

Systematic care for caregivers of people with dementia in community mental health services

Anouk Spijker

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For reasons of consistency, terminology may be changed throughout this thesis when compared to the original publications.

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Systematic care for caregivers of people with dementia in community mental health services

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Promotoren

Prof. dr. M.J.F.J. Vernooij-Dassen

Prof. dr. F.R.J. Verhey (Universiteit Maastricht)

Copromotoren

Dr. H.C.H. Wollersheim

Dr. E.M.M. Adang

Manuscriptcommissie

Prof. dr. B.G.M. van Engelen (voorzitter)

Prof. dr. G.J. van der Wilt

Prof. dr. P.A. Dykstra (Erasmus Universiteit Rotterdam)

Paranimfen

Drs. M.A.J.W. de Werd

Dr. C.H.P.A. van de Steeg-van Gompel

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Chapter 1

General introduction

A large, faint word cloud centered on the page, containing words related to dementia, caregivers, and informal institutionalization. The words are in various sizes and shades of gray, creating a textured background.

Key words visible in the cloud include:

- institutionalization
- depressive
- informal
- caregivers
- overburdened
- sense of competence
- economic
- behavioural problems
- facilitators
- screening
- policies
- skills
- proactive
- delay
- effective psychosocial interventions
- quality of life
- psychoeducation
- cognition
- workload
- social network
- needs
- choice
- counseling
- systematic assessment
- timely
- impact
- strengths
- shame
- time constraints
- trust
- barriers
- quality improvement
- involvement
- affection
- emotional
- distressed
- physical
- clerical burden
- intervention
- leadership
- distress
- decrease
- behavioral impairments
- budgetary constraints
- responsibility
- mental
- training
- professionals

Family caregivers, the backbone of the healthcare system, are frequently themselves the hidden patients. Their commitment to care for frail older relatives may lead to exhaustion, with negative consequences for themselves and their loved ones. – S.K. Ostwald, 1997

Research aim

The strain of caring for people with dementia is not just a social issue, but an economic one: it places a growing burden on the working population and health systems.¹ The Alzheimer's Disease International's first World Alzheimer Report estimated that 35.6 million people worldwide were living with dementia in 2010, which will increase to 65.7 million people by 2030 and 115.4 million by 2050.² The annual total cost of dementia in Western Europe is estimated at 210.12 billion US dollars. The direct costs of social care (mainly the costs of institutional care, but also the costs of community care professionals) and medical care (the costs of treating dementia and other conditions in primary and secondary care) predominate with 58%, while 42% of the total costs accounts for informal care (unpaid care provided by family and others).²

However, the budgetary constraints of the direct costs of social care necessitate the search for care alternatives such as postponement of institutionalization and care at home. Psychosocial interventions may be as effective as pharmaceutical treatment in many areas, but they have been less extensively researched and much less effectively promoted.³ Contemporary policies are therefore designed to develop proactive, cost-effective support programs for informal caregivers and people with dementia at home, which may delay or decrease institutionalization of people with dementia.

The research aim of this thesis was to investigate the effectiveness and efficiency of training community mental health (CMH) professionals in the Systematic Care Program for Dementia (SCPD) in CMH services in the Netherlands, as compared to usual CMH care. The general research questions are: What are the effects of the SCPD on institutionalization of people with dementia (primary outcome) and on the quality of life of the caregiver and the person with dementia (secondary outcome) at the 12-month follow-up, as compared to usual CMH care? What are the costs and benefits of the SCPD at the 12-month follow-up, as compared to usual care?

This introduction successively describes the clinical syndrome of dementia, the impact of dementia, referral, and treatment of informal caregivers and people with dementia in CMH care, the theoretical background and the training in the SCPD, and some design considerations. We conclude with the general and specific research questions of our study and the outline of this thesis.

The dementia syndrome

Dementia affects mainly older people, although there is a growing awareness of cases that start before the age of 65 years. After that, the likelihood of developing dementia roughly doubles every 5 years.² The number of Dutch residents with dementia will rise from 243,000 in 2011 to more than half a million in 2040.⁴ Seventy percent of the people with dementia are cared for at home,^{5;6} and they depend on the care from their informal caregivers (usually the cohabiting spouse, daughter, or daughter-in-law).⁷ Their mean age is 65 years⁸ and 70% of the informal caregivers are women.^{5;8}

Dementia is a clinical syndrome of widespread progressive deterioration of cognitive abilities and normal daily functioning.⁹ These cognitive and behavioral impairments greatly challenge individuals with dementia, family members, and informal caregivers.⁹ Symptoms of dementia are loss of memory, judgment, and reasoning; changes in mood and behavior; and progressive difficulties in performing complex daily activities such as managing finances or medication and, later on, even simple tasks such as eating and toileting.¹⁰

The course, duration of illness, and the prognosis vary with the cause of dementia. The most frequent cause of dementia in the Dutch general population is Alzheimer's disease (70%).⁴ Other common causes are vascular dementia, Lewy body dementia or Parkinson's disease dementia, mild cognitive impairment (MCI), and frontotemporal dementia.⁹ The course of dementia can be divided into seven stages: increased risk, symptoms, MCI, mild, moderate, and severe dementia, and mortality.¹¹ The definitions of the stages vary depending on the method used – for example, the Clinical Dementia Rating (CDR) Scale,^{12;13} Global Deterioration Scale (GDS),¹⁴ Functional Assessment Staging (FAST),¹⁵ DSM-III-TR,¹⁶ or the Mini-Mental State Examination (MMSE).¹⁷⁻²³ During the course of the disease, the number and severity of the symptoms increase.⁴ People with dementia often live for many years after being diagnosed, but they die earlier than their peers without dementia.²⁴ The median survival time of people with

dementia varies from 3 to 9 years.²⁴⁻²⁶ There is currently no cure for dementia, which challenges the quality of life of people with dementia and their caregivers for an extensive period.

The impact of dementia

The impact of dementia demands that we create favorable circumstances for caring for people with dementia at home as long as possible and that we minimize the caregiver risks of undue burden and depression – circumstances that may delay institutionalization of those with dementia. Because our study focuses on the caregiver, we do not discuss the impact of dementia on the person affected by dementia.

Impact of dementia on informal caregivers

Seventy percent of the people with dementia are cared for at home,^{5;6;8} on average 20 hours a week,^{6;8} so their daily functioning depends mainly on the quality of care provided by informal caregivers at home. This includes support in daily activities such as eating, shopping, housekeeping, washing, and dressing; medical-nursing tasks; dealing with financial affairs; and hourly supervision if the person with dementia cannot be left alone.⁷ Love and affection are the motives caregivers mention most for caring for their relative with dementia.²⁷ Other frequently mentioned motives are a sense of duty, the fact that their relative would have helped them too, and not wanting their relative to be institutionalized.²⁷ On average, people with dementia live at home for 4½ years after dementia has been diagnosed.²⁸

Although informal caregivers say they get appreciation for the care they give and draw a lot of satisfaction from it,^{27;29} their caring responsibilities can also lead to declining physical and mental health.²⁹ The National Dementia Program (NDP) reveals that caregivers are most troubled by changes in behavior and the threat of institutionalization of the person with dementia.³⁰ The care for the person with dementia is often too emotionally draining for the caregivers, they feel that they have had insufficient information about the possibilities for support after the diagnosis has been made, and they worry about what things in or around the home are unsafe for the person with dementia.^{30;31} Caregivers of people who have had symptoms of dementia for a longer time (> 1 year) also feel the limitations in their social networks.³⁰ Furthermore, caregivers of people with dementia suffer more from immune disorders and are at greater risk of mortality than their noncaregiving counterparts.³² They carry

a greater burden³³ and suffer more deeply from depression than caregivers of relatives with other chronic illnesses^{32;34} and their noncaregiving counterparts.³⁵ In the Netherlands, spouses of people with dementia had a risk of depression that was four times as great as the risk for spouses of people without dementia.³⁶ About half the caregivers of people with dementia suffer from depression, while only 20% are treated.³⁷ The undertreatment of caregiver depression further depletes the caregiver's own resources and increases direct care costs for the caregiver and the person with dementia (also referred to as "the dyad"), including the costs of earlier institutionalization.³⁸ Systematic reviews have noted that caregiver depressive symptoms, caregiver burden (being overwhelmed with various facets of care), emotional fatigue, and perceptions of entrapment in the caregiving role are at least as important as the functional and cognitive decline of the person with dementia in predicting the risk of institutionalization.^{39;40}

Impact of dementia on society

At least 60,000 people with dementia lived in homes for the elderly or nursing homes in the Netherlands in 2011.⁴ Ninety-seven percent of the total healthcare cost of 3.2 billion euros for dementia (4.7% of the Dutch total cost of healthcare cost) is spent on homes for the elderly, nursing homes, and home care.⁴ The care of institutionalized people with dementia is one of the three most expensive areas of healthcare.⁴¹⁻⁴⁴ Furthermore, as a result of the growing elderly population, shortages within institutional care are expected.^{7;41} If the unpaid informal care provided by caregivers is not available, use of paid professional care at home or in institutions is the consequence, and it would double the direct healthcare costs.^{41;45} Moreover, the potential working population, the population who should bear the cost (people aged 15 to 64 years) is set to continue substantial decline. While there were still 42 potential workers for each person with dementia in 2011, this number will drop to 16:1 in 2050.⁴

