivers. The following exclusion criteria were also applied: assistance from an outpatient geriatric team for cognitive problems, terminal illness, insufficient command of the Dutch language, institutionalisation, participation in other research, and no caregiver. No exclusion criteria were applied for the sample of participants with an IQCODE-SR score below 3.6.

## **Instruments**

### *Postal health questionnaire*

To collect data on participant characteristics, the postal health questionnaire contained questions on socio-demographic and health status variables. Apart from the IQCODE-SR, the health questionnaire covered: age, gender, level of education, last job level,<sup>29</sup> ADL and IADL functioning measured with the Groningen Activity Restriction Scale (GARS),<sup>30</sup> and depressive symptoms measured with the Center for Epidemiologic Studies Depression Scale (CES-D).<sup>31</sup> The participants were asked to indicate whether they completed the questionnaire with or without help.

### *Self-report version of the 16-item IQCODE*

The IQCODE-SR contains the same items as the 16-item informant version, and these are rated on a 5-point scale: 1 'much better', 2 'a bit better', 3 'not changed', 4 'a bit worse', 5 'much worse'.<sup>25</sup> To calculate the IQCODE-SR total score, the scores for each item were added together and divided by the number of completed items. Up to two missing items were allowed. The result was a score that ranged from 1 to 5. A variety of cut-off points have been proposed for dementia screening, but we chose to apply a cut-off point of 3.6, which lies within the range of previously adopted cut-off points (3.4-3.9).<sup>24</sup>

*GP identification*

The GPs identified suspected cases of dementia on a list of their patients who were 75 years of age and older and lived at home.

*Cognitive tests*

Approximately 6-7 months after completing the health questionnaire, the participants underwent two brief comprehensive cognitive tests to measure current cognitive functioning: the Mini-Mental State Examination (MMSE)<sup>32</sup> and the 7 Minute Screen (7MS).<sup>33;34</sup> The MMSE is the most widely used brief screening instrument to assess mental status, and the 7MS has been reported to be a useful tool for discriminating demented and cognitively impaired patients from cognitively intact patients.<sup>34</sup> The MMSE consists of 11 items, and covers orientation, attention, calculation, memory, language, and praxis. The scores range from 0 to 30, with lower scores indicating greater impairment.<sup>32</sup> The 7MS is a compilation of four cognitive tests; Benton Temporal Orientation Test (orientation in time), Enhanced Cued Recall (memory), Clock-Drawing test (visuospatial ability), and Verbal Fluency test (expressive language). The scores of the four subtests are summed up with a formula that indicates the probability of dementia (0-100%).<sup>33;34</sup> Twenty trained interviewers administered the MMSE and the 7MS at the home of the participants, and research assistants interpreted the tests and calculated the test results. All the participants with suspected dementia, according to the tests, were advised to contact their GP, or were referred to community nurses specialized in geriatric care.

**Analyses**

The main outcomes were feasibility, homogeneity, and construct validity.

*Feasibility*

The response rate and proportion of missing data for each item were calculated, as well as the percentage and number of participants who received help in completing the IQCODE-SR. Furthermore, we performed a multiple regression analysis to identify the factors that are associated with self-reports on the IQCODE.

### *Homogeneity*

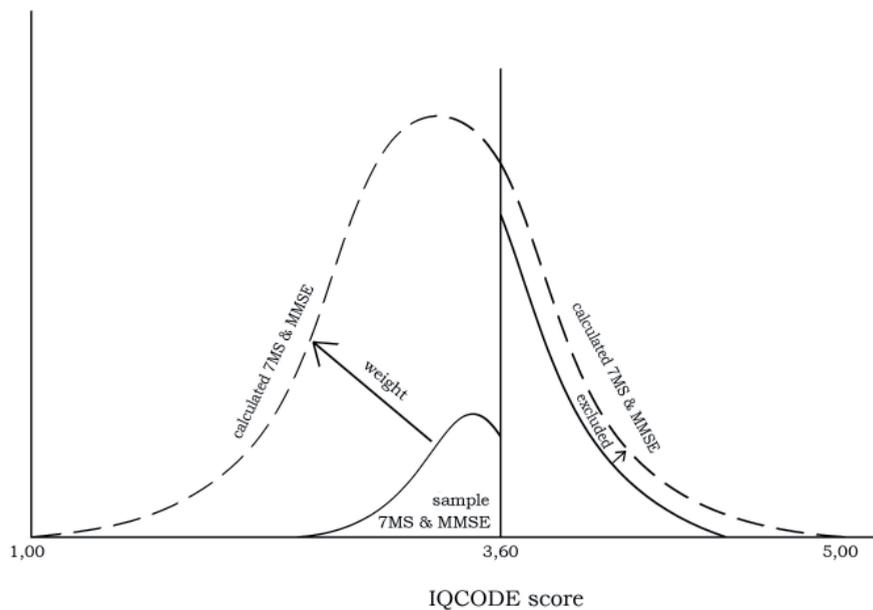
We conducted exploratory principal component analyses (PCA) to identify the number of meaningful factors of the IQCODE-SR. Identification of meaningful factors was based on the Scree test and on the interpretation of the factor solution. Using the Scree plot,<sup>35</sup> we looked for a break between the factors with relatively large eigenvalues and those with smaller eigenvalues. Factors that appeared before the break were assumed to be meaningful. We determined homogeneity per identified factor. Homogeneity of the IQCODE-SR was checked with Cronbach's  $\alpha$ , the item-total correlations, and item-item correlations, both in raw and imputed data. Missing values were replaced by series means. Cronbach's  $\alpha$  between 0.70 and 0.90 is considered to be adequate,<sup>26</sup> and the items should moderately correlate with each other and with the total score between 0.20 and 0.80.<sup>26</sup>

### *Construct validity*

We examined by means of Mann-Whitney tests whether there was a difference in median scores between men and women, participants with and without suspected dementia according to their GP, and participants who completed the questionnaire with and without help. Moreover, we investigated the agreement of the IQCODE score with the cognitive condition of the person as assessed by the GP. Therefore, we performed a ROC analysis and calculated the area under de curve (AUC) with its 95% confidence interval (CI). We also investigated associations between the IQCODE-SR and variables on the health questionnaire (ADL and IADL functioning, gender, level of education, last job level, depression) and the cognitive tests (7MS and MMSE) by calculating rank correlation coefficients (Spearman's  $r_s$ ) and their 95% confidence intervals. In calculating the correlation between the IQCODE score and level of education, last job level, and gender, we needed Spearman's correlation coefficients because these variables are on an ordinal level (ranks). Furthermore, plots of the IQCODE against 7MS, MMSE, (I)ADL, and depression required conclusively Spearman's correlations because they did not show an ellipse. We checked whether mean and median IQCODE-SR scores increased with age, and we also checked whether outcomes on the hypotheses were similar for persons who completed the IQCODE-SR with and without help.

In estimating correlations between the IQCODE-SR and cognitive tests, we corrected for unit non-response due to non-contact both in the

group of persons with IQCODE scores below 3.6 and in the group of persons with scores of 3.6 and over. Unit non-response is the situation in which entire questionnaires or test results are missing in a particular group.<sup>36</sup> In the group with scores below 3.6, some test results are missing because we only contacted a random sample of persons in this group. Meanwhile, some test results in the group with scores of 3.6 and over are missing because we did not contact persons who met the criteria for exclusion from our randomised trial. To estimate 7MS and MMSE scores for all persons who completed the IQCODE-SR, including those who were not cognitively assessed, we made a post-stratification estimation.<sup>36</sup> This weighting procedure is illustrated in Figure 1. We post-stratified for IQCODE score, i.e. we weighted on the basis of persons with IQCODE scores below 3.6, versus those with scores of 3.6 and over. Therefore, all persons in the same group were given the same weight.



**Figure 1** Post-stratification estimation

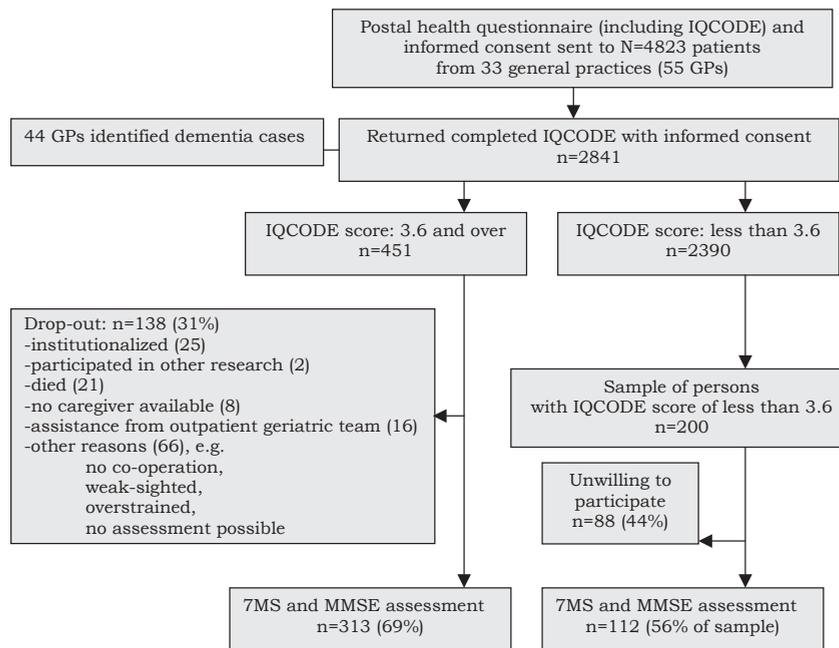
7MS= seven Minute Screen; MMSE=Mini Mental State Examination; IQCODE= Informant Questionnaire on Cognitive Decline in the Elderly

## RESULTS

Figure 2 shows a flow-chart of this study of the psychometric properties of the IQCODE-SR, in which 4823 persons, aged 75 years and older who lived at home, were approached. 2841 participants returned an IQCODE-SR and gave informed consent. Table 1 presents the characteristics of these 2841 participants. Their self-reports were used to investigate feasibility, homogeneity, and construct validity. 44 of the 55 GPs co-operated by identifying dementia cases on a list of their participating patients. 313 of the 451 participants with IQCODE-SR scores of 3.6 and over underwent cognitive tests, as well as 112 participants from a random sample of 200 persons with IQCODE-SR scores of less than 3.6 who agreed to undergo cognitive assessment. Although the random sample of 200 persons resembled the total group of persons with scores of less than 3.6, the 112 participants who underwent cognitive tests did not. Persons who completed the questionnaire with help had a lower probability of participation in cognitive tests (OR=0.54, 95% CI: 0.32-0.89), whereas persons with a higher level of education had a higher probability of participation in cognitive tests (OR=1.53, 95% CI: 1.00-2.35). In addition, persons in the group with scores of 3.6 and over who were tested did not resemble the total group of persons with scores of 3.6 and over. Persons who completed the questionnaire with help had a lower probability of being tested (OR=0.97, 95% CI: 0.95-0.98), as did persons with (I)ADL limitations (per point on the GARS: OR=0.42, 95% CI: 0.23-0.73).

### Feasibility

Of the 4823 older adults who were approached for the screening, 2841 returned a health questionnaire, including a completed IQCODE-SR, and gave informed consent (58.9%). Slightly older persons more often failed to return the questionnaire (mean age of non-respondents 83.5 versus mean age of respondents 81.8,  $t=13.8$ ;  $p<0.001$ ), as did females (percentage of non-respondents among females 41.3% versus 35.8% among males,  $\chi^2=13.4$ ;  $p<0.001$ ). The percentage of suspected cases of dementia, according to the GPs, was higher among non-respondents than respondents (10.9% versus 6.6%,  $p<0.001$ ). At item level, the items 'learning to use a new gadget or machine around the house' and 'learning new things in general' were the items that were most often not answered (7.3% and 7.0%, respectively). The first and last item of the IQCODE-SR, 'remembering things about family



**Figure 2** Flow-chart of the study

IQCODE= Informant Questionnaire on Cognitive Decline in the Elderly; GPs= General Practitioners; 7MS= seven Minute Screen; MMSE= Mini Mental State Examination

**Table 1** Characteristics of persons who completed an IQCODE-SR (n=2841)

Characteristics	Value	N	% missing
<i>Socio-demographics</i>			
Age, mean + SD (range)	80.9 + 4.0 (74.7-99.4)	2841	0%
Gender, female (%)	61.7	2841	0%
Married (%)	42.6	2647	6.8%
Widow(er) (%)	41.5	2647	6.8%
Having an informal caregiver (%)	61.7	2579	9.2%
Level of education: primary school or no education (%)	40.3	2649	6.8%
Last job level: semi-skilled or skilled jobs (%)	91.0	2594	8.7%
<i>General (health) functioning</i>			
Self-reported health: fairly or good health (%)	82.3	2647	6.8%
Chronic disease: one or more chronic diseases (%)	75.1	2619	7.8%
ADL, GARS, mean + SD (range)	15.2 + 5.6 (11-44)	2577	9.3%
IADL, GARS, mean + SD (range)	12.3 + 5.5 (7-28)	2459	13.4%
Depression, CES-D, mean + SD (range)	13.0 + 7.6 (0-49)	2777	2.3%
Cognitive decline, IQCODE, mean + SD (range)	3.3 + 0.4 (1-5)	2841	0%

SD= Standard Deviation; ADL=functioning in activities of daily living; GARS= Groningen Activity Restriction Scale; IADL= Instrumental activities of daily living; CES-D=Center for Epidemiologic Studies Depression Scale; IQCODE=Informant Questionnaire on Cognitive Decline in the Elderly

and friends' and 'using his/her intelligence to understand what's going on and to reason things through', were answered most often (2.5% and 3.0% missing, respectively). No differences were found between men and women in item response. 1723 persons completed their questionnaire independently, 915 had help, and 203 did not answer this question.

Factors associated with the self-rated IQCODE score were depressive symptoms, (I)ADL functioning, age, gender, and help in completing the questionnaire (adjusted R-square: 0.27;  $\text{IQCODE} = 2.33 + 0.02 * \text{depressive symptoms} (p < 0.001) + 0.01 * (\text{I})\text{ADL functioning} (p < 0.001) + 0.01 * \text{age} (p = 0.003) - 0.11 * \text{gender} (p < 0.001; \text{codes: } 1 = \text{men, } 2 = \text{women}) + 0.19 * \text{help} (p < 0.001; \text{codes: } 1 = \text{no help, } 2 = \text{help})$ ). Thus, respondents with more depressive symptoms, respondents with more (I)ADL disabilities, male respondents, respondents who had help in completing the questionnaire, and older respondents were more likely to have high IQCODE scores.

### **Homogeneity**

The IQCODE-SR measured one single construct. Principal component analyses showed a large general factor accounting for 53% of the variance, with subsequent factors accounting for much smaller percentages (1.6-7.3%). In addition, the Scree plot showed a distinct break before factor 2, suggesting that only one factor was meaningful. For homogeneity we found: Cronbach's  $\alpha = 0.94$ , range of item-total correlations (0.62-0.72), and range of item-item correlations (0.36-0.71). The results were similar for imputed and raw data.

### **Construct validity**

The realized outcomes and acceptance of the 8 hypotheses are summarized in Table 2. We also checked whether the realized outcomes were similar across persons who completed the IQCODE-SR with and without help, and found that they were similar, with the exception of the hypothesis concerning age. Among persons who completed the IQCODE-SR independently the mean scores did not increase with age; they only increased with age in persons who completed the IQCODE with help.

**Table 2** Tested hypotheses on construct validity of the IQCODE-SR

We expected:	Value outcome found	Hypothesis accepted?*
1. A negative association $r_s$ (-0.30-0.70) with measures of current cognitive functioning	Association with current cognitive functioning: -7MS ( $r_s$ -0.36, 95% Confidence Interval (CI): -[0.48, 0.28]; n=424); -MMSE ( $r_s$ -0.32, 95% CI: -[0.43, 0.24]; n=424).	+
2. Higher mean and median IQCODE-SR scores in patients with suspected dementia, according to their general practitioner (GP), than in other patients.	-Mean and median scores were higher in patients suspected by their GP (3.7, respectively 3.6) than in other patients (3.3, respectively 3.1), (Mann-Whitney U=75120.000; p<0.001). -AUC: 0.72, 95% CI: [0.66-0.77]	+
3. A moderate positive association $r_s$ (0.40 to 0.60) with ratings of disabilities in (I)ADL functioning.	Association with IADL functioning: ( $r_s$ =0.34; 95% CI: [0.31-0.39]; n=2459); Association with ADL functioning: ( $r_s$ =0.27; 95% CI: [0.24-0.32]; n=2577).	-
4. Higher mean and median IQCODE-SR scores in the oldest persons than in the youngest.	Mean and median IQCODE scores increased with age; we recoded age into categories of five years and found that mean and median IQCODE scores increased from: 3.2, respectively 3.1 (age 75-80, n=1369), 3.3, respectively 3.2 (age 80-85, n=1042), 3.4, respectively 3.3 (85-90, n=338), 3.5, respectively 3.4 (90-95, n=84), to 3.8, respectively 3.7 (95-99, n=8).	+
5. Similar mean and median IQCODE-SR scores for men and women.	Mean and median IQCODE-SR scores were similar for men (3.3, respectively 3.2) and women (3.3, respectively 3.1), (Mann-Whitney U=925200.5; p=0.172).	+
6. A negligible association $r_s$ (-0.10 to 0.10) with level of education and last job level.	Association with level of education: ( $r_s$ -0.10; 95% CI: -[0.14-0.06]; n=2649). Association with last job level: $r_s$ -0.02; 95% CI: [-0.06-0.02]; n=2594).	+
7. A small positive association $r_s$ (0.20-0.45) with depression.	Association with depression: ( $r_s$ 0.38; 95% CI: [0.36-0.44]; n=2777).	+
8. Higher mean and median IQCODE-SR scores in persons who completed the questionnaire with help than in those who completed the questionnaire independently.	Mean and median scores were higher (3.5, respectively 3.3) in persons who completed the questionnaire with help than in persons who completed the questionnaire independently (3.2, respectively 3.1), (Mann-Whitney U=1071.500; p=0.041).	+

IQCODE-SR= self-report version of the Informant Questionnaire on Cognitive Decline in the Elderly; MMSE= Mini Mental State Examination; 7MS= seven Minute Screen; (I)ADL functioning= (Instrumental) activities of daily living

\* hypothesis accepted:  
+ accepted  
- rejected

## DISCUSSION

Self-reports on the IQCODE is a new way of identifying older adults with dementia in the community, and therefore we investigated psychometric properties (feasibility, homogeneity, and construct validity) of these self-reports.

### Feasibility

The achieved response rate of 58.9% for the health questionnaire was in line with what was expected with such an approach in a population of older adults,<sup>37</sup> although a higher response may be possible.<sup>38</sup> Selective non-response to the screening is likely, because the percentage of suspected cases of dementia, according to the GPs, was higher among non-respondents than among respondents. In addition, non-respondents in another study were found to have higher rates of functional and cognitive impairment.<sup>39;40</sup> This limits the potential for implementation, because such a selective non-response could result in poor detection of dementia symptoms. A third of the participants received help in completing the questionnaire, but we do not consider this to be an immediate threat to feasibility. A threat to validity is the risk that the cognitively impaired persons without insight might have completed a questionnaire while over-estimating their cognitive functioning, and cognitively impaired persons who realized that they needed help in completing the questionnaire did not ask for assistance. However, we do not have any information on this issue. The proportion of unanswered items on the IQCODE-SR was acceptable (2.5-7.3% missing answers for each item).

Respondents with more depressive symptoms, respondents with more (I)ADL disabilities, male respondents, respondents who had help in completing the questionnaire with help, and older respondents were more likely to have high IQCODE scores. These factors affect the IQCODE score.

### Homogeneity

The IQCODE-SR measured one distinct construct and showed good homogeneity, just like the informant version,<sup>24;41</sup> and Cronbach's  $\alpha$  was above 0.90. This can be attributed to a high level of item redundancy or too many items in the scale.<sup>26</sup> Therefore, if items are to be deleted, the ones with the highest percentages of missing answers are the first candidates to be investigated. In our study, the items 'learning to use a new gadget or

machine around the house' and 'learning new things in general' were the items with the highest percentages of missing answers.

### **Construct validity**

The majority of hypotheses on construct validity were confirmed, but one was rejected. We expected a moderate positive association between IQCODE-scores and (I)ADL functioning, but found a weak positive association. However, we do not know how the informant version performs with regard to (I)ADL functioning, because no previous research has focused on this subject.

The strength of this study is the application of the IQCODE-SR to a large general practice population of older adults. However, the study also has a few limitations. Firstly, selective non-response to the screening is likely. Non-respondents in another study had higher rates of functional and cognitive impairment.<sup>40</sup> Secondly, information bias may have occurred, because cognitively impaired persons without insight might have completed a questionnaire, while over-estimating their cognitive functioning. We remain uncertain about the validity and number of self-reports of cognitively impaired subjects without insight. Thirdly, cognitive assessment of all participants was not possible. Participants who were at risk of having dementia, such as those who received assistance from an outpatient geriatric team, were excluded from cognitive assessments. The exclusion of these persons, who more often had (I)ADL limitations and received help in completing the questionnaire, may have weakened the estimated correlations between the IQCODE-SR and current cognitive functioning. Lastly, 425 participants underwent cognitive tests 6-7 months after completing the IQCODE-SR. However, we expect that this interval had very little influence on correlations between the IQCODE and cognitive tests with regard to the rather low incidence of dementia.

In conclusion, the IQCODE-SR meets the basic requirements of a good measurement; the psychometric properties of the IQCODE-SR demonstrated acceptable feasibility and good homogeneity, and most of the hypotheses on construct validity were confirmed. The questionnaire could perhaps be made more efficient by omitting redundant items. Nevertheless, further research is necessary to determine the IQCODE-SR's accuracy to identify older adults who are at risk of dementia. We recommend specialist diagnosis of all participants as the validity standard in future studies on

diagnostic accuracy. The influence of selective non-response to the IQCODE-SR from who are at risk of dementia should also be considered. In addition, the extent to which cognitively impaired persons can validly complete the IQCODE with and without assistance needs further evaluation. Therefore, we recommend a comparison of the conventional IQCODE with the self-rated IQCODE.

Consensus on the value of screening for dementia among older adults has not yet been achieved. The potentially negative effects of labelling have to be weighted against the importance for patient and family of prior knowledge and preparation.<sup>42</sup> Therefore, we recommend evaluation of this importance in future research, as well as assessment of the perception of the respondents with regard to feedback on their cognitive capacities, in order to investigate the consequences of early detection of dementia. This information will contribute to the debate on screening.

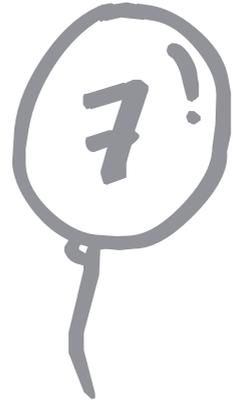
## REFERENCES

1. Hofman A, Rocca WA, Brayne C, Breteler MM, Clarke M, Cooper B *et al*. The prevalence of dementia in Europe: a collaborative study of 1980-1990 findings. Eurodem Prevalence Research Group. *Int.J.Epidemiol.* 1991;20:736-48.
2. Audit Commission. Forget Me Not 2002: Developing Mental Services for Older People in England. London: Audit Commission, 2002.
3. Chodosh J, Petitti DB, Elliott M, Hays RD, Crooks VC, Reuben DB *et al*. Physician recognition of cognitive impairment: evaluating the need for improvement. *J Am.Geriatr.Soc.* 2004;52:1051-9.
4. Eefsting JA, Boersma F, Van den Brink W, Van Tilburg W. Differences in prevalence of dementia based on community survey and general practitioner recognition. *Psychol. Med.* 1996;26:1223-30.
5. O'Connor DW, Pollitt PA, Hyde JB, Brook CP, Reiss BB, Roth M. Do general practitioners miss dementia in elderly patients? *BMJ* 1988;297:1107-10.
6. Valcour VG, Masaki KH, Curb JD, Blanchette PL. The detection of dementia in the primary care setting. *Arch.Intern.Med.* 2000;160:2964-8.
7. van Hout H. Studies on recognition of dementia by primary care physicians are inconsistent. *Arch.Intern.Med.* 2001;161:1238-9.
8. Vernooij-Dassen MJ, Moniz-Cook ED, Woods RT, De Lepeleire J, Leuschner A, Zanetti O *et al*. Factors affecting timely recognition and diagnosis of dementia across Europe: from awareness to stigma. *Int.J Geriatr.Psychiatry* 2005;20:377-86.
9. Iliffe S, Manthorpe J, Eden A. Sooner or later? Issues in the early diagnosis of dementia in general practice: a qualitative study. *Fam.Pract.* 2003;20:376-81.

10. van Hout H, Vernooij-Dassen M, Bakker K, Blom M, Grol R. General practitioners on dementia: tasks, practices and obstacles. *Patient.Educ.Couns.* 2000;39:219-25.
11. Borson S. Should older adults be screened for cognitive impairment? *Med.Gen.Med* 2004;6:30.
12. Husband HJ. Diagnostic disclosure in dementia: an opportunity for intervention? *Int. J Geriatr.Psychiatry* 2000;15:544-7.
13. Pinner G, Bouman WP. Attitudes of patients with mild dementia and their carers towards disclosure of the diagnosis. *Int.Psychogeriatr.* 2003;15:279-88.
14. Smith AP, Beattie BL. Disclosing a diagnosis of Alzheimer's disease: patient and family experiences. *Can.J Neurol.Sci.* 2001;28 Suppl 1:S67-S71.
15. Patterson CJ, Gass DA. Screening for cognitive impairment and dementia in the elderly. *Can.J Neurol.Sci.* 2001;28 Suppl 1:S42-S51.
16. Petersen RC, Stevens JC, Ganguli M, Tangalos EG, Cummings JL, DeKosky ST. Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2001;56:1133-42.
17. Zanetti O, Vallotti B, Frisoni GB, Geroldi C, Bianchetti A, Pasqualetti P *et al.* Insight in dementia: when does it occur? Evidence for a nonlinear relationship between insight and cognitive status. *J Gerontol.B Psychol.Sci.Soc.Sci.* 1999;54:100-6.
18. Dodge HH, Kadowaki T, Hayakawa T, Yamakawa M, Sekikawa A, Ueshima H. Cognitive impairment as a strong predictor of incident disability in specific ADL-IADL tasks among community-dwelling elders: the Azuchi Study. *Gerontologist* 2005;45:222-30.
19. Kurz X, Scuvee-Moreau J, Rive B, Dresse A. A new approach to the qualitative evaluation of functional disability in dementia. *Int.J Geriatr.Psychiatry* 2003;18:1050-5.
20. Brodaty H, Low LF, Gibson L, Burns K. What is the best dementia screening instrument for general practitioners to use? *Am.J Geriatr.Psychiatry* 2006;14:391-400.
21. Drachman DA, Swearer JM. Screening for dementia: Cognitive Assessment Screening Test (CAST). *Am.Fam.Physician* 1996;54:1957-62.
22. Lorentz WJ, Scanlan JM, Borson S. Brief screening tests for dementia. *Can.J Psychiatry* 2002;47:723-33.
23. Jorm AF, Jacomb PA. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): socio-demographic correlates, reliability, validity and some norms. *Psychol.Med.* 1989;19:1015-22.
24. Jorm AF. The Informant Questionnaire on cognitive decline in the elderly (IQCODE): a review. *Int.Psychogeriatr.* 2004;16:275-93.
25. Jorm AF. A short form of the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): development and cross-validation. *Psychol.Med.* 1994;24:145-53.
26. Streiner DL, Norman G. Health Measurement Scales: a practical guide to their development and use. Oxford: Oxford University Press, 2003.
27. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Washington, DC: American Psychiatric Association, 2000.

## Chapter 6

28. Marvel CL, Paradiso S. Cognitive and neurological impairment in mood disorders. *Psychiatr Clin.North Am.* 2004;27:19-36, vii-viii.
29. Dutch central bureau for statistics. Job level classification system 1992. Voorburg/Heerlen: Dutch Central Bureau for Statistics, 2001.
30. Kempen GI, Miedema I, Ormel J, Molenaar W. The assessment of disability with the Groningen Activity Restriction Scale. Conceptual framework and psychometric properties. *Soc.Sci.Med.* 1996;43:1601-10.
31. Radloff LS. The CES-D Scale: a Self-Report Depression Scale for Research in the General Population. *Appl.Psych.Meas.* 1977;1:385-401.
32. Folstein M, Folstein S, McHugh P. "Mini-Mental" State: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.
33. Solomon PR, Pendlebury WW. Recognition of Alzheimer's disease: the 7 Minute Screen. *Fam.Med.* 1998;30:265-71.
34. Solomon PR, Hirschhoff A, Kelly B, Relin M, Brush M, DeVeaux RD *et al.* A 7 minute neurocognitive screening battery highly sensitive to Alzheimer's disease. *Arch.Neurol.* 1998;55:349-55.
35. Streiner DL. Figuring out factors: the use and misuse of factor analysis. *Can.J Psychiatry* 1994;39:135-40.
36. Bethlehem JG. Cross-sectional research. In Adèr HJ, Mellenbergh GJ, eds. *Research Methodology in the Social, Behavioural & Life Sciences*, pp 110-42. London: Sage Publications, 1999.
37. Hardie JA, Morkve O. Non-response bias in a postal questionnaire survey on respiratory health in the old and very old. *Scand.J Public Health* 2003;31:411-7.
38. Smeeth L, Fletcher AE, Stirling S, Nunes M, Breeze E, Ng E *et al.* Randomised comparison of three methods of administering a screening questionnaire to elderly people: findings from the MRC trial of the assessment and management of older people in the community. *BMJ* 2001;323:1403-7.
39. Bowns I, Challis D, Tong MS. Case finding in elderly people: validation of a postal questionnaire. *Br.J Gen.Pract.* 1991;41:100-4.
40. Hebert R, Bravo G, Korner-Bitensky N, Voyer L. Refusal and information bias associated with postal questionnaires and face-to-face interviews in very elderly subjects. *J Clin. Epidemiol.* 1996;49:373-81.
41. Jorm AF, Scott R, Cullen JS, MacKinnon AJ. Performance of the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) as a screening test for dementia. *Psychol.Med.* 1991;21:785-90.
42. Wilson JM, Jungner G. Principles and Practice of Screening for Disease. Public Health Paper. No. 34. Geneva: WHO, 1968.



**Yield of a new method to detect cognitive  
impairment in general practice**

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## ABSTRACT

**Objective** To examine whether a new screening method that identified patients with cognitive impairment who needed further examination on the presence of dementia yielded patients who were not detected by their general practitioner (GP), and to identify factors associated with GPs' awareness of patients identified by the screening.

### Methods

*Design* Cross-sectional comparison between two methods to identify dementia symptoms:

1. Usual identification of dementia by GPs. 2. A two-stage screening to identify cognitive impairment. The two methods were implemented on the same older general practice population.

*Setting* Primary care practices in the Netherlands.

*Participants* Forty-four GPs and 2101 general practice patients aged 75 years and older who lived at home.

*Measurements.* 1. Yield of the screening, 2. Determinants of GPs' awareness of patients identified by the screening.

**Results** The two-stage screening yielded 117 patients with cognitive impairment who needed further examination; in most cases (n=82, 70.1%) their GP was unaware of the symptoms. Among patients identified by the screening, GPs' awareness was associated with co-morbidity of chronic diseases (odds ratio (OR) = 3.19; 95% confidence interval (CI) = 1.25 to 8.15), depressive symptoms (OR = 0.41; 95% CI = 0.17 to 0.99), and cognitive functioning (per point on the MMSE, OR = 0.88; 95% CI = 0.79 to 0.98).

**Conclusion** A two-stage screening method and increased alertness for cognitive impairment and dementia among patients with depressive symptoms may improve detection rate of dementia in general practice.

## **INTRODUCTION**

Primary care physicians are frequently unaware of the presence of cognitive impairment and mild dementia in their older patients. Estimations reveal that 40 to 70% of the patients with dementia are unknown to their general practitioner (GP).<sup>1-5</sup> GPs consider detection of dementia desirable, but few test patients unless impairment is already apparent. This leads to diagnostic delay, often by several years.<sup>6</sup> Timely diagnosis may enable patients and their caregivers to prepare future care and to benefit from facilities that offer information and support when patients' insight is still relatively preserved.

Up till now, innovations to improve detection rates in general practice have primarily focused on the usage of brief screening tools for routine use in patients who attend the practice. Application of these tools is limited.<sup>7</sup> Also, educational interventions that tried to improve GPs' diagnostic accuracy were inconclusive.<sup>8;9</sup> There is a lack of consensus regarding the value of screening for dementia.<sup>6;10-14</sup>

Although the evidence supporting screening of all older persons for dementia is inconclusive, there is value in studying new screening methods and in determining factors that may improve the detection rates in the primary care setting. We designed a two-stage screening to identify persons with cognitive impairment who needed further examination on the presence of dementia. In this study, we examined whether the screening that identified patients with cognitive impairment yielded patients who were not detected by their GP. Moreover, we assessed which factors were associated with GPs' awareness of patients identified by the screening.

## **METHODS**

### **Design**

This study was a cross-sectional comparison between two methods: 1. Usual identification of dementia by GPs, and, 2. A two-stage screening to identify patients with cognitive impairment who needed further examination. Both methods were set up to determine eligibility for entry in a randomised clinical trial.<sup>15</sup> The methods were carried out on the same population. GPs and screeners were blinded to the information of the method they were compared with. Patients completed an informed consent form. Representatives gave

informed consent of incompetent patients. The Medical Ethics Committee of the VU University medical center in Amsterdam approved the study.

## **Participants**

The source population consisted of 3449 patients of 44 GPs in West-Friesland, the Netherlands. Patients were 75 years of age and older and lived at home.

## **Two methods**

### *1. GPs' identification of dementia*

Based on their actual knowledge and filed patient information, GPs identified prevalent and suspected cases of dementia on a list of their patients who were 75 years of age and older and lived at home. They also indicated patients of whom insufficient information was available to provide a judgment.

### *2. Two-stage screening to identify subjects with cognitive symptoms*

We decided the most efficient strategy would be to identify high-risk persons with a postal questionnaire, followed by targeted cognitive assessments among these high-risk persons. In stage one, patients received a postal health questionnaire, including a self-report version of the short Informant Questionnaire on Cognitive Decline (IQCODE).<sup>16</sup> This questionnaire has been successfully in distinguishing demented persons from a general population sample.<sup>16</sup> We used self-reports (with or without help from a proxy) instead of proxy reports. Patients with an IQCODE score of 3.6 and over (strongly suggesting cognitive decline) proceeded to stage two. In stage two, they were assessed at home with the Mini Mental State Examination (MMSE)<sup>17</sup> and the seven minute screen (7MS).<sup>18</sup> The MMSE is the most widely used brief screening test of mental status, and the 7MS has shown to be a useful tool for discriminating demented and cognitively impaired patients from cognitively intact patients.<sup>18</sup> Twenty trained screeners visited participants for cognitive assessments.

## **Instruments**

### *Stage 1: Postal health questionnaire*

Except for the IQCODE, the postal health questionnaire also included questions on socio-demographic variables (i.e. age, sex, educational level, last job, living with a partner) and the following health status variables: chronic diseases; self-reported health; ability to perform basic and instrumental activities of daily living (ADL and IADL functioning), measured by the Groningen Activity Restriction Scale (GARS);<sup>19</sup> and, lastly, depressive symptoms, using the Center for Epidemiologic Studies Depression Scale (CES-D).<sup>20</sup> Representatives were allowed to provide assistance in completing the questionnaire.