Referral and treatment in community mental health services

Referral of the person with dementia to community mental health services

Only 10% of the informal caregivers of people with dementia living at home receive professional care for his or her own symptoms, while 90% of the caregivers say they have one or more problems.³¹ In most cases, the physician is the first healthcare professional whom informal caregivers with a request for help consult because they suspect "something is wrong" with the care recipient. They realize that the person

cannot function properly in daily activities, or observe that the person's behavior cannot be interpreted. The Dutch College of Family Physicians dementia guideline states that the family physician should be alerted by signals that indicate dementia and should actively respond with a diagnosis. If the diagnosis is indeed dementia, the physician should take responsibility for the general supervision of the patient and relatives and teach them how to cope with the disease.⁴⁶

With their expertise, the CMH services can play a prominent role in both the diagnosis and guidance of people with dementia and their caregivers. Thirty percent of the physician dementia referrals are for people with dementia referred to the CMH services, while 24% are referred to a geriatrician; 22% to a neurologist; and 9% to a psychiatrist.^{47;48}

Treatment of caregivers in community mental health services

There are major regional differences in the use of outpatient mental healthcare.^{49;50} Furthermore, in 2010, more than 20% of the patients had to wait longer to start their treatment than is acceptable according the so-called "Treknorm".⁵¹ Once the person with dementia enters the CMH service, accompanying informal caregivers often remain invisible until a crisis occurs.

Informal caregivers are invisible partly because they pay scant attention to their own problems, and CMH professionals may not know how to support them proactively. Many informal caregivers find it difficult to admit their reluctance to be helped with the problems they face, and they consider themselves supporters rather than people in need.^{38;52} Community mental health professionals are challenged to deal with this reluctance and with possible provocations to get involved in family conflicts.⁵² Furthermore, informal caregivers accompanying people with dementia are not registered at the CMH service. Thus they are rarely screened in a timely and structured manner for the problems they may encounter,⁴⁹ nor do they receive a diagnosis.⁵¹ As already mentioned, depressed caregivers are either treated inadequately or not at all.^{37;53} However, the CMH service offers many opportunities to support informal caregivers. Unfortunately, these opportunities are currently not routinely used because of the late detection of caregiver problems.

Theoretical background of the Systematic Care Program for Dementia

Basically, the SCPD consists of a systematic assessment of the informal caregiver's sense of competence and symptoms of depression and suggestions about how to deal with deficiencies. The SCPD can be applied in the first consultation between a CMH professional and a dyad. To our knowledge, neither the proactive elements nor the systematic elements of the study approach are routinely used in the management of dementia in the CMH care setting.

The Family Support Model

Theoretically driven efficacy studies of psychosocial interventions for caregivers of people with dementia can show promising results in practice because they provide a strong foundation for the design of interventions. They indicate the target population and the specific hypothesis and goals to be developed.⁵⁴

The SCPD is theoretically based on the Family Support Model⁵⁵ in response to the Social Breakdown Syndrome to problems of aging.^{56;57} The Social Breakdown Syndrome describes a malignant spiral of increasing incompetence displayed by the members of an aging family confronted with a hazardous event or a threatening problem. Inability to deal with changes may lead to a crisis in such circumstances.⁵⁸ To break the cycle of social breakdown, the Family Support Model suggests ways that health professionals can reduce vulnerability and increase the competency of the elderly person's family. The salient phases are: 1) reduce the vulnerability of the social network in crisis, 2) reduce the sense of doubt in the relatives' own abilities, 3) reduce the sense of hopelessness, and 4) mobilize and reinforce existing skills.^{55;59}

Vernooij-Dassen⁶⁰ translated the Family Support Model into guidelines to help health professionals provide emotional and practical support for caregivers of people with dementia in the Netherlands (Table 1A; Table 1B). These guidelines explain that, in response to the vulnerabilities of normal aging, the health professional must clarify the life event for the family. As part of the first phase, the professional must realistically discuss the level of the probable impairment when dementia is diagnosed. The second phase in the cycle includes reducing dependence on external and inappropriate labels – specifically, moralisms and a sense of obligation, which might lead to guilt. Health professionals can assist by fostering an open dialogue with families and the person with dementia about expectations, resources, and conflicts, which family members are

frequently fearful of confronting openly. Subsequent stages involve the collective redefinition of the event that has been labeled hopeless; the health professional can help identify feasible, appropriate goals for assisting the family and the person with dementia. Finally, there comes a mobilization of realistic coping skills, a focus on strengths and emphasis on what family members can do versus what they might or should do.⁵⁹ Kuypers and Bengtson conclude that: "By looking at the family as a unit, and recognizing the aging individual as a member of an on-going spiral, we see some hope for intervention to what is usually regarded as a relatively hopeless family situation". The health professional can then play a valuable role in monitoring support. Such a function becomes all the more crucial when one realizes that, in many instances, the family member who is the most viable member of the support system is the spouse, who is her/himself often frail and ailing.^{59;61}

Table 1A. Family Support Model, phase 1 and phase 2

Phase 1. Reduce the vulnerability of the social network in crisis

Bengtson and Kuypers (1985)

- a) Clarify the crisis: what is the problem?
- b) Negotiate limited, short-term, and acceptable contributions. Avoid overburdening.
- c) Avoid conflicting demands. Avoid becoming embroiled in conflicting family relationships.
- d) Provide information about the available professional support systems.

M. Vernooij-Dassen et al. (2000)

- Emotional help: listen actively to assess the situation.
- Practical help: provide information and design care guidelines with the caregiver.
- Emotional help: give the caregiver a chance to discuss the sense of burden.
- Practical help: encourage the caregiver to maintain contacts and to ask for help. Check out what the social network wants to do.
- Emotional help: give the family a chance to discuss problems.
- Practical help: try to resolve conflicts by making practical arrangements.
- Emotional help: use active listening skills to clarify what additional support is required.
- Practical help: provide information about local services.

Phase 2. Reduce the caregivers' sense of doubt of their own abilities

Bengtson and Kuypers (1985)

- e) Provide an opportunity to talk openly about feeling guilty and ideas of what one ought to be doing.
- f) Set reasonable duties.

M. Vernooij-Dassen et al. (2000)

- Emotional help: let caregiver and other network members discuss their feelings of guilt.
- Practical help: reduce the tasks to an achievable level.

The Short Sense of Competence Questionnaire

To assist health professionals identify caregiver problems, Vernooij-Dassen and colleagues^{58;62} developed the Sense of Competence Questionnaire (SCQ), as derived from issues identified in the Family Support Model⁶⁰ and Zarit's burden interview.⁶³ The 27 SCQ items reflect caregivers' sense of being capable of caring for a person with dementia in three domains: 1) satisfaction of the person with dementia as a recipient of care, 2) satisfaction with one's own performance as a caregiver; and 3) consequences of involvement in care for the personal life of the caregiver.^{58;62} The Short Sense of Competence Questionnaire (SSCQ) is the short version of the SCQ and consists of 7 items.⁶⁴ The original structure with three domains of possible caregiver problems remains. The SSCQ also enables health professionals to select the proper strategy to manage each domain of caregiver problems (Table 2).⁶⁴

Table 1B. Family Support Model, phase 3 and phase 4

Phase 3. Reduce the sense of hopelessness

Bengtson and Kuypers (1985)

- g) Identify feasible goals.
 - h) Encourage an honest appraisal of the future.
- M. Vernooij-Dassen et al. (2000)**
- Emotional help: let feelings of hopelessness be expressed and develop caregiver's sense of confidence by looking at practical solutions.
 - Practical help: set up a concrete and achievable program.
 - Emotional help: encourage family to come to terms with the situation.
 - Practical help: try to limit fruitless attempts to improve the patient.

Phase 4. Mobilize and reinforce the existing skills

i) Support and reinforce the positive contribution the family makes to the care.

- Emotional help: show understanding for sense of overburden and compliment the care provided regardless.

j) Program a quick demonstration of limited success outcome.

- Practical help: if caregiver feels overburdened, clarify what he/she still can do and where help is required.

k) Encourage joint work of the formal and informal support systems.

- Emotional help: emphasize the success of achieving small goals.
- Practical help: pick a manageable problem and work together at looking for a solution.
- Emotional help: use active listening skills to show understanding of difficulties asking for and accepting help.
- Practical help: find a care coordinator.