### *IQCODE*

The self-report 16-item IQCODE asks about cognitive changes in an older person over the previous ten years. Items are rated on a five-point scale from one 'much better', through three 'not changed', to five 'much worse'. Scores for each item were added and divided by the number of completed items. Up to two missing items were allowed. Scores ranged from one to five.

### *Stage 2: Cognitive assessment*

The MMSE covers orientation, attention, calculation, memory, language, and praxis. Scores range from zero to 30.<sup>17</sup> The 7MS is a compilation of four cognitive tests; Benton Temporal Orientation Test (orientation in time), Enhanced Cued Recall (memory), Clock-Drawing test (visuospatial ability) and Verbal Fluency test (expressive language). Scores of the four subtests are summed with a formula that gives the probability of having dementia (0-100%).<sup>18</sup> Patients who scored less than 24 on the MMSE or who had a probability of having dementia of 70% or more according to the 7MS, were regarded as having cognitive impairment.

Exclusion criteria for stage 2 of the screening were: assistance by an outpatient geriatric team for cognitive problems, terminal illness, insufficient command of the Dutch language, participation in other research, and having no caregiver. In order to estimate the number of 'false negatives' on the IQCODE, a random sample of persons with IQCODE scores less than 3.6 was approached for cognitive assessments. No exclusion criteria were applied for this sample.

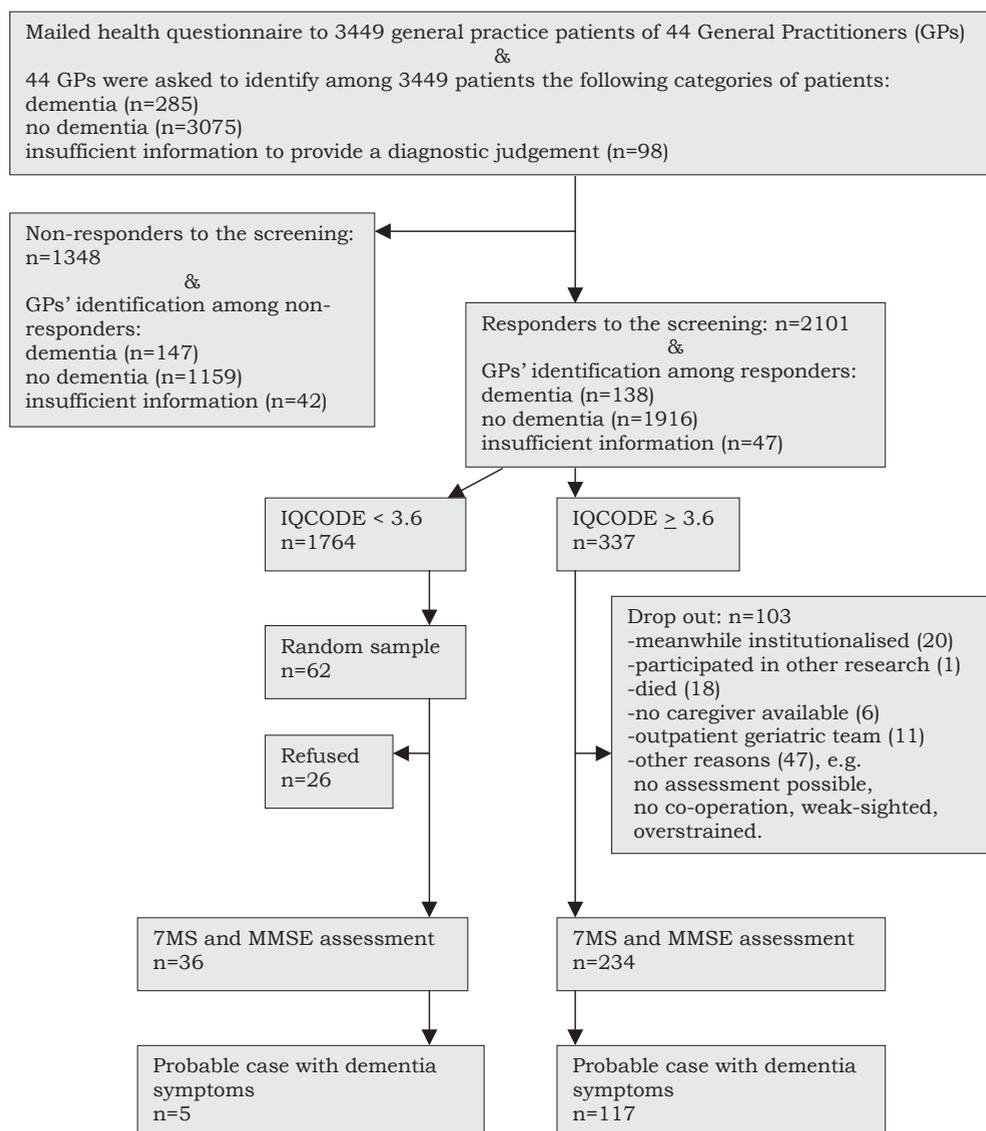
### **Statistical analyses**

We calculated the yield of the screening, i.e. the number of patients identified by the screening but not by their GP. To identify factors associated with GPs' awareness of patients identified by the screening, a multivariable logistic regression analysis was performed. A final model was constructed using a manual backward selection method until further elimination of a variable resulted in a statistically significant lower model fit estimated with the log likelihood ratio test ( $p < 0.05$ ). Variables were regarded as potential determinants when they are impaired in dementia (e.g. cognitive functioning, and ADL and IADL functioning),<sup>21</sup> may affect prevalence (i.e. sex, last job level, and educational level),<sup>22;23</sup> may affect GP contact frequency (i.e. living with a partner, and chronic diseases),<sup>2</sup> and, lastly, when they were found to be determinants in previous research (depression and chronic diseases).<sup>1</sup>

### **RESULTS**

Figure 1 shows a flow-chart of the study. GPs identified 285 out of 3449 (8.3%) patients as suspected of dementia (range: 1.5 - 28.6% per GP). They could not provide a judgment of 89 (2.6%) patients due to insufficient information (range: 0 - 13% per GP). GPs' characteristics are shown in Table 1. From the 3449 persons approached for the screening, 2101 returned a questionnaire (60.9%). From these 2101 participants, 337 (16.0%) reported cognitive decline in the first stage of the screening, and 234 of these 337 patients could be cognitively assessed subsequently. Finally, the screening identified 117 out of 2101 (5.6%) patients as having cognitive impairment.

*Yield of a new method to detect cognitive impairment in general practice*



**Figure 1** Flow-Chart of the Study

7MS=seven Minute Screen; MMSE=Mini Mental State Examination

**Table 1** Characteristics of participating General Practitioners (GPs)

Characteristics	Value
Age, mean $\pm$ SD (range)	47.5 $\pm$ 7.4 (33.0-61.0)
Sex, male (%)	66
Assistance by a practice nurse (%)	27
Types of practices	
• Single-handed practices (%)	43
• GPs in partnership (%)	57

SD=Standard Deviation

### **Number of patients identified by the screening but not by their GP**

Table 2 shows the yield of the screening method in comparison with general practitioners' identification. The two-stage screening identified 117 patients with dementia symptoms. In 82 patients (70.1%) GPs were unaware of the symptoms.

### **'False negatives' on the IQCODE**

36 persons out of a random sample of 62 persons with IQCODE scores less than 3.6 underwent cognitive assessments, and 5 persons were cognitively impaired. None of them was identified by their GP.

### **Patient characteristics associated with GPs' awareness**

The screening yielded 82 patients with cognitive impairment who were not detected by their GP, and 35 who were already noticed. Table 3 presents the univariate and multivariate associations of variables with GPs' awareness. Among patients identified by the screening, GPs' awareness was associated with co-morbidity of chronic diseases (odds ratio (OR) = 3.19; 95% confidence interval (CI) = 1.25 to 8.15), depressive symptoms (OR = 0.41; 95% CI = 0.17 to 0.99), and cognitive functioning (per point on the MMSE, OR = 0.88; 95% CI = 0.79 to 0.98).

**Table 2** Yield of the Screening Method in comparison with General Practitioners' Identification

GP	Screening Method		Stage I <sup>†</sup>		Stage II <sup>‡</sup>		Drop-out
	Responders		Negative <sup>†</sup>	Positive <sup>‡</sup>	Positive <sup>  </sup>	Negative <sup>†</sup>	
Dementia	138		64	74	35	7	32
No dementia	1916		1657	259	80	109	70
Insufficient information	47		43	4	2	1	1
Total compared persons	2101		1764	337	117	117	103

\* Postal IQCODE.

† Patients who scored 3.6 or higher on the IQCODE.

‡ Cognitive tests.

|| Patients who scored less than 24 on the MMSE or who had a probability of having dementia of 70% or more according to the 7MS.

† Patients who scored more than 23 on the MMSE and who had a probability of having dementia of less than 70% according to the 7MS.

**Table 3** Candidate Determinants of General Practitioners' Awareness of 117 Patients identified by the Screening

Determinants	Univariate		Multivariate	
	Odds Ratio (95% Confidence Interval)	P	Odds Ratio (95% Confidence Interval)	P
<i>Socio-demographics</i>				
Age median split ( $\geq 82.47$ versus $< 82.47$ )	1.47 [0.66-3.26]	.344		
Sex Female versus male	0.96 [0.43-2.16]	.921		
Living with a partner Yes versus no	1.81 [0.77-4.26]	.172 <sup>†*</sup>		
Last job level Skilled/higher jobs versus unskilled/semi-skilled jobs	1.56 [0.59-4.12]	.367		
Educational level Secondary/higher education versus primary school/no education	1.48 [0.63-3.47]	.373		
<i>General functioning</i>				
Cognitive functioning (MMSE: 0-30) per point	0.91 [.83-1.00]	.056 <sup>*</sup>	0.88 [0.79-.98]	.024
(I)ADL functioning (GARS: 18-72) median split ( $< 32.00$ versus $\geq 32.00$ )	0.82 [0.34-1.99]	.633		
Depression (CES-D : 0-60) $\geq 16$ versus $< 16$	0.51 [0.22-1.15]	.104 <sup>*</sup>	0.41 [0.17-0.99]	.048
Completing the questionnaire With help versus without help	2.69 [0.73-9.93]	.137 <sup>†*</sup>		
<i>Chronic diseases</i>				
Chronic disease, one or more chronic diseases Yes versus no	1.15 [0.43-3.08]	.781		
Co-morbidity chronic diseases, two or more chronic diseases Yes versus no	1.72 [0.76-3.85]	.191 <sup>*</sup>	3.19 [1.25-8.15]	.015

\* Variables associated with GPs' (un)awareness ( $p < 0.20$ ) and selected as candidate determinants for the multivariable analysis.

† Eliminated from the multivariable model as elimination resulted in a statistically significant lower model fit estimated with the log likelihood test ( $p < 0.05$ ).

### Response to the screening

Table 4 presents the response rate of the screening for the categories as identified by the GP. Among non-responders the GPs identified more persons with dementia than among responders (10.9% versus 6.6%,  $p < 0.001$ ).

**Table 4** Response to the Screening

General Practitioner	Response to the Screening					
	Responders		Non-responders		Total	
Dementia	138	(48.4%)	147	(51.6%)	285	(100%)
No dementia	1916	(62.3%)	1159	(37.7%)	3075	(100%)
Insufficient information	47	(52.8%)	42	(47.2%)	89	(100%)
Total	2101	(60.9%)	1348	(39.1%)	3449	(100%)

### CONCLUSION

This study showed that a new screening method yielded a substantial number of patients with cognitive impairment who needed further examination on the presence of dementia, and who were not already identified with dementia by their GP. Further examination may result in improvement of detection rates of dementia. If so, a simple strategy may improve detection of dementia. If GPs themselves or a third party such as a practice nurse had sent IQCODEs to the target group, every GP would have had to invite approximately six (Table 2: 259+4 / 44 GPs) responding older adults for additional cognitive assessments and examination.

However, the screening has limitations and we do not recommend implementing it before the majority of Wilson and Jungner's criteria on screening are met.<sup>24</sup> The screening may not reach those who need it most: the more severely impaired subjects may have been unable to complete the screening. Selective non-response to the screening is likely, as the percentage of suspected cases of dementia according to the GPs was higher among non-responders than responders. In addition, non-responders in another study had higher rates of functional and cognitive impairment.<sup>25</sup>

This study has a few limitations. Firstly, for the moment we remain uncertain about accuracy of both the screening and GP's identification by lack of a gold

standard for dementia. Clinical follow-up will show which patients develop dementia. Nevertheless, we regard monitoring of all patients identified by the screening as useful. At the end of the trial, 31 of the 82 persons who were identified with the screening and whose GPs were unaware of the symptoms were diagnosed with dementia.

Secondly, GPs' awareness of patients identified by the screening might have been underestimated. In stage two, 32 out of 103 (31%) dropouts for assessment were suspected of dementia by their GP. Probably, the screening identified mainly the mild to moderately cognitively impaired persons within the sample frame, whereas the GPs identified mainly the severely cognitively impaired persons.

Among patients identified by the screening, GPs were more likely aware of patients with co-morbidity of chronic diseases. GPs were less likely aware of patients with depressive symptoms, as well as of patients who functioned cognitively better. Patients with chronic diseases have a higher GP contact frequency which may explain a better detection among these patients.<sup>2</sup> Depressive symptoms might distract clinicians from suspicion of cognitive impairment and dementia. A study among cognitively impaired primary care patients showed that depression treatment was associated with a higher awareness of cognitive impairment.<sup>1</sup> GPs may be more aware of patients with a history of depression treatment compared to those with only depressive symptoms. In contrast with our results on chronic diseases, in the other study physicians' unawareness was associated with diabetes mellitus, hypertension, cancer, or having suffered a heart attack.<sup>1</sup> Conflicting findings might be attributed to differences in gravity of chronic disease.

In conclusion, a two-stage screening and increased alertness for cognitive impairment and dementia among patients with depressive symptoms may improve detection rate of dementia in general practice. To decide whether screening for dementia is useful in general practices, a study of the diagnostic accuracy of screening, and a critical evaluation of the advantages and disadvantages for GPs and patients are needed.

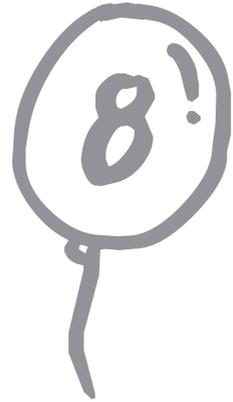
## REFERENCES

1. Chodosh J, Petitti DB, Elliott M, Hays RD, Crooks VC, Reuben DB *et al.* Physician recognition of cognitive impairment: evaluating the need for improvement. *J Am. Geriatr. Soc.* 2004;52:1051-9.
2. Eefsting JA, Boersma F, Van den Brink W, Van Tilburg W. Differences in prevalence of dementia based on community survey and general practitioner recognition. *Psychol. Med.* 1996;26:1223-30.
3. O'Connor DW, Pollitt PA, Hyde JB, Brook CP, Reiss BB, Roth M. Do general practitioners miss dementia in elderly patients? *BMJ* 1988;297:1107-10.
4. Valcour VG, Masaki KH, Curb JD, Blanchette PL. The detection of dementia in the primary care setting. *Arch. Intern. Med.* 2000;160:2964-8.
5. van Hout H. Studies on recognition of dementia by primary care physicians are inconsistent. *Arch. Intern. Med.* 2001;161:1238-9.
6. Borson S. Should older adults be screened for cognitive impairment? *Med. Gen. Med.* 2004;6:30.
7. Somerfield MR, Weisman CS, Ury W, Chase GA, Folstein MF. Physician practices in the diagnosis of dementing disorders. *J. Am. Geriatr. Soc.* 1991;39:172-5.
8. O'Connor DW, Fertig A, Grande MJ, Hyde JB, Perry JR, Roland MO *et al.* Dementia in general practice: the practical consequences of a more positive approach to diagnosis. *Br. J. Gen. Pract.* 1993;43:185-8.
9. Pond CD, Mant A, Kehoe L, Hewitt H, Brodaty H. General practitioner diagnosis of depression and dementia in the elderly: can academic detailing make a difference? *Fam. Pract.* 1994;11:141-7.
10. Brodaty H, Clarke J, Ganguli M, Grek A, Jorm AF, Khachaturian Z *et al.* Screening for cognitive impairment in general practice: toward a consensus. *Alzheimer Dis. Assoc. Disord.* 1998;12:1-13.
11. Patterson CJ, Gass DA. Screening for cognitive impairment and dementia in the elderly. *Can. J. Neurol. Sci.* 2001;28 Suppl 1:S42-S51.
12. Petersen RC, Stevens JC, Ganguli M, Tangalos EG, Cummings JL, DeKosky ST. Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2001;56:1133-42.
13. Boustani M, Peterson B, Hanson L, Harris R, Lohr KN. Screening for dementia in primary care: a summary of the evidence for the US Preventive Services Task Force. *Ann. Intern. Med.* 2003;138:927-37.
14. Sternberg SA, Wolfson C, Baumgarten M. Undetected dementia in community-dwelling older people: the Canadian Study of Health and Ageing. *J. Am. Geriatr. Soc.* 2000; 48:1430-34.
15. Jansen AP, van Hout HP, van Marwijk HW, Nijpels G, de Bruijne MC, Bosmans JE *et al.* (Cost)-effectiveness of case-management by district nurses among primary informal caregivers of older adults with dementia symptoms and the older adults who receive informal care: design of a randomized controlled trial [ISCRTN83135728]. *BMC. Public Health* 2005;5:133.