Effective support programs

Controlled studies of the last 30 years have examined whether supporting caregivers is effective, and some studies report that it is. Besides the Family Support Program,^{55;64} the Meeting Centers Support Program^{65;66} and the Community Occupational Therapy Intervention for dyads^{67;68} have proven effective. These programs and some international support programs have found successively positive changes in caregiver sense of competence,^{65;69} feelings of competence in being a female caregiver sharing the same household with the person with dementia,⁶⁰ caregiver depressive symptoms,⁶⁹⁻⁷² problem behavior of the person with dementia,^{65;72;73} and caregiver distress as related to problem behavior of the person with dementia,^{72;74} as compared to changes among controls. Furthermore, these and other successful support programs appear to significantly improve the quality of life of both the caregiver^{69;75;76} and the person with dementia^{69;72} relative to controls. Moreover, some effective support programs have delayed institutionalization of people with dementia,^{60;66;75;77-79} or proved to be cost-effective.⁶⁸ Support programs that involve both the person with dementia and the caregiver(s), that are more intensive, and that are adapted to the caregivers' needs have been the most successful.⁸⁰

The Systematic Care Program for Dementia

The positive study results led to the Family Support Program^{55;64} being transformed into the SCPD to fulfill the urgent need for proactive and cost-effective support programs and to optimally benefit from the opportunities and expertise in CMH services. The SCPD can be divided into three stages:

1. *Screening.* Community mental health professionals screen the caregiver's sense of competence and depressive symptoms with the SCPD screening tool (inventory and interpretation; Table 2). This means that CMH professionals provide data from the SSCQ,⁶⁴ depressive symptoms,⁸¹ and caregiver type.⁸² They also provide their observations of the severity of dementia according to the Diagnostic and statistical manual of mental disorders, 3rd text revision (DSM-III-TR).¹⁶
2. *Psychosocial support.* The assessment of caregiver problems alerts health CMH professionals to flexibly activate proactive interventions. The SCPD offers three possible intervention strategies to initiate support:
 - a. Define acceptable goals of involvement. Organize additional professional support.

- b. Open a dialogue about expectations, resources, conflicts, stigmas, and feelings of guilt. Engage in a dialogue about what the caregiver thinks she or he has to do and what she or he actually can do.
- c. Clarify the relationship between the behavior of the person with dementia and the dementia syndrome.

Supportive actions that CMH professionals might take as a result of the screening during and after each contact with the dyad are registered on the "action list".

- 3. *Transfer to regular healthcare.* Along with psychosocial support, CMH professionals could organize medical, home, or respite care. If the screening for caregiver depression is positive, the CMH professional may also refer the caregiver or start treatment. After ending their contacts with the dyad, they hand the care over to the regular healthcare or home.

The training to teach CMH professionals to use the SCPD consists of three sessions of 2 hours each. One meeting is for explaining the program, and two meetings are for practicing, evaluating the use of the program, and preparing suggestions on how to hand over the responsibility for care after the health service's work is completed. Table 3 summarizes the objectives and methods used in the three training sessions.

Several aids have been developed to facilitate the use of the SCPD:

- 1. The SCPD screening tool. The questions for screening a caregiver's sense of competence and depressive symptoms are printed on a handy plasticized pocket card.
- 2. The SCPD manual consists of the items to be discussed during the training sessions (i.e., background information and methods), and some supporting literature has been added.
- 3. The starter package and action list. Several forms have been developed for the requested data. The starter package contains the forms that CMH professionals need to gather these data. The action list contains 60 possible intervening and supportive actions that CMH professionals might undertake as a result of the screening. They are divided into nine categories: intake, diagnostics, psychoeducation, psychosocial care, medical care, how to hand over care, legal aspects, case management, and crisis management.

Table 3. The objectives and methods of the SCPD training

First training session

Objective: the professional is able to assess the caregiver's sense of competence

Method

- Background and objective of the SCPD
- Sharing experience of obstacles to care for caregivers
- Instruction about how to apply the SCPD
- Role playing to assess the sense of competence
- Further reading, and the SCPD manual
- Preparation of the next training session and casuistic practical experience
- Evaluation

Second training session

Objective: the professional is able to recognize deficiencies in the caregiver's sense of competence and brings up solutions for best practices

Method

- Sharing experiences of applying the SCPD
- Sharing experiences of using the SCPD screening tool
- Organizational obstacles, e.g., those involving caregivers at the first consultation
- Role-playing best practices, finding solutions for deficiencies in competence
- Discussing what is needed for using the SCPD in practice
- Evaluation

Evaluation session

Objective: the professional is able to assess and to suggest solutions for deficiencies in caregivers' sense of competence

Method

- Sharing experiences of applying the SCPD
 - Finding solutions for logistic, organizational, and emotional obstacles
 - Sharing experiences of the tailor-made SCPD screening tool
 - Discussing what is needed to use the SCPD in practice
 - Evaluation
-

Design considerations

New insights about the prevalence and incidence of caregiver depression are the reasons that the SCPD extended the Family Support Program with screening questions concerning caregiver depressive symptoms. Since it is important that the SCPD is embedded in usual care for implementation, we tried to reduce the intensity of the program by adapting it more to individual caregiver needs. Therefore, the intensity of the SCPD was not standardized beforehand. The intensity of the intervention depended

on the judgment of the CMH professional, optimization of the flexibility of the SCPD to individual caregiver needs, and the acknowledgment of the expertise in the CMH services. Moreover, only interventions that were already available in CMH services were used. The "action list" was developed in collaboration with a staff member and CMH professional from participating CMH services. Before the first training session, CMH professionals were asked to provide a social chart consisting of 10 regional service providers – i.e., support groups, Alzheimer café, meeting centers, and home care – to whom dyads could be referred in case a service was not available within their own CMH service.

Research questions and outline

The research aim of this thesis was to investigate the effectiveness and efficiency of the SCPD training for CMH professionals in CMH services in the Netherlands, as compared to usual CMH care. The general research questions are: What are the effects of the SCPD on institutionalization of people with dementia (primary outcome) and on the quality of life of the caregiver and the person with dementia (secondary outcome) at the 12-month follow-up, as compared to usual CMH care? What are the costs and benefits of the SCPD at the 12-month follow-up, as compared to usual care?

Chapter 2. Several support programs for informal caregivers of people with dementia have been developed, but results about the effectiveness of these programs that intend to prevent or delay institutionalizing the person with dementia are conflicting.^{85,86} No systematic review with a meta-analysis was performed to estimate the overall effectiveness of support programs intended to delay this institutionalization. This raised the following questions to be answered in this chapter: What support programs are available, and what is known about their overall effectiveness in preventing or delaying the institutionalization of the person with dementia? Which intervention characteristics distinguish effective psychosocial interventions from ineffective ones?

Chapter 3. This chapter describes the study design in detail to determine the effectiveness and efficiency of the SCPD relative to usual CMH care. Considering our general research questions, we hypothesized that:

1. Use of the SCPD will have decreased the rate of the institutionalization and increased the delay of institutionalization of people with dementia at the 12-month follow-up, as compared with usual CMH care.
2. Use of the SCPD will have effected positive changes in important quality-of-life measures (e.g., better caregiver sense of competence, fewer caregiver depressive symptoms, and less caregiver distress in connection with problem behavior of the person with dementia as well less severe problem behavior of this person, and better quality of life for both members of the dyad) at the 12-month follow-up, as compared to usual CMH care.
3. Use of the SCPD will be cost-effective for all potential values of the willingness to pay for a quality-adjusted life-year, or a unit of time-to-institutionalization of the person with dementia at the 12-month follow-up, as compared with usual CMH care.

This chapter also addresses the intended performance of a retrospective process evaluation of the SCPD as an important tool that can meticulously describe the SCPD intervention itself, the actual exposure of CMH professionals and caregivers to the SCPD, and the experience of the CMH professionals using the SCPD in daily practice. This information is crucial, not only for understanding the success – or lack of it – of psychosocial interventions, but also for providing basic data for economic evaluation of quality improvement research. The general research questions answered in this chapter, specified below and examined in the succeeding chapters, are:

- Were CMH professionals trained in the SCPD as planned?
- Did caregivers receive the care as planned?
- What were the effects on the outcomes of institutionalization and caregivers' quality of life across variability in carrying out the SCPD in practice versus the SCPD as planned?
- What barriers and facilitators did the CMH professionals encounter in carrying out the SCPD as planned?

Chapter 4 focuses on the effect of the SCPD on the primary outcome of institutionalization. We questioned: What is the effect of the SCPD on institutionalization of the person with dementia at the 12-month follow-up, as compared to usual CMH care? And which determinants influence the relation between treatment and institutionalization of the person with dementia as seen at the 12-month follow-up?

Chapter 5 focuses on the effect of the SCPD on the secondary outcome measures of quality of life and the influence of CMH professionals' treatment variability on these measures. Performing a quantitative process evaluation, we questioned: What is the influence of CMH professionals' adherence to the SCPD intervention protocol on quality-of-life measures – the caregiver's sense of competence, depressive symptoms, and distress due to problem behavior of the person with dementia and its severity – at the 12-month follow-up?