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16. Jorm AF, Jacomb PA. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): socio-demographic correlates, reliability, validity and some norms. *Psychol.Med.* 1989;19:1015-22.
17. Folstein M, Folstein S, McHugh P. "Mini-Mental" State: a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.
18. Solomon PR, Hirschhoff A, Kelly B, Relin M, Brush M, DeVeaux RD *et al.* A 7 minute neurocognitive screening battery highly sensitive to Alzheimer's disease. *Arch.Neurol.* 1998;55:349-55.
19. Kempen GI, Miedema I, Ormel J, Molenaar W. The assessment of disability with the Groningen Activity Restriction Scale. Conceptual framework and psychometric properties. *Soc.Sci.Med.* 1996;43:1601-10.
20. Radloff LS. The CES-D Scale: a Self-Report Depression Scale for Research in the General Population. *Appl.Psych.Meas.* 1977;1:385-401.
21. Diagnostic and Statistical Manual of Mental Disorders (DSM-IV). Washington, DC: American Psychiatric Association, 2000.
22. Copeland JR, McCracken CF, Dewey ME, Wilson KC, Doran M, Gilmore C *et al.* Undifferentiated dementia, Alzheimer's disease and vascular dementia: age- and gender-related incidence in Liverpool. The MRC-ALPHA Study. *Br.J Psychiatry* 1999;175:433-8.
23. Letenneur L, Launer LJ, Andersen K, Dewey ME, Ott A, Copeland JR *et al.* Education and the risk for Alzheimer's disease: sex makes a difference. EURODEM pooled analyses. EURODEM Incidence Research Group. *Am.J Epidemiol.* 2000;151:1064-71.
24. Wilson JM, Jungner G. Principles and Practice of Screening for Disease. Public Health Paper. No. 34. Geneva: WHO, 1968.
25. Hebert R, Bravo G, Korner-Bitensky N, Voyer L. Refusal and information bias associated with postal questionnaires and face-to-face interviews in very elderly subjects. *J Clin. Epidemiol.* 1996;49:373-81.





# General discussion

This thesis focuses on case management by district nurses among older adults with dementia symptoms and their primary informal caregivers. Our objective was to investigate whether case management is more effective than usual care in improving caregivers' sense of competence, quality of life, psychological well-being, burden, and older adults' quality of life, and in decreasing hospital days, days until institutionalisation and death of the older adults. A randomised clinical trial with assignment to either case management or usual care was executed after both a screening for dementia symptoms and cognitive testing on indication of the GPs among older general practice patients living at home.

In this chapter, firstly, we will give an overview of our main findings and conclusions. Secondly, we will discuss two important topics related to the trial and its recruitment procedure: 1) Was it possible to evaluate the case management intervention, 2) Was the recruitment procedure adequate for determining eligibility for trial entry. Next, some methodological topics will be discussed. Then, we will discuss what this thesis adds to the existing knowledge on case management and screening. Finally, recommendations for further research and health care will be given.

### **Main findings and conclusions**

#### *Related to the effectiveness of the case management intervention*

1. Case management by district nurses showed neither statistically significant nor clinically relevant benefits compared to usual care with regard to caregiver's sense of competence, quality of life, psychological well-being, burden, and patient's quality of life, days of temporary institutionalisation, and days until permanent institutionalisation and death.

Several issues may have contributed to the fact that we found no benefits of case management over usual care.

Firstly, and most important, we have included participants who had fewer health problems than we had expected: informal caregivers reported little distress and older adults had milder cognitive impairments and fewer health problems. Probably, the relatively mild health problems of the included participants had consequences for the relevance of the case management intervention. The intervention may not have been experienced as necessary yet for the participants by both the nurses and the participants themselves. And this, in turn, may have contributed to the fact that some elements of the

case management intervention were not delivered completely as designed. Due to the issues mentioned above the intervention had less chance of success. Lastly, 12 months of case management among the group with relatively mild health problems may have not been long enough to establish a beneficial change in outcome measures. We cannot rule out that case management is effective in the long term, among care recipients with early (diagnosed) dementia and informal caregivers who experience more distress than our participants, or when the case management intervention is more adapted to the relatively mild problems of persons in our target group.

*Related to the primary outcome instrument*

2. The fact that we have included participants with relatively mild health problems may have had consequences for the relevance of the chosen primary outcome instrument. The choice of our outcomes measures and instruments was based on the assumption that our target group would be similar to informal caregivers of patients with diagnosed dementia and the patients themselves, although they would have milder health problems. The three subscales of the SCQ showed good homogeneity and feasibility, but only the subscale 'Consequences of involvement in care for the personal life of the caregiver' was found to be partly valid. The two other subscales might not be relevant yet for this population. Many of the items on these scales refer to problem behaviour and problematic interactions while these behaviours were only present to a small extent in our population. Furthermore, a ceiling effect occurred on the subscale 'Satisfaction with the care recipient'. Our suggestion to clinicians and researchers is to use only the subscale 'Consequences of involvement in care for the personal life of the caregiver' among informal caregivers of older adults with dementia symptoms.

*Related to the screening for dementia symptoms*

3. The IQCODE-SR was used for screening for dementia symptoms. The IQCODE-SR meets the basic requirements of a good measurement instrument: the psychometric properties demonstrated acceptable feasibility and good homogeneity, and most of the hypotheses on construct validity were confirmed. Further research is necessary to determine the IQCODE-SR's accuracy to identify older adults who are at risk of dementia. In addition, the extent to which cognitively impaired persons can validly complete the IQCODE with and without assistance needs further evaluation.

4. A two-stage screening yielded 117 patients with cognitive impairment who needed further examination; in most cases (n=82, 70.1%) their GP was unaware of the symptoms. Among patients identified by the screening, GPs' awareness was associated with co-morbidity of chronic diseases, depressive symptoms, and cognitive functioning. Therefore, a two-stage screening and increased alertness for cognitive impairment and dementia among patients with depressive symptoms may improve the detection rate of dementia in general practice. To decide whether screening for dementia is useful in general practice, a more detailed study of the diagnostic accuracy of the screening, and a critical evaluation of the advantages and disadvantages for GPs and patients is needed. The screening has limitations and we do not recommend implementing it before the majority of Wilson and Jungner's criteria on screening are met.<sup>1</sup>

### **Was it possible to evaluate the case management intervention**

From a research point of view, evaluating the case management intervention was rather complex. There may be discussion about to what extent it was possible to evaluate such an intervention appropriately.

#### *Hypotheses*

We based our hypothesis concerning the course of the caregiver's situation on models that are often used in research among informal caregivers and patients with diagnosed dementia (i.e. the tear and wear model and adaptation model). At first sight it seems that we have hypothesized the right things since both groups remained stable or declined over time in accordance with both the tear and wear model and adaptation model. However, there is a lack of knowledge about informal caregivers of persons in the early stages of dementia and persons with dementia symptoms. Therefore, in order to formulate relevant hypotheses in future trials, firstly, we need to refine our understanding of the early caregiver career by means of longitudinal research. Only thereafter, assumptions about the change in the caregivers' situation achieved by means of an intervention can be made. Note that it may be impossible to grasp 'the' caregiver career with one model because the course may differ across individuals.

*Content of the intervention and control condition*

A case management intervention is a complex intervention that combines different elements and that covers many potential 'active ingredients'. It is impossible to unravel the contribution of each element to our findings. Exactly the same can be said about usual care. Furthermore, both the case management intervention and usual care are not standardized which implies that both treatment arms comprised various health care and welfare services that differed considerably across participants within treatment arms. We noticed considerable heterogeneity in the situation of participating older adults and their informal caregivers. From a research point of view this is less ideal. In performing a randomised clinical trial homogeneous and standardized treatment arms are preferable for a reliable and simple evaluation. Together with the heterogeneous situations of older adults with dementia symptoms and their informal caregivers, this is a rather complex randomised clinical trial to perform and to interpret.

*Contrast between the two treatment arms*

One might argue that the contrast of the case management group with the usual care group was too small. During the 12 months of the trial, apart from the case management intervention by district nurses, who spent a mean of 10.8 hours a year per patient-caregiver dyad, no other relevant differences were found in care consumption between the case management group and usual care group based on cost diaries. It is unclear whether the intensity of the case management intervention (a mean time of 10.8 hours a year) can be sufficiently to establish a change in outcomes. We think that it depends heavily on the needs of the individual dyads and the quality of care delivered whether this time-intensity suffices. Although the nurses differed in mean time spent on the intervention per dyad, this difference did not lead to differences in outcomes of the intervention across the three nurses. It appears that nurses spent more time on participants with more health problems (i.e. older care recipients with lower MMSE scores and spousal caregivers). Furthermore, a dose-effect relation for time spent on case management was absent.

*Insight into the delivery of the intervention*

In performing randomised clinical trials, it is still common practice to focus on the outcome measures and to pay less attention to what exactly happened in the treatment arms. Insight into the delivery of the different

elements may yield valuable information for researchers and health care professionals planning to implement similar interventions. We performed a process evaluation to examine the delivery of the intervention and noticed that some elements of the case management intervention had little chance of success. Especially the co-ordination and monitoring task were not executed as planned. Moreover, we found indications of fragmented care. The nurses indicated that a minority of the participating patients had health problems and they were shocked that these patients were not provided with care already. However, in general, the nurses thought that their case management intervention would be more appropriate for dependent older adults with more severe dementia symptoms and their informal caregivers. Case managers thought that some elements were not necessary yet for the relatively mild health problems of the participants. Participating older adults suffered from relatively mild impairments, whereas participating informal caregivers reported relatively good sense of competence, and little distress due to patients' behavioural health problems, as well as low severity of behavioural health problems in patients when compared to informal caregivers of community-dwelling patients with dementia.<sup>2-5</sup> In conclusion, the relatively healthy population of patients and caregivers and fragmentation of care might be an explanation for an incomplete delivery of the case management intervention.

#### *Drop out rates*

Drop out rates in this trial turned out lower than the expected drop out rate of 25% (18% including death and 11% excluding death). Although some studies reported (almost) no drop-out during follow-up,<sup>2,6</sup> drop out rates around 20% are more common among this type of studies.<sup>5,7-9</sup> The relatively low drop out rate in our study may be related to the relatively good situation of the participants. Dyads dropped out because they regarded the strain related to participation in the study as too much or because they simply refused further participation. Furthermore, spouses were more likely to withdraw than other informal caregivers.

#### *Outcome measures and instruments*

Sense of competence was our main outcome measure and was measured with the SCQ. The SCQ has been validated among informal caregivers of older adults with diagnosed dementia and, later, in stroke caregivers.

In both populations, it was found to be a valid instrument.<sup>5,10</sup> Content validity among informal caregivers of patients with diagnosed dementia was evaluated on the basis of classifications of the items made by a panel of experts, including professional caregivers and clinical researchers. The three dimensions of the SCQ were shown to have a high degree of correspondence with classifications made by this panel. Construct validity was checked with a principal-components analysis that revealed the three subscales.<sup>5</sup> In our psychometric evaluation of the SCQ among informal caregivers of older adults with dementia symptoms, exploratory principal component analyses showed that the SCQ measured three constructs similar to those found in the study among caregivers of older adults with dementia.<sup>5</sup> However, we studied construct validity in a different and more detailed way than by means of an exploratory principal component analysis. We found only the subscale ‘Consequences of involvement in care for the personal life of the caregiver’ to be valid. Another problem is the lack of knowledge on the responsiveness to change of the SCQ, just like on other ‘burden’ scales.

We do not have doubts about the validity of the other caregiver outcomes and instruments, because these were found to be valid instruments among various groups and their items do not refer to patients’ characteristics such as behavioural problems and problematic interaction in contrast to two of the subscales of the SCQ.

Most outcomes in patients were based on previous research on the effects of home visits among (frail) older adults: temporary days of institutionalisation and time until institutionalisation and death. In the long term, effects on these outcomes may be observed, but a follow-up of 12 months in our participants with relatively mild impairments was probably too short to reach a postponement of institutionalisation and death and a decline in days spent in institutions.

Health related and dementia specific quality of life instruments are being developed in abundance. We choose to use the Dementia Quality of Life instrument (DQoL) to measure patient’s quality of life although there is a lack of knowledge about its responsiveness to change over time, just like other quality of life instruments for older adults with dementia.

In sum, including participants with fewer health problems than expected had limited consequences for our outcome measures and instruments. Two subscales of the SCQ seemed to be less relevant.

## *Chapter 8*

Interestingly, although we did not find beneficial effects of the case management intervention for the caregivers and care recipients, the case management intervention was partly continued afterwards in daily practice. On request of the GP, in situations anticipated beneficial, the district nurses administer the RAI-HC. In addition, the nurses continued with organising family-meetings and providing guides for caregivers with information about available social and welfare services. This raises the question: Have we missed some (potential) benefits and related outcome measures on the level of the care providers? Therefore, in future, we may also take into account outcomes on the level of the care providers. We could ask them on beforehand to mention their needs and wishes to be fulfilled by means of the case management intervention.

### *Duration of the trial*

The case management intervention may have lacked sufficient duration to establish a change in outcomes. We cannot rule out that providing this type of early case management may be effective in the long term. A previous study showed that those individuals who utilized inhome help services earlier in their dementia caregiving careers were more likely to delay institutionalisation over a 3-year period.<sup>11</sup> On other outcomes, effects on the long-term may also be possible: when case managers start in an early stage with pro-active monitoring of both patients and caregivers, it seems logical that crises and burden can be prevented by bringing in care well in advance. Moreover, the case management intervention may give informal caregivers a head start: They may be better prepared and empowered for the future than caregivers who only receive usual care. A 12-month follow up seems therefore not long enough to pick up relevant outcomes; a follow up of at least 5 years will satisfy. However, obtaining financial support for such a follow-up time is almost impossible.

### *Interpretation of effectiveness*

The effects of the intervention are made up by the case management intervention, the influence of both the course of informal caregiving and the course of the dementia symptoms on outcome measures, and the influence of confounders or effect modification on the outcome measures. Confounders and effect modification were absent or could not be reliably demonstrated due to the small sample sizes of subgroups. Although we

have implemented the most effective elements of home visits (i.e. a multi-dimensional geriatric assessment and multiple follow-up home visits)<sup>12</sup> and of interventions among dementia patients and their informal caregivers (i.e. multi-component and individually tailored),<sup>13-16</sup> we found no benefits of case management over usual care. Beneficial effects were absent in any outcome. Although generalizability of the trial findings may be limited by the fact that only three nurses executed the case management intervention, we have no doubt that there actually was a relevant effect.

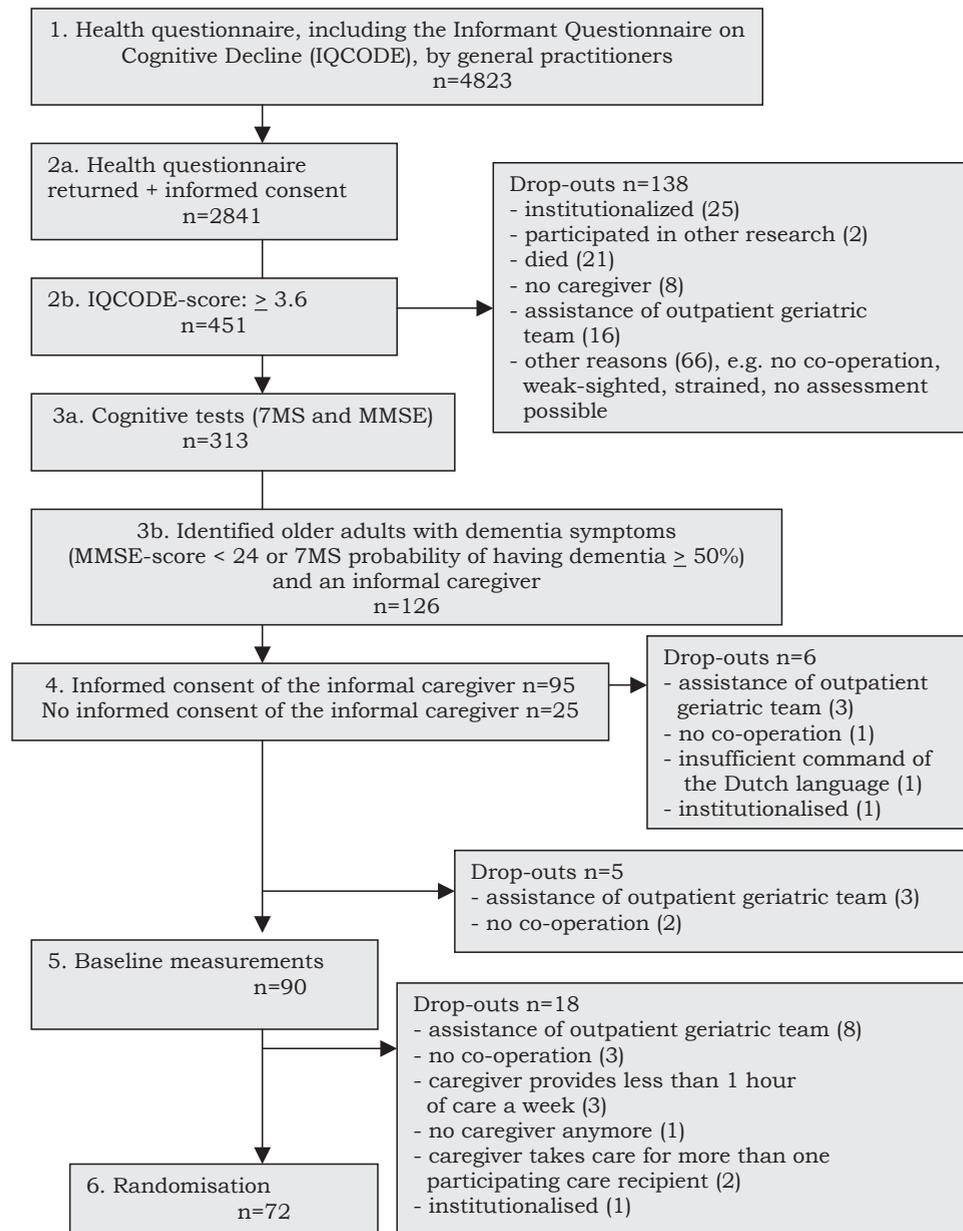
### **Was the recruitment procedure for dementia symptoms adequate for determining eligibility for trial entry**

For implementation purposes it is important to pay attention to the evaluation of the recruitment process and to describe it clearly. Describing the process may yield valuable information for researchers and health care professionals planning to implement similar recruitment procedures. Furthermore, describing the process may give insight into whether we collected a representative sample of older adults with dementia symptoms and their primary informal caregivers.

#### *Feasibility and efficiency of the recruitment procedure*

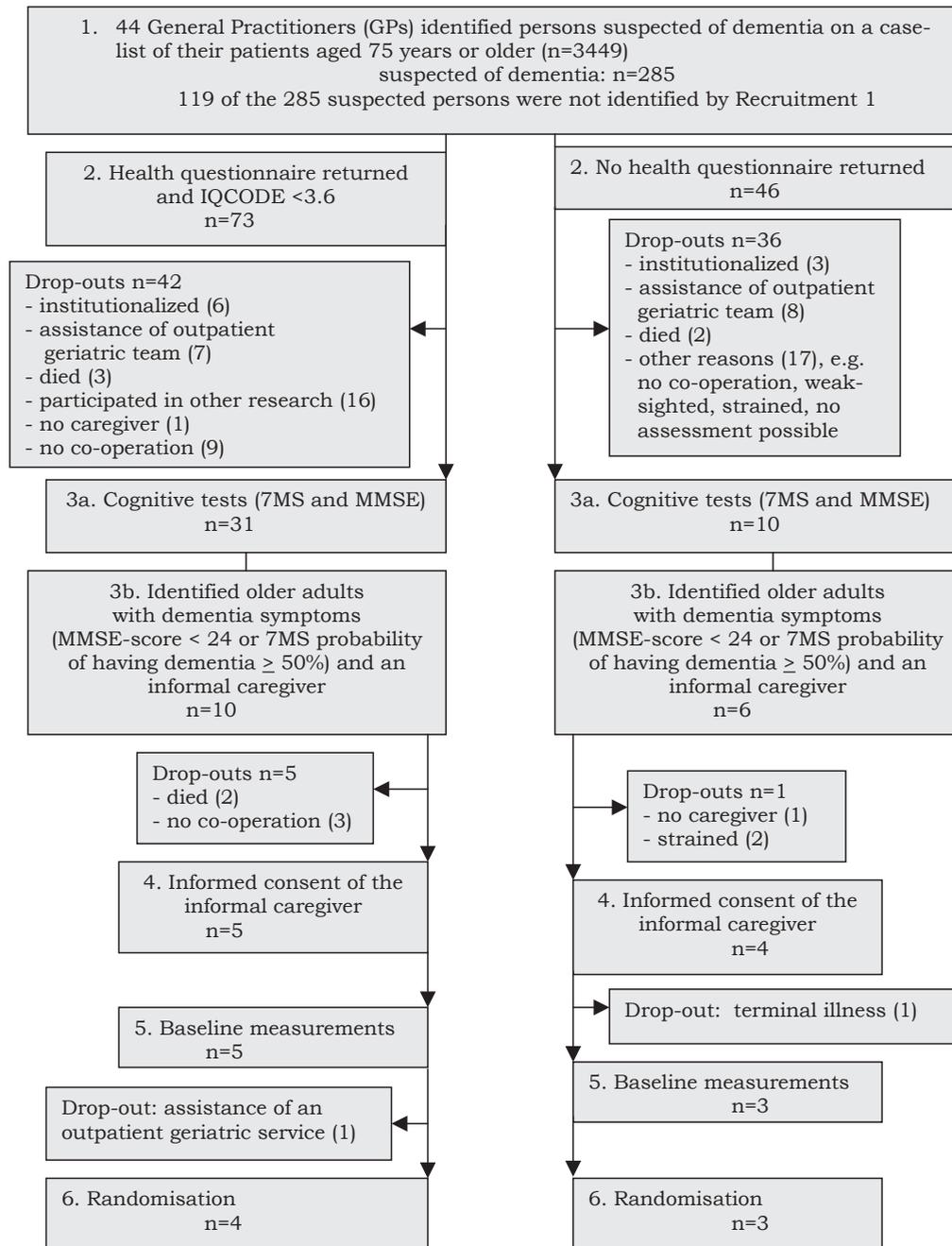
99 pairs of informal caregivers and care recipients were enrolled in the study in three ways:

- 1) 72 care recipients, aged 75 years or older, were identified by means of a health questionnaire sent by their general practitioners (GPs) and subsequent cognitive testing with the MMSE and 7MS (Figure 1). The procedure was part of a broader screening that screened for depressive symptoms and general vulnerability as well;
- 2) 7 care recipients, aged 75 years or older, were suspected of dementia by their GP and identified by subsequent cognitive testing (Figure 2). They had not responded to the health questionnaire or they were not suspected of early dementia symptoms according to the questionnaire;
- 3) 20 care recipients, aged 65 years or older, were identified by means of a health questionnaire sent by a primary care Diabetic Research Center (DRC) and subsequent cognitive testing (Figure 3).



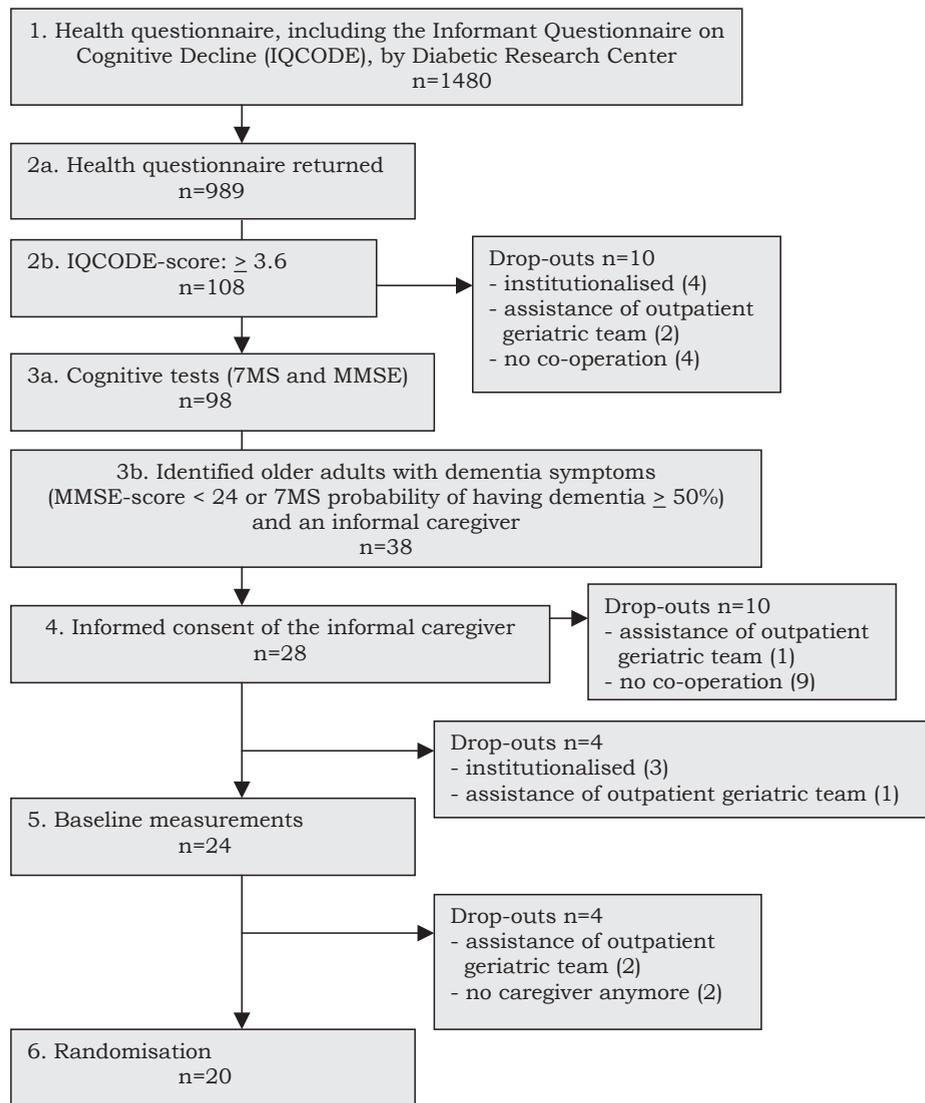
**Figure 1** Recruitment 1

7MS=seven Minute Screen; MMSE=Mini Mental State Examination



**Figure 2** Recruitment 2

7MS=seven Minute Screen; MMSE=Mini Mental State Examination



**Figure 3** Recruitment 3

7MS=seven Minute Screen; MMSE=Mini Mental State Examination

The first and third way of recruitment concern the screening for dementia symptoms, whereas the second way of recruitment concerns the cognitive testing on indication of the GPs. If we put the three ways of recruitment into persons needed to approach in order to include 1 person, the following figures emerge: recruitment 1)  $4823/72=67$ , recruitment 2)  $119/7=17$ , recruitment

3)  $1480/20=74$ . These figures suggest that a recruitment with a starting point of cognitive testing on indication of the GPs may be a more efficient way of recruitment for trial entry than the screening for dementia symptoms. Note that this is the only method that fits easily in daily practice.

We approached 6303 persons to include 99 persons with dementia symptoms and their informal caregivers. There may be more feasible and efficient ways of recruiting participants, for example screening for informal caregivers,<sup>17</sup> case-finding by GPs or other primary health care professionals, and cognitive testing of all patients suspected of dementia by their GP (as suggested above). Therefore, we do not recommend the screening for dementia symptoms again for trial entry.

### *Instruments*

The quality of a screening instrument depends on its psychometric characteristics, including its feasibility, its relevance when used for screening for dementia symptoms, its reliability over time and its accuracy. To what extent do the IQCODE, GPs' identification, the 7MS and the MMSE meet these quality criteria?

### *Feasibility*

We used the IQCODE because of its speed, inexpensiveness, simplicity and its absence of adverse effects. The same can be said about GPs' identification. Only among a limited group we executed targeted cognitive assessments with the 7MS and MMSE. In comparison with the IQCODE and GPs' identification these targeted assessments are more expensive and may have more adverse effects. Furthermore, they are still relatively fast to administer in comparison with extensive test-batteries. For practical and ethical reasons it was impossible to expose potential participants to more invasive and valid instruments such as MRI and extensive test-batteries.

### *Relevance*

In the first stage of the screening, we used the IQCODE which measures cognitive decline over the past 10 years in older persons. However, it also covers functioning in the instrumental activities of daily living (IADL). Both cognitive decline and IADL are closely related to dementia symptoms. The GPs' identification is very relevant as well. The same can be said about the 7MS and MMSE that both measure cognitive status. Orientation, attention,

calculation, memory, (expressive) language, praxis and visuospatial ability are covered. The 7MS was developed for use in primary care. Limitations of the 7MS include that it has been developed for and used in patients with or at risk of Alzheimer's disease, and that it is necessary to calculate a score for interpretation. The MMSE is affected by age and level of education.<sup>18</sup> However, when an overall cut-off value of 23/24 is used in persons aged 75 years and older, this is only a limitation among higher educated persons, and these were rare in our study population

#### *Reliability over time*

Probably, GPs' identification is very reliable over time, whereas the 7MS and MMSE may be sensitive to day-to-day fluctuations and to rater variability. The overall test-retest reliability of the 7MS as described in previous research was  $r=0.91$  one to two months after initial administration. The interrater reliability was  $r=0.93$ .<sup>19</sup> Test-retest reliabilities over three months of the MMSE in older adults varied between 0.48 and 0.65,<sup>20;21</sup> whereas the interrater reliability was  $r=0.83$ .<sup>22</sup> The reliability of the IQCODE may depend on the person who completes the questionnaire (the proxy or the older adult him or herself). In the proxy-version the reported test-retest reliability was  $r=0.96$  over three days<sup>23</sup> and  $r=0.75$  over one year.<sup>23;24</sup> More research is needed on the reliability over time of the self-report IQCODE.

#### *Accuracy*

For the moment we remain uncertain about the accuracy of our recruitment procedure. We were not able to expose all 6303 persons approached to a high quality reference standard for dementia for practical, ethical and budgetary reasons. Thus, we were not able to determine criterion validity of the recruitment procedure and we remain uncertain about the sensitivity and specificity of the recruitment procedure. Nevertheless, we did ask one outpatient diagnostic service whether any of the following two groups of participating older adults received a diagnosis of dementia: 1. The participating older adults in the trial ( $n=99$ ), and 2. The older adults identified by the screening whose GPs were unaware of the symptoms ( $n=82$ ). At the end of the trial, 31 of the 82 persons of the second group were diagnosed with dementia, as well as 23 of the 99 participants of the trial. Note that there is an overlap between the participating older adults in the trial ( $n=99$ ) and the older adults identified by the screening ( $n=82$ ): 38 of the 82 older adults

identified by the screening subsequently participated in the trial and 12 of them were diagnosed with dementia at the end of the trial.

Overall, the choice for using a dichotomised cut-off point (such as 3.6 on the IQCODE, 24 on the MMSE and 50 or 70% on the 7MS) is always arbitrary; it goes along with simplifying reality with which valuable information may be lost. Moreover, it passes over the disability continuum and departs from a dichotomisation in disabled and not-disabled persons. It may be time for clinicians and researchers to get used to the disability continuum and to stop classifying persons into two groups.

The IQCODE was examined in more depth. We administered the IQCODE in a new way and used self-reports (with or without help from a proxy) instead of proxy reports only. A threat to validity is the risk that the cognitively impaired persons without insight might have completed the IQCODE while over-estimating their cognitive functioning. However, we remain uncertain about the validity and number of such self-reports of cognitively impaired subjects without insight. Another threat to validity is selection bias: there may be factors that differ between those willing to get tested and those who are not. The IQCODE may have not reached those who need it most. In our study, selective non-response to the screening is likely, as the percentage of suspected cases of dementia according to the GPs was higher among non-responders than responders. In addition, non-responders in another study had higher rates of functional and cognitive impairment.<sup>25</sup> This selection-bias limits the potential for implementation, because such a selective non-response could result in poor detection of dementia symptoms.

Further research is necessary to determine the IQCODE-SR's accuracy to identify older adults who are at risk of dementia. The influence of potential selective non-response to the IQCODE-SR from persons who are at risk of dementia should also be considered. In addition, the extent to which cognitively impaired persons can validly complete the IQCODE with and without assistance needs further evaluation. Therefore, we recommend a comparison of the conventional IQCODE with the self-rated IQCODE.

In sum, as often, the instruments used in screening and for indicated cognitive assessments were not perfect. However, to our knowledge, almost no other methods would have been feasible taking the size of the base population (N=6303) into account.

*Yield of the screening when executed alongside the usual identification by general practitioners*

Further examination of persons identified with the two-stage screening method may result in improvement of detection rates of dementia. Moreover, increased alertness for cognitive impairment and dementia among patients with depressive symptoms may improve detection rate of dementia in general practice as well, because GPs were less likely aware of patients with depressive symptoms. However, the results on depressive symptoms originated only from cross-sectional analyses and not from causal analyses. For this reason further examination is necessary to verify the hypothesized improvement.

*To screen or not to screen*

At first sight, identifying dementia (symptoms) earlier seems better. Although screening may lead to earlier identification, this does not automatically mean that it is beneficial to the persons being screened. Even in case of excellent accuracy of a screening method, other aspects should be taken into account to make a decision on whether a screening is beneficial to a population. At the moment, there is a lack of consensus regarding the value of screening for dementia.<sup>26-29</sup>

In chapter 5 we advised not to implement our screening (first stage: IQCODE-SR and second stage: 7MS and MMSE) before the majority of Wilson and Jungner's criteria on screening are met.<sup>1</sup>

According to Wilson and Jungner, screening is justified when the following conditions are met:

- The condition is an important health problem, i.e. high prevalence and burden of illness;
- The natural history of the condition is understood;
- There is a recognizable presymptomatic phase;
- An effective treatment is available, which is more beneficial when applied in the presymptomatic phase, than when treatment is delayed until symptoms appear;
- There must be evidence, that early identification changes the natural history in a beneficial way without negative effects such as labelling;
- A suitable test is available to detect the condition (high sensitivity, high specificity);

- The test is acceptable to the population screened;
- The health care system has the capacity to apply the test and deal with the consequences: facilities for diagnosis and treatment should be available (i.e. clinical pathways) and there should be an agreed policy on who to treat;
- Case-finding/screening should be a continuous process, not just a “once and for all” project;
- The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole.

With the expanding understanding of the pathophysiology of dementia associated advances in diagnosis and treatment are expected. Therefore, in future, the debate on screening for dementia may change.

Although the evidence supporting screening of all older persons for dementia is inconclusive, there is value in studying new screening methods and in determining factors that may improve the detection rates of dementia in the primary care setting. Increasing knowledge about the realisation of the criteria of Wilson and Jungner may contribute to the debate on screening for dementia.

#### *The external validity of the results*

An important question with regard to the interpretation of a randomised clinical trial is whether the included participants resemble all persons eligible for trial entry. Is it allowed to generalize the results of the trial to all these persons eligible for trial entry? A threat to representative sampling is selection-bias. In our recruitment procedure, selection bias may be caused by selective response to the IQCODE or selective misinformation by cognitively impaired persons on the IQCODE, as well as by selective drop-out during the cognitive assessments. As described earlier, selective non-response to the IQCODE is likely, as the percentage of suspected cases of dementia according to the GPs was higher among non-responders than responders. In addition, non-responders in another study had higher rates of functional and cognitive impairment.<sup>25</sup> Moreover, during the cognitive assessments persons dropped out who were weak-sighted or strained by the assessments (e.g. panic, angry), who disliked the assessment and who did not want to co-operate further and performed that poor on the assessments that it was

unethical to continue with the assessments. Furthermore, GPs' identification could be biased, because GPs are better informed about patients who request for help and not of those who do not.