Chapter 6 provides a qualitative process evaluation exploring CMH professionals' experiences while adhering to the SCPD intervention protocol in daily clinical practice. The main question is: Which barriers to and facilitators of the systematic and timely use of the SCPD intervention protocol in daily clinical practice are active at these six levels of healthcare: the SCPD innovation, the CMH professional, the caregiver, the social context, the organizational context, and the economic and political context?

Chapter 7 summarizes the main results of the foregoing chapters and places them in a broader scientific, methodological, and societal context. This chapter discusses clarifications of the main results, some methodological considerations that might have affected the results, possible adverse events of the intervention study, and implications for future study, policy, and practice.

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Chapter 2

Effectiveness of nonpharmacological interventions in delaying the institutionalization of people with dementia: A meta-analysis

Anouk Spijker

Myrra Vernooij-Dassen

Emmelyne Vasse

Eddy Adang

Hub Wollersheim

Richard Grol

Frans Verhey

Journal of the American Geriatrics Society 2008; 56: 1116–1128.



Abstract

Contemporary healthcare policies are designed to shape the conditions that can help delay the institutionalization of people with dementia. This can be done by developing support programs that minimize healthcare risks for the people with dementia and their informal caregivers. Many support programs have been developed, and some of them are effective, but there has been no systematic review with a meta-analysis of all types of nonpharmacological support programs with odds of institutionalization or time to institutionalization as an outcome measure. A systematic review with a meta-analysis was therefore conducted to estimate the overall effectiveness of nonpharmacological support programs for informal caregivers and people with dementia that are intended to delay institutionalization.

Thirteen support programs with a total of 9,043 people with dementia were included in the meta-analyses. The estimated overall effectiveness suggests that these programs significantly decrease the odds of institutionalization (odds ratio (OR)=0.66, 95% confidence interval (CI)=0.43–0.99, $P=.05$) and significantly increase the time to institutionalization (standardized mean difference (SMD)=1.44, 95% CI=0.07–2.81, $P=.04$). A meta-analysis of the best-quality studies still showed a positive significant result for the odds of institutionalization (OR=0.60, 95% CI=0.43–0.85, $P=.004$), although the time to institutionalization was no longer significant (SMD=1.55, 95% CI=−0.35–3.45, $P=.11$). The analysis of the intervention characteristics showed that actively involving caregivers in making choices about treatments distinguishes effective from ineffective support programs. Further investigation should be directed toward calculating the potential efficiency of these support programs by applying net-benefit or cost-effectiveness analysis.

Introduction

In Western Europe, the rapidly aging population will, according to the estimates, peak in approximately 2040.¹ An aging population demands more health care and puts pressure on the healthcare budget. The institutionalized care of people with dementia is one of the three most expensive areas of health care.^{2,3} This budgetary constraint necessitates the exploration of temporary alternatives, such as care at home and the postponement of institutionalization.

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Care at home is often intensive and burdensome. Informal caregivers of people with dementia reportedly carry a greater burden than informal caregivers of other chronically ill people,⁴ and they are at greater risk of depression.⁵⁻⁷ Support is required to prevent informal caregivers from becoming overburdened and depressed. An informal caregiver's sense of competence (feelings of being capable of giving care) is a strong determinant of delaying institutionalization.⁸ Contemporary policies, therefore, are designed to shape conditions favorable for caring for people with dementia at home as long as possible and to minimize the risks for informal caregivers.

Several support programs for caregivers of people with dementia have been developed, but the results concerning the effectiveness with regard to same outcome measures are conflicting.^{9,10} This raises the question "What support programs are available, and what is known about their effectiveness?" No systematic review has included a meta-analysis of the data to estimate the effectiveness of all types of nonpharmacological support programs with the odds of institutionalization or time to institutionalization as an outcome measure. Therefore, the literature has been systematically reviewed to estimate the overall effectiveness of nonpharmacological support programs for caregivers and people with dementia in delaying or preventing institutionalization.

Methods

Study design

This study was a systematic review of the literature and a meta-analysis of the data of the relevant publications.

Search strategy

A multicomponent search strategy was used to optimize the identification of relevant studies. The computerized databases of PubMed (including Medline), Web of

Knowledge, and PsycInfo were searched in March 2006. The PICO worksheet¹¹ was used to identify subject-specific keywords to describe the population, comparison, and outcomes of interventions. The search terms referred to six subject-specific keywords: controlled studies, dementia, costs, institutionalization, time spent giving care, and caregivers. Depending on the nature of the selected database sources, medical subheading terms, a thesaurus or a combination of a thesaurus and free text, and words from the selected subject-specific keywords were combined with the Boolean operator "OR". The three searches referring to the outcome measure were then combined with the Boolean operator "OR". The results were combined with the Boolean operator "AND" for the subject-specific keywords referring to controlled studies, dementia, and caregivers. Database source-specific filters were used wherever possible to limit the search period to January 1990 to March 2006. In addition, an unindexed search strategy with the same set of six subject-specific keywords was developed to identify studies in PubMed that would not yet have been cited or indexed. The results obtained from both searches were scrutinized for studies that met the inclusion criteria. The snowball method was used to manually check the references of the included studies to identify any relevant studies that had not yet been included.

Inclusion criteria

Two reviewers (AS, MVD) independently assessed the retrieved studies for inclusion. The initial selection for inclusion was based on the title and abstract of the study. In cases of doubt, a full copy of the study was scanned to determine whether it should be discarded. For the final selection, fulltext copies of the candidate studies were scrutinized. Both reviewers used the inclusion criteria that required:

1. a study population of people with dementia and their informal caregivers
2. community-dwelling people with dementia and informal caregivers
3. an outcome measure of institutionalization
4. a single-study design (not a review or a meta-analysis)
5. a controlled, clinical study
6. a nonpharmacological study
7. a study written in English

Disagreement between the reviewers about whether to include a particular study was resolved by discussion.

Methodological quality

The methodological quality of the included studies was assessed and reported in accordance with the guidelines of the Cochrane Consumers and Communication Review Group,¹² which recommends the evaluation of selection bias, performance bias, detection bias, and attrition bias. Each source of potential bias was assessed with respect to the following quality elements: randomization, allocation concealment, baseline comparability (selection bias), blinding of participants or providers (performance bias), blinding of outcome assessors (detection bias), reporting of attrition rate, and the use of intent-to-treat analyses (attrition bias). Two reviewers (AS, EV) independently assessed the methodological quality of the studies. If assessment was not possible, the quality element under consideration was scored as "unknown". All positively scored quality elements were counted; the maximum total score was 7. Disagreements between reviewers were resolved by discussion, which led to consensus.

Data extraction

Data extracted from the studies comprised a description of the methods used, the participants, the intervention and its characteristics, the measured outcomes and their effect or effect size, and the methodological quality. To ensure standardized scoring, the Cochrane Group's predesigned table¹³ was used and modified until a tailor-made, workable format evolved. Because the studies were expected to be heterogeneous with respect to methods, participants, and interventions, they were described qualitatively in detail. The results are summarized alphabetically according to author in Table 1.

Meta-analysis

The Cochrane Collaboration Group's Review Manager 4.2 (the Cochrane Collaboration, Copenhagen, Denmark) was used to present the overall estimate of the differences between the experimental group and the control group in the odds of institutionalization and time to institutionalization. The odds ratio (OR) and its 95% confidence interval (CI) were calculated as the effect size for the dichotomous outcome measure odds of institutionalization. The OR is a relative measure of risk indicating how much more likely it was that a person with dementia whose caregiver had received the support program would be institutionalized than a person with dementia whose caregiver had not. The standardized mean difference (SMD) and its 95% CI were calculated for the continuous outcome measure time to institutionalization. The SMD

compares the time to institutionalization in the experimental and control groups in terms of a uniform standardized score. The SMD was calculated as the difference between the mean change in time to institutionalization (number of days from baseline to institutionalization) in the experimental group and the control group divided by the standard deviation of the difference. By convention, an SMD of 0.8 indicates large intervention effects, 0.5 a moderate effect, and 0.2 a small effect.¹⁴ For both effect sizes, the OR and the SMD, a P≤.05 (two-tailed) or a 95% CI not including the null point was regarded as statistically significant.

Separate analyses using a fixed-effects model were undertaken for both measurements of institutionalization. The fixed-effects model assumes that all studies consider a common homogeneous population and that the effect size (OR or SMD) is not significantly different between the various trials. This assumption was tested using the test for heterogeneity that uses the I^2 statistic. The I^2 value provides an estimate of the amount of variance across studies due to heterogeneity rather than chance. If the test for heterogeneity is significant ($P<.05$), the fixed-effects model may be invalid.¹⁵ In this case, the analysis was repeated using the random-effects model, in which the random variation within each study and the variation between the various studies are both incorporated. This tends to give a more conservative estimate (broader CI), but the results from the two models usually agree when there is no heterogeneity.¹⁶

It occurred that more than one study by the same authors, with the same study participants but different follow-up periods, were included in this systematic review. Because only one of these same participant studies could be included in the meta-analysis, studies with follow-up periods closest to the mean follow-up periods of the other studies included were selected in the interests of the potential homogeneity across studies.