The primary outcomes of our trial were on the level of the informal caregiver. For that reason it was less ideal that the recruitment of informal caregivers depended completely on the persons identified by means of the screening and cognitive assessments on indication of the GPs. Not all identified persons with dementia symptoms had an informal caregiver. Furthermore, among the identified persons with an informal caregiver approximately 20% of the potential participating informal caregivers refused to participate. We were not able to examine whether this was a matter of selective refusal of caregivers, because we have no data about the refusing informal caregivers. Moreover, we may have missed some eligible informal caregivers of persons with dementia symptoms: the informal caregivers of drop-outs and non-responders during the recruitment of persons with dementia symptoms. In conclusion, we remain uncertain about the extent to which the included participants resemble all persons eligible for trial entry.

## **Methodology**

In this section several methodological considerations are described. Several issues have already been discussed in the chapters of this thesis and in this general discussion, for example:

- The many requirements for a high quality randomised clinical trial that were met;
- The combination of a relatively small sample size and heterogeneity of participants in the trial that may have hindered to establish subgroup effects;
- The difference between an efficacy and effectiveness study;
- The possible consequences of the relatively good health situation of participants;
- The extent to which it was possible to investigate the effects of the intervention;
- The risk of subjectivity in the analysis of qualitative interviews;
- The need for further research on the accuracy of the recruitment method.

Below some additional considerations will be described: the execution of the psychometric evaluations, the sample size calculation of the randomised clinical trial and the analyses with linear mixed models in SPSS.

#### *Psychometric evaluations*

We had not planned beforehand to perform psychometric evaluations. As a consequence, in formulating hypotheses for construct validity we were dependent on the data available. Nevertheless, we think we have constructed valuable hypotheses and we obtained increased knowledge of the SCQ and IQCODE-SR.

#### *Post hoc sample size calculation*

Sample size calculations were initially based on dichotomised sum-scores on the SCQ reported by informal caregivers of patients with diagnosed dementia (mean 17.9 SD 5.2, range 4-27).<sup>5</sup> However, during the trial we decided to use only the three subscales of the SCQ with raw scores instead of dichotomised total sum-scores for two reasons. Firstly, it is common practice not to use an overall score if subscales exist, but rather to use sum-scores on the subscales. Secondly, we preferred raw scores above dichotomised scores because with raw scores no valuable information can be lost: the risk of hidden (individual) changes over time is less present. The sample size was calculated again with similar assumptions ( $\alpha=0.05$ , a desired power of 0.80), but with an equation adjusted with an indication of the correlation between the repeated measurements (i.e. 0.7) because of the longitudinal study design,<sup>30</sup> and with an anticipated difference in mean values between the two groups of 4 points on a 32 point scale. The calculation was based on baseline measurements of our trial of the subscale 'Consequences of involvement in care for the personal life of the caregiver' (mean 28.9, SD 6.8, range 8-40) since previous reports on raw subscale scores lack. Furthermore, the subscale 'Consequences of involvement in care' was found to be the only valid subscale of the three subscales of the SCQ in our target group. For that reason, this subscale became our primary outcome instrument. As we expected a drop out rate of about 25% during the one-year follow-up, a total of 104 patients and caregivers had to be included in the study and 78 had to retain into the trial. We succeeded in retaining enough participants in the trial (n=81).

*Linear mixed models*

Linear Mixed Models (SPSS version 12.0.2) with an unstructured covariance type was used to analyse differences over time between the case management and usual care group. For lack of a clearly interpretable regression coefficient, potential confounding due to baseline differences was checked by looking at potential changes in the patterns over time and potential changes in p-values (T\*G). When we performed analyses with four groups (usual care, nurse 1, nurse 2, and nurse 3) usual care was used as the reference measurement. The baseline measurement was used as the reference measurement over time and we used a fixed model. Strictly speaking, the use of a fixed model implies that we are not allowed to generalize our findings to all nurses in the Netherlands.

There may be discussion about the fact that we used two-sided tests to solve a one-sided formulated superiority hypothesis (i.e. case management is better than usual care). Although we have strong prior expectations we cannot be sure that the intervention might even have a negative effect. For that reason we used two-sided tests. An advantage of using two-sided tests is that, if you may accept the alternative hypothesis, it leaves open the possibility that you have been wrong, whereas in using one-sided tests, this possibility is absent and you have to formulate a new hypothesis and test further. Nevertheless, a glance at the pattern of mean/median scores over time per group gives much more insight in the presence or absence of relevant effects than simply performing (one- or two-sided) tests and searching for statistical significance.

**What does this thesis add?**

*Case management*

What was already known about case management in general and case management in persons with dementia and their informal caregivers? While case management programmes theoretically may offer benefits, few examples of effective programmes exist.<sup>31</sup> Moreover, there is little evidence for case management in people with chronic illnesses.<sup>32</sup> The evidence for case management in dementia is inconclusive. If beneficial effects are found, these effects are modest in size.<sup>14;33</sup> Among community-dwelling older adults with dementia and their primary informal caregivers, some studies showed promising effects for case management programmes and home visits.<sup>2;6;11;12;34-38</sup>

What does our trial add? Although we have implemented the most effective elements of home visits (i.e. a multi-dimensional geriatric assessment and multiple follow-up home visits)<sup>12</sup> and of interventions among dementia patients and their informal caregivers (i.e. multi-component and individually tailored)<sup>13-16</sup> in our case management programme, we found no benefits of case management over usual care for patients with (early) dementia symptoms and their informal caregivers. However, we applied case management to clients who did not ask for case management. In the real world, patients and carers are usually only offered, or considered for case management if there is a clinical problem that needs to be managed. Case management may be able to address present problems such as care burden and behavioural disturbances, but it may not be able to prevent these problems.

Taking the existing literature on case management into consideration, how likely is it that case management is effective? Although it seems not realistic to expect huge effect sizes with regard to health outcomes on the level of the patient and caregiver, case management programmes are increasingly being developed and implemented. Possibly, health care organisations seek to deliver care in a more rational and cost-effective manner. If case management is beneficial what elements are responsible for the beneficial outcomes? Probably, we will never know the contribution of each element to the findings as there are too many potential active elements and these elements differ across case management programmes.

#### *Early identification and support in general practice*

What was already known about (early) identification of persons with dementia and their informal caregivers in general practice? GPs are frequently unaware of the presence of cognitive impairment and dementia in their older patients. Estimations reveal that 40 to 70% of the patients with dementia are unknown to their GP.<sup>39-43</sup> Moreover, there is evidence that their vulnerable informal caregivers remain unnoticed by health care professionals until they are at a point of crisis.<sup>44</sup> Although strong evidence lacks, researchers assume that early identification of patients with dementia (symptoms) and their caregivers may yield a profit for them.

What does our study on the screening for dementia symptoms and cognitive testing on indication of GPs add? To our knowledge this is one of the first studies dealing with the boundaries of timely identification. The moment that persons with early dementia are in need of early support, are

willing to receive early support and may profit of early support is difficult to determine. It appears even more difficult to find an identification method that identifies persons with dementia right in that crucial moment.

In chapter 7 we concluded that the screening method and increased alertness for cognitive impairment and dementia among patients with depressive symptoms might ultimately improve detection rate of dementia in general practice. However, it is too early to implement screening for dementia (symptoms). In addition, figures comparing the screening and cognitive testing on indication of the GPs suggest that the last one might be the most efficient in identifying persons who successively accept an offer of care. Therefore, for the moment, identifying persons with dementia (symptoms) through existing clinical pathways seems favourable, for examine by means of case-finding in general practice or cognitive testing of all older patients suspected of dementia by their GP and testing all older patients whose current health status is unknown to their GP. The GP's practice nurse, collaborative district nurses, and other collaborative health care professionals in primary care may monitor the situation of the patient and the informal caregiver. Moreover, they may inform the GP about the situation. However, we do not think that case-finding and cognitive testing on indication will be implemented on a large scale by GPs because currently GPs do not consistently believe in the value of early identification and support.<sup>45</sup>

### **Recommendations for future research**

#### *Case management intervention*

- We recommend refining our understanding of the caregiver career of informal caregivers in the early stages of dementia and informal caregivers of persons with dementia symptoms. We need longitudinal studies on this topic.
- We recommend researchers to map the care needs of the informal caregivers and the persons with dementia symptoms, for example by means of caregiver assessments<sup>46-48</sup> and comprehensive geriatric assessments.<sup>9</sup> In the ideal situation, the recruitment procedure, the subsequent case management intervention and the outcome measures fulfil the needs and wishes of the target group for the intervention. Provided the target group indicates unfulfilled needs that can benefit of preventive activities, researchers may develop suitable interventions.

- We recommend researchers to develop evidence based interventions. If not possible, at least a theoretical background concerning the design of the intervention should be presented. A possible approach to develop evidence based interventions may be intervention mapping.<sup>49</sup> Furthermore, care preferences, drop out, (un)met care needs, and satisfaction with the intervention should be registered to evaluate the intervention.
- We recommend researchers planning to perform a randomised clinical trial to assess the delivery of the elements of the intervention during the whole study, as well as the experiences of the care providers and care recipients. This process evaluation helps to explore why the intervention works (not) and whether this is attributable to the level of implementation. Thus, researchers should monitor interventions very closely during trials.
- We recommend researchers planning to perform a randomised clinical trial to add process measures related to the potential working mechanism of the intervention. This process evaluation may help to explore whether the intervention works as hypothesized.
- We recommend researchers planning to perform a randomised clinical trial to add some process measures on the level of the health care provider and the organisation of health care as well. It may be worthwhile to explore which outcome measures would be valuable for health care providers, for example by means of focus groups interviews.
- We recommend researchers planning to perform a randomised clinical trial on the effectiveness of an intervention to pay more attention to the training and monitoring of the care providers who execute the intervention (i.e. implementation of the intervention for the purpose of the trial). Researchers should monitor whether professionals execute the protocol in a more or less uniform way before and during the trial. Furthermore, before starting the trial, researchers should be aware of case managers' attitude towards the intervention and possible prejudices against elements of the intervention. Researchers should try tackling negative attitudes and unrealistic prejudices. If necessary, before starting the trial, they can adapt the intervention to the experience of the case managers.
- We recommend researchers to increase the duration and follow-up

time of future interventions in order to pick up potential preventive effects.

- We recommend researchers to describe clearly the interventions studied. The poor uniformity in case management programmes and the ambiguous definition of case management is not ideal for comparing the effects of different studies: a clear description of programmes is always necessary and new subgroup-names for different case management programmes are welcome to improve the comparability of similar programmes.

### *Screening*

- We recommend more feasible ways of recruiting participants with early dementia symptoms for trial entry, for example screening for informal caregivers,<sup>17</sup> case-finding by GPs or other primary health care professionals, and cognitive testing for all patients suspected of dementia by their GP. In case-finding, testing for a disease or its complications is performed among patients who come to their physicians for unrelated reasons. When the screening test is abnormal, the patient is invited for a detailed disease-directed history.
- We recommend researchers to evaluate screening methods for dementia or dementia symptoms (not for the purpose of trial entry) and to assess the perception of the respondents with regard to feedback on their cognitive capacities, in order to investigate the consequences of early detection of dementia. This information will contribute to the debate on screening.

### **Recommendations for daily practice**

- We advise against mass screening for dementia (symptoms) as long as there is no consensus about whether the majority of Wilson and Jungner's criteria on screening are met.
- This study provides no reason to recommend case management in primary care above usual care for patients with dementia symptoms and their primary informal caregivers. Nevertheless, we cannot rule out that case management is effective in the long term or among care recipients with early (diagnosed) dementia and informal caregivers

who experience more distress.

- We recommend clinicians to pay attention to the implementation of case management. Case management will only be potential effective if other health care professionals accept and clearly understand the case manager's role and if it fits into existing clinical pathways. Furthermore, we recommend paying attention to the realisation of the planned activities during the implementation of case management interventions.
- We recommend competing health care organisations to keep in mind that the main interest of care is arranging adequate and integrated health care for the patient and his/her supportive social system and not self-interest of providing fragmented care to as much patients as possible. To arrange care for a complex target group, adequate collaboration is necessary.

During evaluative interviews, the case managers mentioned some important themes for future implementation:

- Announce the case management intervention and its interests to participants and all other health care professionals involved, including competing professionals;
- Collect and optimise knowledge about all other health care and welfare professionals and volunteers in the region;
- Take into account that caregivers may not live near the care recipient.

## REFERENCES

1. Wilson JMC and Jungner G. Principles and Practice of Screening for Disease. Public Health Paper. No. 34. Geneva: WHO, 1968.
2. Eloniemi-Sulkava U, Notkola IL, Hentinen M, Kivela SL, Sivenius J, Sulkava R. Effects of supporting community-living demented patients and their caregivers: a randomized trial. *J Am.Geriatr.Soc.* 2001;49:1282-7.
3. Mittelman MS, Roth DL, Haley WE, Zarit SH. Effects of a caregiver intervention on negative caregiver appraisals of behavior problems in patients with Alzheimer's disease: results of a randomized trial. *J Gerontol.B Psychol.Sci.Soc.Sci.* 2004;59:27-34.
4. Pot AM, Deeg DJ, van Dyck R, Jonker C. Psychological distress of caregivers: the mediator effect of caregiving appraisal. *Patient.Educ.Couns.* 1998;34:43-51.
5. Vernooij-Dassen, M. [Dementia and home-care. PhD thesis]. Amsterdam/Lisse: Swets & Zeitlinger B.V., 1993.
6. Mittelman MS, Ferris SH, Shulman E, Steinberg G, Levin B. A family intervention to delay nursing home placement of patients with Alzheimer disease. A randomized controlled trial. *JAMA* 1996;276:1725-31.
7. van den Heuvel ETP, de Witte LP, Sanderman R, Schure LM, Meyboom-de Jong B. Non-participation and drop-out in support programs for caregivers of cognitively impaired elderly. *Supporting caregivers of stroke patients: an intervention study*, pp 99-113. 2002.
8. Mohide EA, Pringle DM, Streiner DL, Gilbert JR, Muir G, Tew M. A randomized trial of family caregiver support in the home management of dementia. *J.Am.Geriatr.Soc.* 1990;38:446-54.
9. Stuck AE, Aronow HU, Steiner A, Alessi CA, Bula CJ, Gold MN *et al.* A trial of annual in-home comprehensive geriatric assessments for elderly people living in the community. *N.Engl.J.Med.* 1995;333:1184-9.
10. Scholte op Reimer WJ, de Haan RJ, Pijnenborg JM, Limburg M, van den Bos GA. Assessment of burden in partners of stroke patients with the sense of competence questionnaire. *Stroke* 1998;29:373-9.
11. Gaugler JE, Kane RL, Kane RA, Newcomer R. Early community-based service utilization and its effects on institutionalization in dementia caregiving. *Gerontologist* 2005;45:177-85.
12. Stuck AE, Egger M, Hammer A, Minder CE, Beck JC. Home visits to prevent nursing home admission and functional decline in elderly people: systematic review and meta-regression analysis. *JAMA* 2002;287:1022-8.
13. Acton GJ, Kang J. Interventions to reduce the burden of caregiving for an adult with dementia: a meta-analysis. *Res.Nurs.Health* 2001;24:349-60.
14. Brodaty H, Green A, Koschera A. Meta-analysis of psychosocial interventions for caregivers of people with dementia. *J.Am.Geriatr.Soc.* 2003;51:657-64.
15. Pusey H, Richards D. A systematic review of the effectiveness of psychosocial interventions for carers of people with dementia. *Aging Ment.Health* 2001;5:107-19.
16. Sorensen S, Pinquart M, Duberstein P. How effective are interventions with caregivers? An updated meta-analysis. *Gerontologist* 2002;42:356-72.

17. Maine Primary Partners in Caregiving project (MPPC). <http://www.umaine.edu/mainecenteronaging/mppc.htm> . 2007 (accessed February 2007).
18. Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the Mini-Mental State Examination by age and educational level. *JAMA* 1993;269:2386-91.
19. Solomon PR, Hirschhoff A, Kelly B, Relin M, Brush M, DeVeaux RD *et al.* A 7 minute neurocognitive screening battery highly sensitive to Alzheimer's disease. *Arch.Neurol.* 1998;55:349-55.
20. Tombaugh TN. Test-retest reliable coefficients and 5-year change scores for the MMSE and 3MS. *Arch.Clin.Neuropsychol.* 2005;20:485-503.
21. Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. *J.Am.Geriatr.Soc.* 1992;40:922-35.
22. Folstein M, Folstein S, McHugh P. "Mini-Mental" State: A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189-98.
23. Jorm AF, Scott R, Cullen JS, MacKinnon AJ. Performance of the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) as a screening test for dementia. *Psychol.Med.* 1991;21:785-90.
24. Jorm AF, Jacomb PA. The Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE): socio-demographic correlates, reliability, validity and some norms. *Psychol.Med.* 1989;19:1015-22.
25. Hebert R, Bravo G, Korner-Bitensky N, Voyer L. Refusal and information bias associated with postal questionnaires and face-to-face interviews in very elderly subjects. *J Clin. Epidemiol.* 1996;49:373-81.
26. Borson S. Should older adults be screened for cognitive impairment? *MedGenMed* 2004;6:30.
27. Brodaty H, Clarke J, Ganguli M, Grek A, Jorm AF, Khachaturian Z *et al.* Screening for cognitive impairment in general practice: toward a consensus. *Alzheimer Dis.Assoc. Disord.* 1998;12:1-13.
28. Patterson CJ, Gass DA. Screening for cognitive impairment and dementia in the elderly. *Can.J Neurol.Sci.* 2001;28 Suppl 1:S42-S51.
29. Petersen RC, Stevens JC, Ganguli M, Tangalos EG, Cummings JL, DeKosky ST. Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology* 2001;56:1133-42.
30. Twisk J. *Applied Longitudinal Data Analysis for Epidemiology: A Practical Guide.* Cambridge: Cambridge University Press, 2003.
31. Ferguson JA, Weinberger M. Case management programs in primary care. *J.Gen. Intern.Med.* 1998;13:123-6.
32. Singh D. Transforming chronic care: a systematic review of the evidence. *Evid.Based. Cardiovasc.Med.* 2005;9:91-4.
33. Peacock SC, Forbes DA. Interventions for caregivers of persons with dementia: a systematic review. *Can.J Nurs.Res* 2003;35:88-107.

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34. Dröes RM, Breebaart E, Meiland FJ, Van Tilburg W, Mellenbergh GJ. Effect of Meeting Centres Support Program on feelings of competence of family carers and delay of institutionalization of people with dementia. *Aging Ment. Health* 2004;8:201-11.
35. Elkan R, Kendrick D, Dewey M, Hewitt M, Robinson J, Blair M *et al.* Effectiveness of home based support for older people: systematic review and meta-analysis. *BMJ* 2001;323:719-25.
36. Newcomer R, Yordi C, DuNah R, Fox P, Wilkinson A. Effects of the Medicare Alzheimer's Disease Demonstration on caregiver burden and depression. *Health Serv. Res.* 1999;34:669-89.
37. Vernooij-Dassen M, Huygen F, Felling A, Persoon J. Home care for dementia patients. *J.Am.Geriatr.Soc.* 1995;43:456-7.
38. Weuve JL, Boult C, Morishita L. The effects of outpatient geriatric evaluation and management on caregiver burden. *Gerontologist* 2000;40:429-36.
39. Chodosh J, Petitti DB, Elliott M, Hays RD, Crooks VC, Reuben DB *et al.* Physician recognition of cognitive impairment: evaluating the need for improvement. *JAm.Geriatr.Soc.* 2004;52:1051-9.
40. Eefsting JA, Boersma F, Van den Brink W., Van Tilburg W. Differences in prevalence of dementia based on community survey and general practitioner recognition. *Psychol. Med.* 1996;26:1223-30.
41. O'Connor DW, Pollitt PA, Hyde JB, Brook CP, Reiss BB, Roth M. Do general practitioners miss dementia in elderly patients? *BMJ* 1988;297:1107-10.
42. Valcour VG, Masaki KH, Curb JD, Blanchette PL. The detection of dementia in the primary care setting. *Arch.Intern.Med.* 2000;160:2964-8.
43. van Hout H. Studies on recognition of dementia by primary care physicians are inconsistent. *Arch.Intern.Med.* 2001;161:1238-9.
44. Butler SS, Turner W, Kaye LW, Ruffin L, Downey R. Depression and caregiver burden among rural elder caregivers. *J.Gerontol.Soc.Work* 2005;46:47-63.
45. Iliffe S, Manthorpe J, Eden A. Sooner or later? Issues in the early diagnosis of dementia in general practice: a qualitative study. *Fam.Pract.* 2003;20:376-81.
46. Orrell M., Cooper C, Braithwaite S. Do carer's need assessments make a difference? Results from the Forget me not study. *Age Ageing* 2006;35:444-5.
47. Carer eligibility and needs assessment for the National Respite for Carers Program. <http://www.carersvic.org.au/Assets/pdfs/PolicyDocs/ResponseEligibilityNeedsAssessmentNRCP.pdf> . 2007 (accessed February 2007).
48. What is the purpose of a carer's assessment? <http://www.carersuk.org/Information/Helpwithcaring/Carersassessmentguide> . 2007 (accessed February 2007).
49. Kok G, Schaalma H, Ruiter RA, van Empelen P, Brug J. Intervention mapping: protocol for applying health psychology theory to prevention programmes. *J.Health Psychol.* 2004;9:85-98.

# Summary

## *Summary*

The main focus of this thesis is the effectiveness of a case management intervention by district nurses directed towards older adults with dementia symptoms and their primary informal caregivers. In this thesis persons with dementia symptoms are defined as persons with multiple cognitive impairments (i.e. memory impairment and at least one other of the following impairments: aphasia, apraxia, agnosia, disturbances in executive functioning) that lead to significant limitations in social functioning and progressive decline in general functioning. Our definition of dementia symptoms implies that it covers cognitive impairment, pre-diagnostic dementia and dementia in its early stages. In this thesis informal caregivers were spouses, children or other relatives and friends responsible for the organisation of most (informal) care or providing the most hours of care to the care recipient. They provided at least one hour of unpaid care a week. In *Chapter 1* the main concepts used in this thesis are introduced and the objectives of this thesis are presented.

Caring for patients with (early) dementia symptoms may have a major impact on informal caregivers. However, there is evidence that vulnerable informal caregivers remain unnoticed by health care professionals until they are at a point of crisis, while general practitioners (GPs) are frequently unaware of the presence of cognitive impairment and dementia in their older patients. In contrast to conventional care, pro-active care with timely detection followed by structured care focusing on both patients and informal caregivers, may be more suitable for this vulnerable group. By identifying patients with dementia symptoms and their caregivers before they are in a crisis, interventions may be offered to prevent adverse consequences of caregiving for both caregiver and patient. Moreover, both the patient and the caregiver can prepare future care and benefit from facilities that offer information and support when patient's insight is still relatively preserved.

Among community-dwelling older adults with diagnosed dementia and their primary informal caregivers, some studies showed promising effects for case management programmes and home visits on caregivers' sense of competence, well-being and burden, and on institutionalisation rate and mortality of older adults. We expected that case management would also be effective among older adults with dementia symptoms and their informal caregivers, because both older adults with early detected dementia symptoms and their primary informal caregivers may yield a profit of early identification with subsequent case management.

In co-operation with general practitioners and an organisation for home care in West-Friesland, a region in the north-western part of the Netherlands, we developed an early intervention: case management by district nurses aimed at both the care recipients with dementia symptoms and their primary informal caregivers. Preferably, the identified older adults and their informal caregivers did not receive dementia care so far. We aimed to identify the care recipients with dementia symptoms by means of a) a two-stage screening and b) cognitive testing as indicated by general practitioners.

We expected that the case management intervention would show statistically significant and clinically relevant benefits compared to usual care with regard to caregiver's sense of competence, quality of life, psychological well-being, burden, and patient's quality of life, days of temporary institutionalisation, and days until permanent institutionalisation and death.

*Chapter 2* presents the study protocol of the randomised clinical trial we performed to determine the effectiveness of a case management programme directed towards older adults with dementia symptoms and their primary informal caregivers. This study protocol includes an extensive description of the content of the case management programme, the screening for dementia symptoms and the subsequent recruitment of informal caregivers.

*Chapter 3* presents the results of a randomised clinical trial on the effectiveness of case management. The effects of the case management intervention and usual care were compared among community-dwelling older adults with dementia symptoms and their primary informal caregivers. 99 pairs of informal caregivers and older adults with early dementia symptoms were enrolled in the study: 45 pairs were allocated to the usual care group and 54 pairs to the case management group. For the last group, three district nurses who were specialised in geriatric care, acted as case-manager of dyads of informal caregivers and their care recipients during one year. The case manager had mainly a co-coordinating function consisting of assessment, giving advice and information, planning, co-ordination, organising collaboration, and monitoring of care. The case managers provided practical, informational and socio-emotional support.

In the usual care group, the participants could receive care depending on their own initiative. Usual care comprehended a diversity of health care

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and welfare services and could differ across participants. However, the participants had no or only limited access to important elements of the case management intervention because these elements were not offered regularly.

The primary outcome was caregiver's sense of competence. Secondary outcomes were caregiver's quality of life, psychological well-being, and burden, and patient's quality of life, days of temporary institutionalisation, days until permanent institutionalisation, and days until death. Measurements took place at baseline (before randomisation) and at 6 and 12 months after randomisation.

During follow-up, 8 pairs in the case management group and 3 pairs in the usual care group withdrew from the study. Furthermore, 3 patients died in both groups whereas 1 caregiver died in the usual care group. Finally, 81 pairs retained in the trial during the 1-year follow-up. Linear mixed model analyses showed no statistically significant and clinically relevant differences over time between the two groups on caregiver's sense of competence, quality of life, psychological well-being and burden, and on patient's quality of life. Moreover, survival analyses showed no statistically significant and clinically relevant differences between the patient groups with respect to days until death and days until permanent institutionalisation. Furthermore, logistic regression analysis showed no statistically significant and clinically relevant differences between the two patient groups on days of temporary institutionalisation. Therefore, we concluded that this study provides no reason to recommend case management in primary care above usual care for persons with dementia symptoms and their primary informal caregivers.

*Chapter 4* describes the results of a process evaluation on the delivery of the case management intervention. We found no evidence of effectiveness of case management by district nurses compared to usual care. To get insight into one of the possible causes of this absence of effectiveness, we investigated whether the case management intervention was delivered appropriately. 54 pairs of older adults with dementia symptoms and their informal caregivers allocated to the case management group and the three nurses who acted as case manager participated in this process evaluation.

Delivery of the intervention was revealed with four assessments:

1. Time between date of assignment and the first home visit (preferably

within one month); 2. Intervention fidelity (i.e. whether or not participants received the intervention as designed) of nurses according to the informal caregivers by means of marking the elements received out of a list with elements of the intervention; 3. Intervention fidelity reported by the nurses in semi-structured qualitative interviews, as well as nurses' opinion about the intervention; 4. Hours spent on case management by the nurses; 5. Caregivers' satisfaction with the quality of care received.

Our main findings on the delivery of the case management intervention comprehend:

1) Almost none of the participants received the first home visit within one month after randomisation. The mean time between randomisation and the first home visit was 3.2 months (range: 0.5-8.1 months).

2 +3) The intervention was delivered incompletely according to the participating caregivers and nurses.

4) The mean time per dyad spent on the intervention differed per nurse (range: 5.5 – 15.2 hours), but this difference did not lead to differences in outcomes of the intervention across the three nurses.

5) No differences were found in caregivers' satisfaction with the quality of care received across the three nurses. The following aspects of care could be improved: care co-ordination, spending more time on consultations, trying to understand the patient's problems, discussing problems, and organising a replacement when the regular help is absent.

This study shows that incomplete implementation of a case management intervention delivered by district nurses in a randomised clinical trial is one possible reason for not finding any surplus value of case management above usual care. The nurses often did not experience the intervention as necessary yet for the included participants. This may have contributed to the fact that the case management intervention was not delivered completely as designed. We recommend paying attention to the realisation of the planned activities during the implementation of case management interventions.

*Chapter 5* presents the results of a psychometric evaluation of the main outcome measure of the randomised clinical trial: the Sense of Competence Questionnaire (SCQ). This questionnaire was originally developed and validated for informal caregivers of patients with diagnosed dementia. It consists of three domains: 1. Satisfaction with the care recipient, 2.

## *Summary*

Satisfaction with one's own performance, and 3. Consequences of involvement in care for the personal life of the caregiver. In order to study the validity and usefulness of the SCQ when applied to informal caregivers of older adults with dementia symptoms, a psychometric evaluation was performed among 99 informal caregivers who participated in our randomised clinical trial.

We investigated the SCQ its construct validity, feasibility, subscales, homogeneity, and floor and ceiling effects in the new target group of informal caregivers of older adults with dementia symptoms. Firstly, to investigate construct validity, hypotheses were tested concerning the association between sense of competence and burden, mental quality of life, depressive symptoms, and mastery. Most hypotheses on construct validity were rejected. Moreover, only the subscale 'Consequences of involvement in care' was found to be partly valid. Secondly, feasibility was assessed on the basis of response rate and the proportion of missing data for each item. 93 out of 99 persons completed the SCQ. The proportion of unanswered items per item ranged from 0 - 3%. Thirdly, an exploratory principal component analysis was used to investigate whether the SCQ comprises the three subscales established in previous studies. We found that the SCQ comprised the three expected subscales. Fourthly, homogeneity was assessed for each subscale with Cronbach's  $\alpha$  and item-total correlations and they were satisfactory. Lastly, floor and ceiling effects were explored and a ceiling effect occurred on the subscale 'Satisfaction with the care recipient'.

In conclusion, the three subscales of the SCQ showed good homogeneity and feasibility, but their validity for using in our target group is insufficient: only the subscale 'Consequences of involvement' was found to be partly valid. The two other subscales might not be relevant yet for the new target population, since many of the items on these scales refer to problem behaviour and problematic interactions. Our message to clinicians and researchers is not to use these subscales among informal caregivers of older adults with dementia symptoms.

*Chapter 6* presents the results of a psychometric evaluation of the self-report Informant Questionnaire on Cognitive Decline (IQCODE-SR). The IQCODE-SR was the first stage of the two-stage screening for dementia symptoms. The original proxy version of the IQCODE has been successful in identifying demented persons in a general population. However, we administered the IQCODE in a different way: we used self-reports (with

or without help from a proxy) instead of proxy reports only. Therefore, we investigated feasibility, homogeneity and construct validity of the IQCODE-SR. 4823 community-dwelling older adults received an IQCODE-SR. Feasibility was assessed on the basis of response rate, the proportion of missing data for each item, and the number of persons who received help in completing the questionnaire. Feasibility was acceptable, with a response rate of 58.9%. Missing answers per item ranged from 2.5-7.3%, and 915 out of 2841 participants received help in completing the questionnaire. Homogeneity was checked with Cronbach's  $\alpha$  and was good, with Cronbach's  $\alpha=0.94$ . To investigate construct validity, hypotheses on performance of the IQCODE-SR were tested. The majority of hypotheses on construct validity were confirmed.

We concluded that the IQCODE-SR meets the basic requirements of a good measurement instrument: the psychometric properties of the IQCODE-SR demonstrated acceptable feasibility and good homogeneity, and most of the hypotheses on construct validity were confirmed. Further research is necessary to determine the IQCODE-SR's accuracy to identify older adults who are at risk of dementia. In addition, the extent to which cognitively impaired persons can validly complete the IQCODE with and without assistance needs further evaluation.

*In chapter 7* the results of a cross-sectional comparison between two methods to identify older adults with dementia symptoms is presented:

- 1) The usual identification of dementia by general practitioners (GPs);
- 2) A two-stage screening method that we used to identify older adults with dementia symptoms. The methods were carried out on the same population: 3449 community-dwelling older patients of 44 GPs in West-Friesland, the Netherlands. We examined whether the screening that identified patients with dementia symptoms who needed further examination yielded patients who were not detected by their GP. Moreover, we assessed which factors were associated with GPs' awareness of patients identified by the screening.

What did the usual identification of dementia by GPs imply? Based on their actual knowledge and filed patient information, GPs identified prevalent and suspected cases of dementia on a list of their patients who were 75 years of age and older and lived at home. They also indicated patients of whom insufficient information was available to provide a judgment.

What did the two-stage screening imply? In stage one, patients

## *Summary*

received a postal health questionnaire, including a self-report version of the short Informant Questionnaire on Cognitive Decline (IQCODE). This questionnaire has been successfully in distinguishing demented persons from a general population sample. We used self-reports (with or without help from a proxy) instead of proxy reports only. Patients with an IQCODE score of 3.6 and over (strongly suggesting cognitive decline) proceeded to stage two. In stage two, they were assessed at home with the Mini Mental State Examination (MMSE) and the seven minute screen (7MS). The MMSE is the most widely used brief screening test of mental status, and the 7MS has shown to be a useful tool for discriminating demented and cognitively impaired patients from cognitively intact patients. Patients who scored less than 24 on the MMSE or who had a probability of having dementia of 70% or more according to the 7MS, were regarded as having dementia symptoms.

Of the 3449 persons approached for the screening, 2101 returned a questionnaire (60.9%). Therefore, we were able to compare the two methods among 2101 community-dwelling older general practice patients aged 75 years and older. The two-stage screening yielded 117 patients with cognitive impairment who needed further examination; in most cases ( $n=82$ , 70.1%) their GP was unaware of the symptoms. Among patients identified by the screening, GPs' awareness was associated with co-morbidity of chronic diseases (odds ratio (OR) = 3.19; 95% confidence interval (CI) = 1.25 to 8.15), depressive symptoms (OR = 0.41; 95% CI = 0.17 to 0.99), and cognitive functioning (per point on the MMSE, OR = 0.88; 95% CI = 0.79 to 0.98).

We concluded that a two-stage screening and increased alertness for cognitive impairment and dementia among patients with depressive symptoms may improve the detection rate of dementia in general practice. To decide whether screening for dementia is useful in general practice, a more detailed study of the diagnostic accuracy of the screening, and a critical evaluation of the advantages and disadvantages for GPs and patients is needed. The screening has limitations and we do not recommend implementing it before the majority of Wilson and Jungner's criteria on screening are met.

*Chapter 8* summarises the main findings and conclusions of this thesis. Important topics related to the trial are discussed in more depth, as well as the methodology used. Finally, recommendations for further research and daily health care are given.

*The main finding of this thesis is:*

Case management by district nurses showed neither statistically significant nor clinically relevant benefits compared to usual care with regard to caregiver's sense of competence, quality of life, psychological well-being, burden, and patient's quality of life, days of temporary institutionalisation, and days until permanent institutionalisation and death.



# Samenvatting

## **De effectiviteit van case management bij ouderen met dementie-symptomen en hun mantelzorgers**

Dit proefschrift gaat over de effectiviteit van case management gegeven door wijkverpleegkundigen aan thuiswonende ouderen met dementiesymptomen en hun belangrijkste mantelzorgers. We gingen met een onderzoek na of case management beter is dan de bestaande zorg voor de ouderen en hun mantelzorgers.

Met case management bedoelen een vorm van zorg waarbij een zorgverlener zich richt op het vervullen van de zorgbehoeften van een patiënt en zijn naasten. De zorgverlener brengt daarbij samenhang en afstemming in het zorgaanbod. In ons onderzoek wordt het case management uitgevoerd door wijkverpleegkundigen die gespecialiseerd zijn in ouderenzorg.