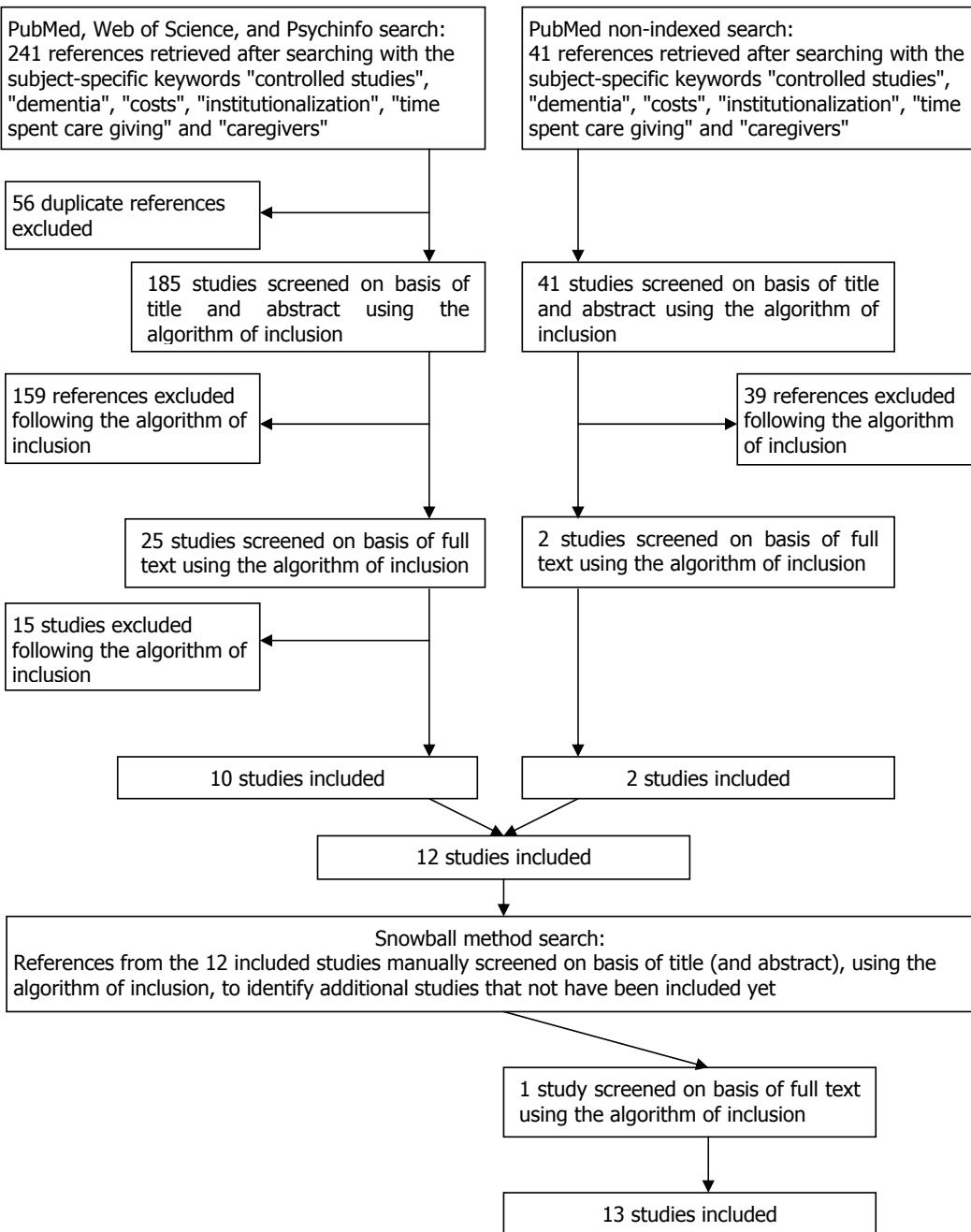
Results

Study selection

The computerized, indexed search resulted in 241 references; PubMed retrieved 106 references, Web of Science 73, and PsychInfo 62 (Figure 1). The computerized, unindexed search in PubMed resulted in 41 references. The main reasons for the exclusion of studies from the computerized searches on the basis of the algorithm of inclusion were that care was given in hospitals or nursing homes; neither odds of

institutionalization nor time to institutionalization was an outcome measure in at least one arm of the study; the study was designed as a review; and the study was predictive, modeling, or noninterventional.

Figure 1. Flowchart of the search strategy



There were no non-English-language European studies that met all inclusion criteria other than that of English language. After exclusion of the irrelevant studies, 12 studies remained. The snowball search of these studies yielded one additional study for inclusion, so that 13 studies were included for further systematic review.

Study characteristics

Of the 13 studies, 10 used a randomization procedure to allocate the interventions (Table 1). The follow-up periods ranged from 3 to 102 months. The studies were predominantly conducted in Europe ($n=6$) and the United States ($n=4$). Although the populations of all the studies consisted of community-dwelling participants, the interventions of five studies took place in outpatient settings (e.g., day care, a university, or a mental health service), and they returned home after each session. In four studies, participants were treated in their own home-care setting. In two studies, participants were hospitalized (inpatient setting) for the duration of the treatment. Two interventions were conducted in a combined outpatient and home-care setting. The sample size (the number of caregiver–people with dementia dyads eligible to participate in the study) ranged from 60 to 8,095. With the exception of the 8,095 dyads from one study,¹⁷ the mean sample size of the studies \pm standard deviation was 120.9 ± 49.1 . The proportion of female people with dementia varied from 41% to 67.2%. The proportion of female caregivers varied from 50.5% to 89%. Because the authors used diverse methods to chart the ages of people with dementia and their informal caregivers, it was not possible to quote a reliable range or average of ages for the participants. In all the studies, most people with dementia shared a household with the participating caregiver; in five studies, each dyad lived together. The mean length of caregiving since the diagnosis of dementia or the commencement of the study was reported in six studies and varied from 32.0 to 72.4 months. In most studies, the severity of dementia at baseline varied from mild to severe.

Methodological quality

The overall score for the methodological quality of the studies ranged from 1 to 6 (maximum 7), with a mean overall score of 4.2 ± 1.6 (Table 1). Two studies^{18–20} with low methodological quality, basically due to their unrandomized design, accounted for most of the variance. The authors of three studies^{17;20;21} did not report whether the outcomes were assessed blindly, and the author of one study^{9;22} reported that outcomes were not assessed blindly, which may be a source of bias.

Table 1. Characteristics of the included 13 studies

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	p < 0.05	
Brodaty et al. 1991	RCT; Follow-up 7 months	Country: Australia; Setting: inpatient; psychiatry unit, general teaching hospital; Number: 96 PWD-CG dyads; Mean age PWD 70.2 (SD 6.5) with mild to moderate AD and a mean duration of dementia of 3.9 years (SD 2.4, range 0.5-10 years), 47.92% women; Mean age CG 67.7 (SD 8.2), 54.17% women; Living arrangement: cohabiting; Drop out: 4%; Attrition rate: 2.08%; Referral: U	E1: Immediate CG Training E2: Delayed CG Training, with mild to moderate AD and approximately 6 months after application	Approach: Multicomponent: Content: A, B, E, G, H Tailor-made: No Professionals: Case manager: No Counselor: No Training: U Caregivers: Memory Training, 10 days respite for Intensity: High Involvement: Active Choice: No	E1: 14.58% Comparing E1 E2: 18.75% and E2 with C: 26.04% +	E1: Selection bias E2: Randomized: + Allocation concealed: + Comparable baseline characteristics: + Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: + Attrition bias Attrition rate reported: + Intention-to-treat analysis: + Total: 6	
Brodaty et al. 1997	Follow-up between 6.5 and 8.5 (mean 7.7, SD 0.50) years	Country: Australia; Setting: inpatient; psychiatry unit, general teaching hospital; Number: 93 PWD-CG dyads; Mean age PWD 70.1 (SD 6.6) Two experimental groups years with mild to moderate AD (average CDRS 1.1; SD 0.6), 48.4% women; Mean age CG 67.5 (SD 8.0) years, 53.8% women, 93% spouses; living arrangement: cohabiting; Drop out: 3.13%; Attrition rate: 0%; Referral through self-referral (41.66%), local doctors (16.66%), Alzheimer Disease and Related Disorders Society (15.62%), media publicity	Same	Same	E1: 79% Comparing E1 and E2: NS E2: 83% C: 90%	E1: Selection bias E2: Randomized: + Allocation concealed: + Comparable baseline characteristics: + Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: + Attrition bias Attrition rate reported: + Intention to treat analyses: - Total: 5	