Met dementiesymptomen bedoelen we de aanwezigheid van diverse cognitieve problemen die leiden tot beperkingen in het dagelijkse leven. De cognitieve problemen zijn geheugenproblemen en ten minste 1 van de volgende beperkingen: problemen met het uitvoeren van complexe handelingen, moeite met het vinden van de juiste woorden of de zinsopbouw, problemen met het plannen van taken en het verlies van het vermogen om bekende voorwerpen en mensen te herkennen. Dit soort problemen komt onder andere voor bij mensen die dementie hebben. Toch hadden de deelnemers aan ons onderzoek niet allemaal dementie. De problemen die deelnemers van dit onderzoek hadden, liepen uiteen: sommigen hadden last van cognitieve problemen en stoornissen, anderen hadden dementie in de beginfase van het syndroom of een dementie die nog niet gediagnosticeerd was. Ze hadden echter 1 ding gemeen: ze ontvingen geen hulp van de ggz die speciaal gericht was op personen met dementie.

Mantelzorgers zorgen onbetaald en gedurende een langere periode voor een hulpbehoevende persoon waar ze een persoonlijke band mee hebben, bijvoorbeeld een partner, kind of een vriend. In dit onderzoek zorgden de mantelzorgers ten minste 1 uur per week voor hun naaste. Alleen de 'belangrijkste' mantelzorger van een persoon werd betrokken in dit onderzoek. Wanneer er meer dan 1 mantelzorger betrokken was bij de zorg hebben we ervoor gekozen om de persoon die de meeste zorg verstreekte of de (mantel)zorg coördineerde te beschouwen als de belangrijkste mantelzorger.

In *hoofdstuk 1* staat beschreven waarom we dit onderzoek uitgevoerd hebben. Het zorgen voor mensen met dementiesymptomen kan een behoorlijke invloed hebben op mantelzorgers. Daarom is het zorgwekkend dat kwetsbare mantelzorgers niet altijd opgemerkt worden door huisartsen en andere hulpverleners. Ze worden vaak pas opgemerkt wanneer er sprake is van een crisis. Huisartsen zijn vaak niet op de hoogte van de aanwezigheid van dementiesymptomen bij hun oudere cliënten. Wellicht is een zorgvorm waarbij deze doelgroep (ouderen met dementiesymptomen en hun mantelzorgers) actief wordt opgespoord en benaderd beter dan de traditionele afwachtende zorg voor deze doelgroep. Zo kan preventieve hulp worden aangeboden aan de mantelzorger en patiënt om nadelige gevolgen van het geven van mantelzorg te voorkomen.

We lazen over enkele veelbelovende onderzoeken naar de effecten van case management en huisbezoeken bij thuiswonende ouderen met een diagnose dementie en hun mantelzorgers. Er was een gunstig effect voor de deelnemende mantelzorgers op de volgende uitkomstmaten: het gevoel van competentie van de mantelzorgers (dit is het gevoel dat je de zorg al dan niet goed aan kunt), het welbevinden en de ervaren druk door het geven van mantelzorg. Ook was er een gunstig effect op het aantal opnames in verpleeg- en verzorgingshuizen en sterfte bij ouderen. Wij verwachtten daarom dat case management ook dergelijke effecten zou hebben bij een groep met mildere problematiek. Mantelzorgers van ouderen met dementiesymptomen zouden kunnen profiteren van vroegtijdige opsporing met aansluitend daarop case management.

Samen met huisartsen en een thuiszorgorganisatie in West-Friesland ontwikkelden we een dergelijke interventie: case management uitgevoerd door wijkverpleegkundigen gericht op zowel de ouderen met dementiesymptomen en hun belangrijkste mantelzorgers. De ouderen en hun mantelzorgers ontvingen bij voorkeur nog geen zorg die speciaal bedoeld is voor personen met dementie. De ouderen met dementiesymptomen werden opgespoord via a) een screening die uit 2 stappen opgebouwd was b) cognitieve testen bij ouderen die door de huisarts verdacht werden van dementie.

We verwachtten dat deelnemers aan het case management programma gezondheidswinst zouden hebben ten opzichte van deelnemers die aangewezen waren op gebruikelijke zorg.

## *Samenvatting*

In hoofdstuk 2 beschrijven we hoe we de effectiviteit van het case management bij thuiswonende ouderen met dementiesymptomen en hun belangrijkste mantelzorgers onderzoeken. Het onderzoeksprotocol bevat een uitgebreide beschrijving van de inhoud van het case management programma, de screening om ouderen met dementiesymptomen op te sporen en de daaropvolgende werving van mantelzorgers.

Het protocol van het case management omvatte enkele standaard activiteiten en optionele activiteiten. Het zag er als volgt uit:

### **Standaard activiteiten**

*Inhoud van het eerste huisbezoek (binnen een maand na randomisatie):*

- In kaart brengen van de situatie van de patiënt met het Resident Assessment Instrument Home Care (RAI-HC). Dit is een gestructureerd anamnese-instrument op de computer. Na het invullen zijn er automatisch probleemgebieden op te vragen. Na afname van het instrument worden samen met de patiënt en mantelzorgers problemen gekozen waar een zorgplan voor wordt gemaakt;
- Achterlaten van een 'zorgpaspoort' waarin afspraken met andere hulpverleners worden genoteerd zodat hulpverleners van elkaars activiteiten op de hoogte zijn.

*Inhoud van het tweede huisbezoek:*

- In kaart brengen van de situatie van de mantelzorgers aan de hand van een draagkracht-draaglast lijst;
- Opstellen van een zorgplan voor de mantelzorgers;
- Achterlaten van een gids voor mantelzorgers. Dit is een gids met praktische informatie voor mantelzorgers en adressen van allerlei instanties die mantelzorgers kunnen ondersteunen.

*Na twee huisbezoeken:*

- Monitoren van de situatie door iedere drie maanden contact op te nemen met de mantelzorgers en patiënt;
- Het bezoeken van de huisarts van de patiënt om hem/haar te informeren over de situatie (aan de hand van de problemen die geïdentificeerd zijn met het RAI-HC).

### **Optionele activiteiten**

- Verwijzen naar andere hulpverleners (waaronder diagnostische centra);

- Het organiseren van familiebijeenkomsten. Dit zijn bijeenkomsten die als doel hebben om het sociale netwerk van de patiënt en mantelzorger voorlichting te geven, de mantelzorger te ontlasten en om te zorgen dat de mantelzorger meer sociale steun ervaart.

*Hoofdstuk 3* beschrijft de resultaten van het onderzoek naar de effecten van het case management. In totaal wilden 99 paren meedoen aan het onderzoek. Via een loting werd bepaald welke zorg een deelnemerspaar kreeg: 54 paren werden in de case management groep geloot en 45 in de groep met normale zorg. De paren in de case management groep kregen gedurende een jaar case management van 3 wijkverpleegkundigen die gespecialiseerd waren in ouderenzorg. Deze verpleegkundigen hadden voornamelijk een coördinerende taak. Ze deden gezondheidsmetingen, gaven advies en informatie, planden zorg, coördineerden zorg, werkten samen met andere hulpverleners en hielden structureel de situatie van de deelnemersparen in de gaten (monitoren). De case managers gaven informatie en praktische en sociaal-emotionele steun. De zorg die deelnemers in de ander groep kregen was afhankelijk van hun eigen initiatief. Zij konden een beroep doen op de normale zorg die voor handen was in West-Friesland.

Bij de mantelzorgers keken we naar de invloed van case management en normale zorg op het gevoel van competentie, depressieve gevoelens, de kwaliteit van leven en de ervaren druk door het geven van zorg. Bij de thuiswonende ouderen keken we naar de invloed op de kwaliteit van leven, het aantal tijdelijke opnamedagen in zorginstellingen en de tijd tot sterfte en tijd tot een definitieve opname in een verpleeghuis of verzorgingshuis. We verwachtten dat deelnemers aan het case management programma gezondheidswinst zouden hebben ten opzichte van deelnemers die aangewezen waren op gebruikelijke zorg.

Tijdens het onderzoeksjaar stopten 8 paren uit de case managementgroep en 3 uit de gebruikelijke zorg groep met het onderzoek. Daarnaast stierven 3 ouderen met dementiesymptomen in beide deelnemersgroepen en stierf er 1 mantelzorger uit de gebruikelijke zorg groep. Uiteindelijk bleven er dus 81 paren deelnemen aan het onderzoek. De belangrijkste bevinding van het onderzoek is dat case management gegeven door wijkverpleegkundigen geen statistisch significante of klinisch relevante voordelen biedt ten opzichte van gebruikelijke zorg voor wat betreft het gevoel van competentie, kwaliteit van leven, depressieve gevoelens, de ervaren druk door het geven van mantelzorg

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bij mantelzorgers, én de kwaliteit van leven, aantal tijdelijke opnamedagen (o.a. in ziekenhuizen, verpleeghuizen en verzorgingshuizen), tijd tot sterfte en tijd tot permanente opname in een verpleeghuis of verzorgingshuis van patiënten. Het onderzoek leverde dus geen aanwijzingen op om case management aan te bevelen in plaats van gebruikelijke zorg voor ouderen met dementiesymptomen en hun belangrijkste mantelzorgers.

*In hoofdstuk 4* gaan we na in hoeverre het case management werd uitgevoerd zoals de bedoeling was. Een incomplete uitvoering van het case management kan één van de vele verklaringen zijn voor de bevinding dat case management niet effectiever was dan gebruikelijke zorg. 54 ouderen en hun mantelzorgers ontvingen het case management van drie wijkverpleegkundigen. We gingen op een aantal manieren na in hoeverre het case management werd uitgevoerd zoals de bedoeling was. De evaluatie van de uitvoering van de zorg laat zien dat een incomplete uitvoering van het case management één van de mogelijke redenen is waarom we geen meerwaarde van case management vonden ten opzichte van gebruikelijke zorg. Vaak werden onderdelen van het case management door de verpleegkundigen nog niet als noodzakelijk ervaren voor de deelnemers. Dat kan eraan bijgedragen hebben dat het case management niet werd uitgevoerd zoals de bedoeling was. Wanneer organisaties case management willen gaan toepassen zullen ze aandacht moeten besteden aan hoe ze zorgen dat verpleegkundigen de geplande activiteiten daadwerkelijk gaan realiseren en hoe ze zorgen dat case management daadwerkelijk toegesneden wordt op de situatie van de zorgontvanger.

Om het effect van het case management en de gebruikelijke zorg te meten gebruiken we vragenlijsten. De vragenlijst die we gebruiken voor het meten van het gevoel van competentie bij de mantelzorger heet de Sense of Competence Questionnaire (SCQ). De vragenlijst was oorspronkelijk ontwikkeld voor mantelzorgers van personen met dementie. Wij verwachtten dat deze vragenlijst ook geschikt zou zijn voor mantelzorgers van personen met dementiesymptomen. In een aparte studie bekeken we of de vragenlijst ook daadwerkelijk geschikt is om bij mantelzorgers van personen met dementiesymptomen te gebruiken. *In hoofdstuk 5* beschrijven we hoe we deze vragenlijst beoordeeld hebben op een aantal eigenschappen. Bij de deelnemers aan het onderzoek in hoofdstuk 3 gingen we na hoe geschikt

de SCQ is voor onze doelgroep. De SCQ vragenlijst is opgebouwd uit een drietal subschalen. Uit onze evaluatie bleek dat de vragenlijst minder geschikt is voor mantelzorgers van mensen met dementiesymptomen. Twee van de drie subschalen waren (nog) niet relevant voor onze doelgroep. Alleen de subschaal consequenties voor het dagelijkse leven komt nog enigszins goed uit de evaluatie. Ons advies is om de andere twee subschalen niet te gebruiken bij mantelzorgers van ouderen met dementiesymptomen.

Om mensen met dementiesymptomen op te sporen maakten we gebruik van een stapsgewijze screening.

Stap 1: huisartspatiënten van 65 jaar en ouder ontvingen een gezondheidsvragenlijst. Deze lijst bevatte onder andere de Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE). Deze vragenlijst meet cognitieve achteruitgang bij ouderen. Eigenlijk is de IQCODE een lijst waarbij een informant een oordeel geeft over de cognitieve achteruitgang bij een ouder iemand die hij/zij goed kent. In onze screening vroegen we de oudere persoon om zelf de lijst in te vullen (met of zonder hulp van een informant). Een IQCODE score van 3.6 of hoger staat in dit onderzoek voor een grote kans op cognitieve achteruitgang. Personen met een IQCODE score van 3.6 of hoger gingen door naar stap 2 van de screening.

Stap 2: ouderen ondergingen twee cognitieve testen. Er werd aangenomen dat mensen die slecht scoorden op de cognitieve testen van stap 2 dementiesymptomen hadden.

*In hoofdstuk 6* bekijken we in hoeverre de zelfrapportage IQCODE (waarbij mensen zelfstandig of met hulp van anderen de IQCODE-lijst invulden) daadwerkelijk geschikt is om te gebruiken voor het opsporen van ouderen met dementiesymptomen. We concludeerden dat de zelfrapportage IQCODE voldoet aan de basiseisen van een goed meetinstrument. Toch is verder onderzoek nodig om te bepalen of de IQCODE accuraat mensen kan opsporen die risico lopen op dementie. Ook moet nog bekeken worden in hoeverre mensen met cognitieve problemen de IQCODE goed kunnen invullen met en zonder hulp van anderen.

*In hoofdstuk 7* bekijken we of de twee-staps screening om mensen met dementiesymptomen op te sporen daadwerkelijk mensen opspoorde waarvan de huisarts nog niet wist dat er sprake was van dementiesymptomen.

## *Samenvatting*

Daarnaast bepaalden we welke factoren samenhangen met of de huisarts de opgespoorde mensen via de screening al of niet kende. Hiervoor vergeleken we 2 methoden om ouderen met dementiesymptomen op te sporen:

- 1) de gebruikelijke opsporing door huisartsen. De huisarts gaf op een lijst met zijn patiënten aan wie hij verdacht van dementie en wie hij onvoldoende kende om een dergelijk oordeel te vellen;
- 2) de stapsgewijze screening.

We konden de 2 methoden bij 2101 mensen vergelijken. Zij deden mee aan de screening én hun huisarts gaf een oordeel over hen. De screening spoorde 117 personen op met dementiesymptomen. Meestal was de huisarts er niet van op de hoogte dat er sprake was van dementiesymptomen: bij 82 van de 117 personen was de huisarts niet op de hoogte (70%). Of de huisarts op de hoogte was van de dementiesymptomen hing af van de aanwezigheid van chronische ziekten, depressieve symptomen en het cognitief functioneren. Wanneer iemand cognitief goed functioneerde of depressieve symptomen had, dan was de kans kleiner dat de huisarts op de hoogte was van de dementiesymptomen dan dat hij wel op de hoogte was. Wanneer iemand chronische ziekten had, dan was de kans groter dat de huisarts op de hoogte was van de dementiesymptomen dan dat hij niet op de hoogte was. We concludeerden dat de screening en een verhoogde alertheid op dementiesymptomen onder ouderen met depressieve symptomen op de lange termijn wellicht kan leiden tot een beter detectiepercentage van dementie in de huisartsenpraktijk. De screening wordt niet aangeraden: meer onderzoek is nodig naar de accuraatheid van de screening en de voor én nadelen van screening voor huisartsen en patiënten.

*Hoofdstuk 8* vat de belangrijkste bevindingen en conclusies uit dit proefschrift samen. Daarnaast worden belangrijke onderwerpen uitvoerig besproken, evenals de gebruikte methoden. Ook doen we aanbevelingen voor toekomstig onderzoek en de dagelijkse praktijk.

De belangrijkste bevinding van het onderzoek is dat case management gegeven door wijkverpleegkundigen geen statistisch significante of klinisch relevante voordelen biedt ten opzichte van gebruikelijke zorg voor wat betreft het gevoel van competentie, kwaliteit van leven, depressieve gevoelens, de ervaren druk door het geven van mantelzorg bij mantelzorgers, én de kwaliteit van leven, aantal tijdelijke opnamedagen, tijd tot opname en sterfte bij patiënten.

Ondanks dat het case management geen meerwaarde had ten opzicht van de gebruikelijke zorg voor ouderen en hun mantelzorgers, is een deel van de case management interventie voortgezet in het onderzoeksgebied (een aantal huisartsenpraktijken in Hoorn). Wanneer huisartsen een ‘niet pluis’ gevoel hebben bij oudere patiënten vragen ze een wijkverpleegkundige om langs te gaan om het Resident Assessment Instrument (RAI-HC) af te nemen. Ook houden ze de huisarts op de hoogte van de situatie van de oudere patiënten. Daarnaast gingen wijkverpleegkundigen door met het uitdelen van de gidsen voor mantelzorgers in geheel West-Friesland.



# Dankwoord

## *Dankwoord*

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- Alle mensen uit West-Friesland die bereid waren een gezondheidsvragenlijst in te vullen, alle mensen die bereid waren cognitieve testen te ondergaan én alle mensen die bereid waren deel te nemen aan een onderzoek naar het nut van huisbezoeken én zorgcoördinatie door wijkverpleegkundigen. Dit proefschrift was er niet geweest zonder uw bereidheid om mee te doen aan dit project! Dit proefschrift heeft me ook kennis laten maken met het nuchtere West-Friese volk, West-Friese krentenmik en broeder, en het mooiste streekmuseum (te Hoorn) dat ik ooit gezien heb. De kennismaking met West-Friesland beviel me dus prima;
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Daniëlle

# Curriculum Vitae

## *Curriculum Vitae*

- 1977 • Born in Terneuzen
- 1989-1995 • Secondary school  
Jansenius Scholengemeenschap, Hulst
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- 1999-2002 • Student Mental Health Sciences  
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- 2002-2006 • PhD student Department of General Practice  
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