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	p <0.05	
Dröes et al. 2004	Pretest/posttest control group design; Follow-up at 3 and 7 months, 18 months endpoint	(8.33%), and other sources (17.70%) Country: the Netherlands; Setting: outpatient; Number: 73 PWD-CG dyads; EGr (n = 36); CG mean age 63.6 (SD 13.3), 72.2% women, 77.8% partner, 22.2% daughter/son/in-law, 72.2% shared household, PWD mean severity of dementia (BCRSO-56) 31.1 (SD 7.5); CGr (n = 19); CG mean age 60.9 (SD 12.7), 68.4% women, 36.8% partner, 47.4% daughter/son/in-law, 52.6% shared household, PWD mean severity of dementia (BCRS) 35.2 (SD 7.2); Drop out: 8.75%; Attrition rate: 24.66%; Recruitment through health services or self-referral	E: Meeting Centres Approach: Support Program C: Psychogeriatric daycare	Multicomponent: Yes Content: B, C, F, G, H Tailor-made: Partly Professionals: Case manager: No Counselor: No Training: Yes Caregivers: Intensity: High Involvement: Passive Choice: Yes	After 3 months: E: 5% C: 18.2% After 7 months: E: 7.5% C: 39.3% 18 months: E: 11.95 M C: 5.79 M	After 3 months: + After 7 months: + 18 months: + Total: 2	Selection bias Randomized: - Allocation concealed: - Comparable baseline characteristics: - Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: + Attrition bias Attrition rate reported: + Intention-to-treat analysis: --
Dröes et al. 2006	Pre-test/post-test control group design; Follow-up at 7 months, 18 months endpoint	Country: the Netherlands; Setting: outpatient Number: 128 PWD-CG dyads; EGr (n = 71); CG mean age 64.5 (SD 12.4), 83.1% women, 64.8% partner, 26.8% daughter/son (in law), 67.6% shared household, PWD severity of dementia: slight to moderate; CGr (n = 13); CG mean age 60.8 (SD 13.6), 76.9% women, 38.5% partner, 53.8% daughter/son	Same		After 7 months: E: 4% C: 25% 18 months: E: 9.61 M C: 5.81 M	After 7 months: + 18 months: +	After 7 months Same

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	P <0.05	
Eloniemi-Sulkava et al. 2001	RCT; Follow-up at 1 and 2 years	(in law), 61.6% shared household, PWD severity of dementia: moderate to moderately severe; Drop out: 11.72%; Attrition rate: 15.96%; Recruitment through health services or self-referral	Country: Finland; Setting: combination outpatient and in-home care; Number: 100 PWD-CG dyads; EGr PWD (n = 53); mean age 78.8 (range 65-97), 49% women, mean MMSE score 14.4 (SD 6.2); EGr CG (n = 53); mean age 64.8 years (range 34-83), 75% women, 60% spouse; CGr PWD (n = 47); mean age 80.1 (range 67-91), 57% women, mean MMSE score 15.3 (SD 5.5); CGr CG (n = 47); mean age 63.3 (range 40-86), 62% women, 51% spouse; Living arrangement: 91% cohabiting; Drop out: 41%; Attrition rate: 0%; Recruitment through 5 Social Insurance Institutions	E: Nurse case management C: Usual services provided for geriatric patients in community care by the municipal social and healthcare system	Approach: Multicomponent: Yes Content: A, H, F Tailor-made: Yes Professionals: Case manager: No C: 30% Counselor: Yes Training: Yes Caregivers: Intensity: High Involvement: Passive Choice: Partly	1 st year: E: 8% C: 19% 2 nd year: E: 32% C: 30%	Selection bias Randomized: + Allocation concealed: + Comparable baseline characteristics: - Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: + Attrition bias Intention-to-treat analysis: + Total: 5
Miller et al. 1999	RCT; Follow-up at 3 years	Two experimental PWD-CG dyads; EGr (n = 4,151); PWD range 65-90 years of age 90.6%, 61.3% women, MMSE 0-10 27.7%; 11-15 15.8%; 16-20 21.4%;	Country: USA; Setting: outpatient; Number: 8095	E1: Model A, expanded community based services and case management. Target case manager-to-client	Approach: Multicomponent: Yes Content: F Tailor-made: Yes Professionals: Case manager:	E: 44.1% C: 42.9% E: 33.7 M C: 34.1 M	All sites combined: NS Randomized: + Allocation concealed: + Comparable baseline characteristics: + Performance bias Blinded providers/

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	P <0.05	
Mittelman et al. 1993	RCT, no pre-defined endpoint of treatment; Follow-up at one-year	21-25 19.9%; 26-30 9.2%; missing 6%; CG < 70 years of a monthly age 58.1%, range 70-84 years community of age 33.5%, at least 68.3% services women, CG relationship to PWD: 46.9% partners, 28.8% daughter, 8.1% son Living arrangement: 70.2% cohabiting with relative; CG (n = 3,944); PWD range 65-90 years of age 90.4%, 59.2% women, MMSE 0-10 28.1%; 11-15 16.3%; 16-20 21.1%; 21-25 18.6%; 26-30 10%; missing 6%; CG < 70 years of age 59.4%, range 70-84 years of age 32.5%, at least 69.1% women, CG relationship to PWD: 46.4% partners, 27.6% daughter, 8.4% son; living arrangement: 70.2%; cohabiting with relative; Drop out: 3.48%; Attrition rate: 10.02%; Recruitment through physician and self-referral Country: USA; Setting: outpatient; Number: 206 PWD-CG dyads	ratio of 1:100 with Yes Counselor: No Training: U Caregivers: Intensity: U Involvement: U Choice: U	Each site separately: NS, except for Rochester, New York - Subgroups: NS	participants: - Detection bias Blinded outcome assessors: U Attrition bias Attrition rate reported: + Intention-to-treat analysis: - Total: 4		
		E2: Model B, target case manager-to-client ratio of 1:30 with a reimbursement cap of \$430-\$699 per month per client					Selection bias Randomized: + Allocation concealed: + Comparable baseline characteristics: + Performance bias Blinded providers/ participants: - Detection bias
		C: Usual care					

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	p < 0.05	
Mittelman et al. 1996	RCT, no pre-defined endpoint	60 years of age 13.1%, 60-69 28.2%, 70-79 43.7%, 80-89 15.0%, 58.3% women; Living arrangement: cohabiting; Spouse 100%; Drop out: 11.38%; Attrition rate: 0%; Recruitment through Aging and Development Research Centre, Alzheimer Associations and other agencies that provide social services	support upon request	Caregivers: Intensity: High Involvement: Active Choice: Yes			Blinded outcome assessors: - Attrition bias Attrition rate reported: + Intention-to-treat analysis: + Total: 5

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	P <0.05	
Mohide et al. 1990	RCT, stratified by CG gender and PWD attending day care	arrangement: cohabiting; Spouse 100%; Drop out: U; Attrition rate: 7.28%; Recruitment through Aging and Development Research Centre, Alzheimer Associations and other agencies that provide social services	Country: Canada; Setting: in-home care; Number: 60 PWD- CG dyads; EGr (n = 30); PWD (CSP) mean age 77.80 (SD 9.19), 50% women, mean MMSE score 13.21 (SD 6.83). CG mean age 66.10 (SD 13.47), 70% women, mean months of nursing caregiving 39.80 SD 30.23), wife 47%; CGr (n = 30); PWD mean age 75.90 SD 7.70), 47% women, mean MMSE score 11.04 (SD 6.17). CG mean age 69.40 (SD 8.61), 73% women, mean months of care giving 72.40 (SD 61.93), wife 57%; Living arrangement: cohabiting; Drop out: 58.90%; Attrition rate: 13.33%; Referral through physicians, community health services, social services and self-referral	E: Caregiver Support Program Multicomponent: Yes Content: A, B, C, E, H C: Conventional (existing) community Tailor-made: Yes Professionals: Case manager: No Counselor: Yes Training: Yes Caregivers: Intensity: High Involvement: Active Choice: Partly	E: 36.66% C: 36.66%	NS	Selection bias + Randomized: + Allocation concealed: + Comparable baseline characteristics: - Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: + Attrition bias Attrition rate reported: + Intention-to-treat analysis: + Total: 5

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	P <0.05	
Nobili et al. 2004	RCT Follow-up at one year	Country: Italy; Setting: in-home care; Number: 69 PWD- visits by a CG dyads; EG (n = 35 PWD); mean age 74 years (SD 9.0), 60% women, mean MMSE score 11.1 (SD 7.0); CGr (n = 34 PWD); mean age 75 years (SD 10.0), 59% women, mean behavior MMSE score 12.0 (SD 7.4); E (n = 35 CG); mean age 53 years (SD 16.0), 89% women, usual 33 months length of care (SD 25), 4.9 hours/day time spent caring (SD 3.9); CGr (n = 34 CG); mean age 59 years (SD 12.0), 74% women, 34 months of care (SD 24), 2.5 hours/day time spent caring (SD 2.3); Living arrangement: > 80% cohabiting; Spouse 46.5%; Drop out: 33%; Attrition rate: 20.29%; Recruitment through Alzheimer Italia	Approach: Multicomponent: Yes Content: A, D Tailor-made: Yes Professionals: Case manager: No Counselor: No Training: U Caregivers: Intensity: Low Involvement: Passive Choice: No	E: 11.4% C: 11.8%	u; small numbers of institutionalization did not allow statistical comparison	Selection bias Randomized: + Allocation concealed: + Comparable baseline characteristics: + Performance bias Blinded providers/participants: U Detection bias Blinded outcome assessors: U Attrition bias Attribution rate reported: + Intention-to-treat analysis: - Total: 4	
Teri et al. 2003	RCT Follow-up at two years	Country: USA; Setting: in-home care; Number: 153 PWD-CG dyads; PWD: ranged in age from 55–93 years, 41% training in women, and had dementia for an average of 4.3 years and a mean MMSE score of 16.8 (SD 7.1), CG: ranged in age from 24–91 years, 70% women; Spouse 80%; Living arrangement: U; Drop out:	E: Home-based exercise program combined with CG	Approach: Multicomponent: Yes Content: A, E, G Tailor-made: U Professionals: Case manager: No Counselor: No Training: U Caregivers: Intensity: High	E: 68% C: 67%	NS	Selection bias Randomized: + Allocation concealed: + Comparable baseline characteristics: + Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: +

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TIM	P < 0.05	
Vernoij-Dassen, 1993	RCT, stratified by PWD gender and availability of regular home help; Follow-up at 10-months	Country: The Netherlands; Setting: in-home care; Number: 126 PWD-CG dyads; PWD: mean age 78 years of age, 69% women, light dementia 12.77%, moderate dementia 58.16%, and severe dementia 29.08%. CG: mean age 63 years, 67.3% women, mean duration of care 48.8 months; 49% spouses, 36% children, and 15% friends and neighbors; Living arrangement: respectively 63% and 87% of the women and male CG shared a household; Drop-out: 10.64%; Attrition rate: 5.56%. Referral through GP	E: Home-based support program consisting of guidelines for emotional and practical support	Approach: Multicomponent: Yes Content: E, H Tailor-made: Yes Professionals: Case manager: No Counselor: Yes Training: Yes Caregivers: Intensity: High Involvement: Active Choice: Yes	E: 14% C: 28%	+	Attrition bias Attrition rate reported: + Intention-to-treat analysis: + Total: 6 Selection bias Randomized: + Allocation concealed: + Comparable baseline characteristics: - Performance bias Blinded providers/participants: - Detection bias Blinded outcome assessors: + Attrition bias Attrition rate reported: + Intention-to-treat analysis: + Total: 5
Woods et al. 2003	Comparison group quasi-experimental design; Follow-up at 8 months	Country: UK; Setting: combination in-home care and Services outpatient care; Number: 104 PWD-CG dyads; EGr (n=43); PWD mean age of 80.88 years (SD 7.80), 48.8% women, mean CDR score 1.37 (SD 0.61). CG: mean age 62.40 years (SD 15.91), 74.4% women, duration of care 3.74 years (SD 3.79), 76.7% co-residing, 44.2% spouse,	E: Admiral Nurse C: Conventional Services	Approach: Multicomponent: Yes Content: F Tailor-made: Yes Professionals: Case manager: No Counselor: Yes Training: U Caregivers: Intensity: U Involvement: U	E: 12% C: 11%	NS	Selection bias Randomized: - Allocation concealed: - Comparable baseline characteristics: - Performance bias Blinded providers/participants: U Detection bias Blinded outcome assessors: U Attrition bias

Study	Method	Participants	Intervention	Intervention characteristics	Outcomes		Methodological quality
					NI/TTIM	P <0.05	
		44.2% child; CGr (n=61); PWD mean age 79.73 years (SD 7.24), 67.2% women, mean CDR score 1.30 (SD 0.70); CG: mean age 58.83 years (SD 13.24), 70.5% women, duration of care 2.67 years (SD 2.59), 55.7% co-residing, 34.4% spouse, 50.8% children; Living arrangement: 64.42% co-residing Spouse: 38.5%; Drop-out: 18.75%; Attrition rate: 18.8%; Referral through GPs and Memory Clinics	Choice: U			Attrition rate reported: + Intention-to-treat analysis: - Total: 1	

Method: CG = caregiver, PWD = person/people with dementia, RCT = randomized controlled trial. Participants: in-home care setting = intervention took place at home, outpatient care setting = people went to an organization for the intervention and returned home after each session, inpatient care setting = people were hospitalized during the intervention and returned home after completion of this part of the intervention. AD = Alzheimer disease, EGr = experimental group, CDR = the Clinical Dementia Rating Scale, CGr = control group, MMSE = the Mini Mental State Examination, BCRS = Brief Cognitive Rating Scale, SD = standard deviation, U = unknown. Duration of caregiving = the mean duration of caregiving or the mean duration of caregiving since diagnosis of dementia. Dropout = the number of participants invited to participate minus the number of participants eligible at baseline. Attrition rate = the number of participants eligible at baseline minus the participants who dropped out during the study period due to reasons other than institutionalization. Intervention characteristics: A = psychoeducation, B = cognitive behavioral therapy, C = respite care, D = environmental modification, E = skills training/problem solving, F = case management, G = person with dementia focused memory training, H = general support, U = unknown, Case manager = person who facilitates the access, coordinates, and obtains appropriate formal health care services for caregivers and/or people with dementia. The case manager provides continuity and advocacy over time, Counselor = person who helps caregivers and people with dementia cope with mental or emotional distress, understanding and resolving problems that come up. Sometimes counselors also act as case managers. Intensity, high = support program consists of at least 10 professional – caregiver contacts/sessions. Involvement, passive = no active collaboration from the caregiver required. Choice, yes = caregivers and people with dementia can choose out of different support strategies and services. Outcomes: NI = outcome measure: number of institutionalizations in percentages; TTIM = outcome measure: time to institutionalization in months, E = experimental group, C = control group, p < 0.05 (+ = statistically significant in favor of the experimental group, NS = not significant, - = statistically significant in favor of the control group, u = unknown).

Meta-analysis

Odds of institutionalization. Three pairs of studies used the same study population. Only the first study of each pair was included in the meta-analysis so that the mean follow-up periods of the 10 studies in the meta-analysis would be as similar as possible.^{9;19;23} A total of 9,043 people with dementia (4,622 in experimental groups and 4,421 in control groups) participating in the 10 studies were included in the meta-analysis. Given the evidence of the heterogeneity of the treatment effect of the studies (chi-square (X^2)=24.90, degrees of freedom (df)=9, $P=.003$, $I^2=63.9\%$), studies were entered into the meta-analysis using a random-effects model.

The analyses show that, overall, people with dementia involved in experimental interventions were significantly less likely to be institutionalized than people with dementia in control groups ($OR=0.66$, 95% CI=0.43–0.99, $P=.05$; Figure 2). Because the methodological quality of the studies might influence the effects, and some studies might put a disproportionate weight on the results, additional analyses were performed. Of the high-quality studies^{9;10;23–26} (score 5–7) using a fixed-effects model ($X^2=10.86$, $df=5$, $P=.05$, $I^2=53.9\%$), similar significant estimated overall effects were found in which people with dementia involved in experimental interventions were less likely to be institutionalized than people with dementia in control groups ($OR=0.60$, 95% CI=0.43–0.85, $P=.004$).

One study¹⁷ disproportionately influenced the overall effect, with a sample size much larger than the sample sizes of the other studies (difference >7,500 people with dementia). Eliminating this study from the original analysis using a fixed-effects model ($X^2=14.70$, $df=8$, $P=.07$, $I^2=45.6\%$) resulted in an estimated overall effect that was significantly larger in favor of people with dementia involved in the experimental interventions ($OR=0.59$, 95% CI=0.43–0.81, $P=.001$).

Time to institutionalization. Of the 13 included studies, five were suitable for the meta-analysis, although two of these five studies used the same study population. Again, only one of these overlapping population studies¹⁹ was included in the meta-analysis. The remaining eight studies were excluded, because the authors did not report any tests (six studies) or they did not report the means and standard deviations for the test scores before and after the intervention (two studies).

The four studies entered in the meta-analyses yielded a total of 498 people with dementia (277 in experimental groups and 221 in the control groups). Use of a fixed-effects model provided evidence of heterogeneity of the treatment effects across the studies ($X^2=89.28$, $df=3$, $P<.001$, $I^2=96.6\%$). The SMD, calculated in a random-effects model, showed a significant estimated overall effect in favor of the experimental interventions ($SMD=1.44$, 95% CI=0.07–2.81, $P=.04$; Figure 3). The mean change in mean time to institutionalization from baseline to follow-up was significantly greater in people with dementia involved in the experimental interventions than in the control groups. Furthermore, because the four studies included in the meta-analyses each contributed 25% to the overall effect, a SMD of 1.44 reflects a mean difference of 4.9 months in time to institutionalization in favor of people with dementia involved in the experimental groups over controls.

Concentrating on high-quality studies^{22;25;27} (score 5–7) and using random-effects models ($X^2=83.00$, $df=2$, $P<.001$, $I^2=97.6\%$), no change was found in mean time to institutionalization from baseline to follow-up between the experimental group and the control group ($SMD 1.55$, 95%CI=−0.35–3.45, $P=.11$).

Characteristics of effective interventions

Significant positive effects were found in seven of the 13 studies after the experimental intervention at the last follow-up.^{9;18;19;22;23;26;27} One study²⁴ had not produced any significant positive effects at the last follow-up, but subgroup analyses revealed a significant positive effect in favor of people with severe dementia involved in the experimental intervention (Table 1). All support programs were multicomponent in offering a comprehensive program with a range of specific, supportive care-giving interventions. Furthermore, most interventions were individualized, intensive, individualized interventions designed to meet the unique needs of people with dementia and their informal caregivers at the appropriate time. The function of professionals (e.g., a case manager or counselor) who received intervention-specific training varied with each study, and no distinctive intervention seemed to be characteristic of the estimated effectiveness in the odds of being institutionalized and the delay of institutionalization. Conversely, a combination of involvement and choice seemed to be the main intervention characteristic that distinguished effective support programs from ineffective ones.

Figure 2. Forest plot of odds of institutionalization

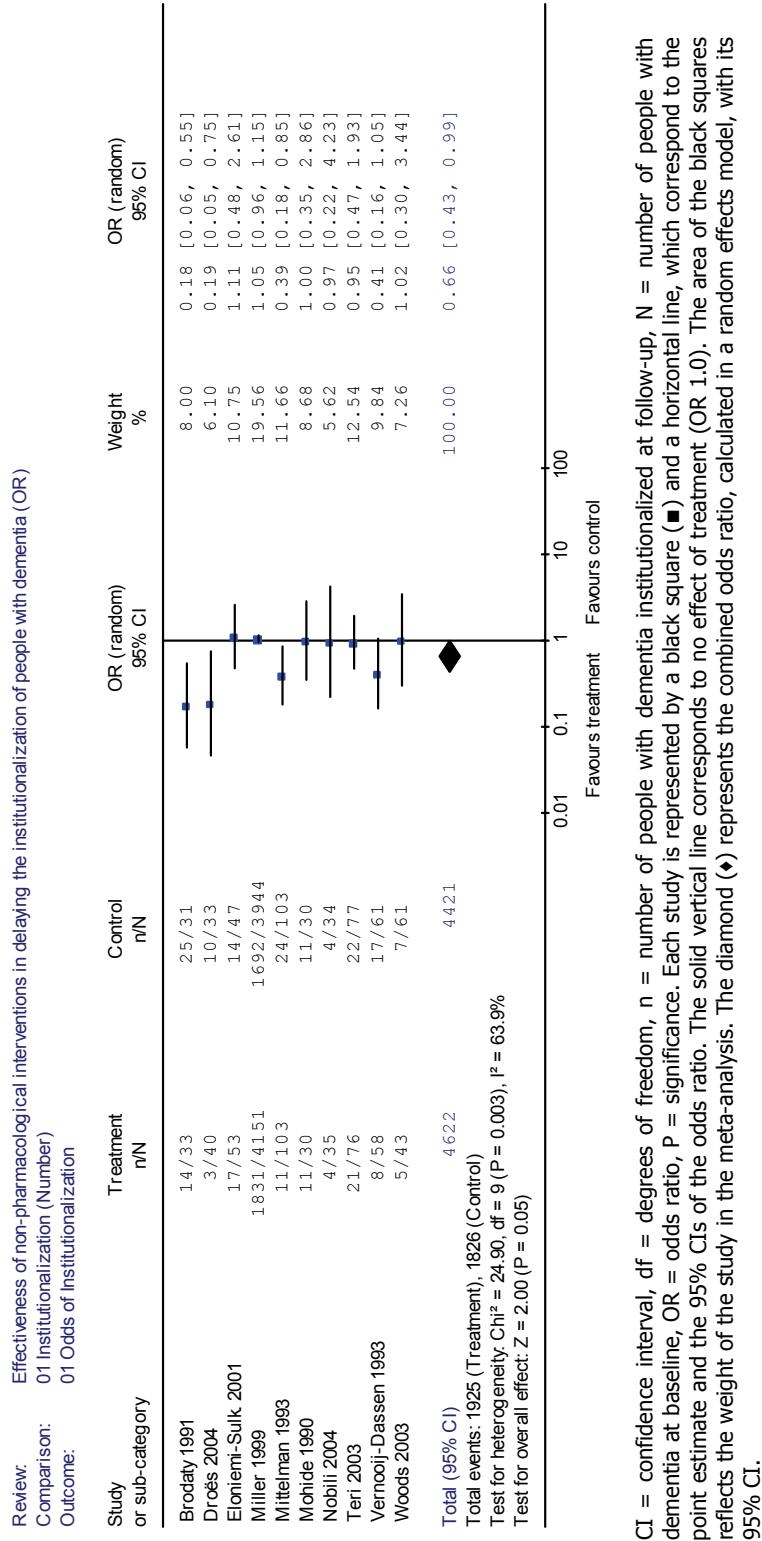
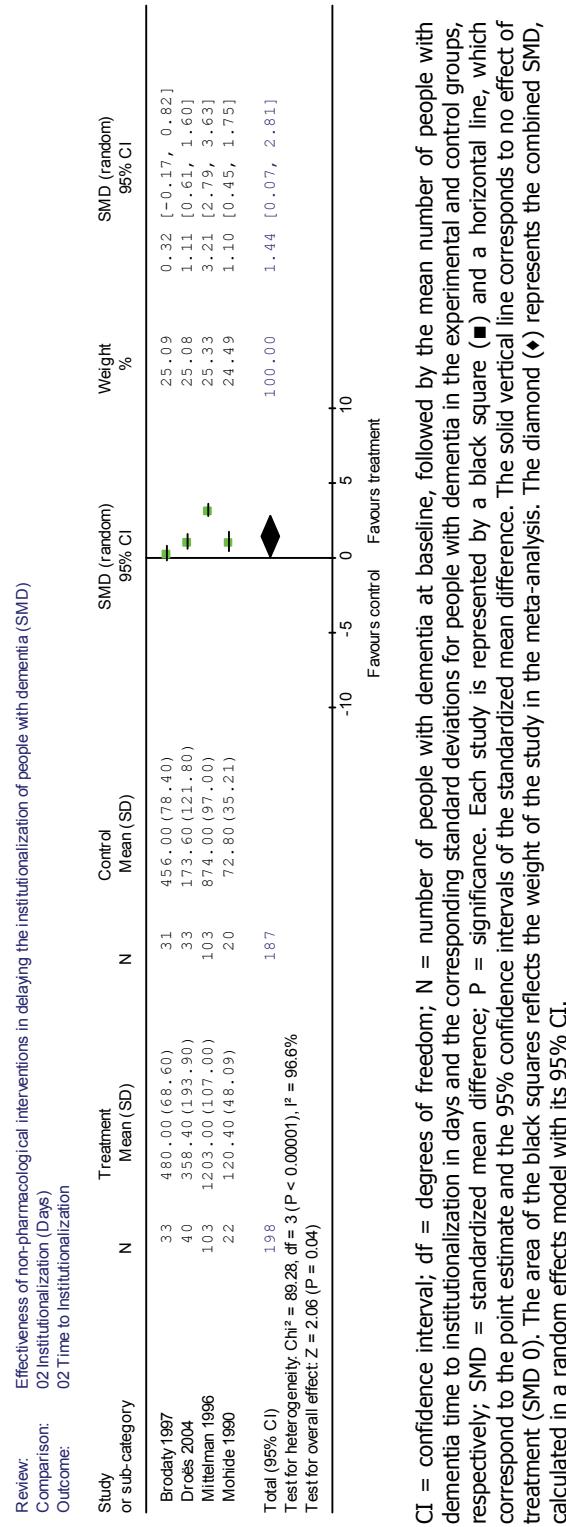


Figure 3. Forest plot of time to institutionalization



CI = confidence interval; df = degrees of freedom; N = number of people with dementia at baseline, followed by the mean number of people with dementia time to institutionalization in days and the corresponding standard deviations for people with dementia in the experimental and control groups, respectively; SMD = standardized mean difference; P = significance. Each study is represented by a black square (■) and a horizontal line, which correspond to the point estimate and the 95% confidence intervals of the standardized mean difference. The solid vertical line corresponds to no effect of treatment (SMD 0). The area of the black squares reflects the weight of the study in the meta-analysis. The diamond (♦) represents the combined SMD, calculated in a random effects model with its 95% CI.

Discussion

To the authors' knowledge, this is the first systematic review applying a meta-analysis to estimate the overall effectiveness of all types of nonpharmacological support programs for informal caregivers and people with dementia about odds of institutionalization and time to institutionalization. The meta-analysis of 13 support programs showed that these programs can significantly decrease the odds of institutionalization and significantly increase the time to institutionalization. This is a promising result in view of contemporary policies designed to allow informal caregivers to care for people with dementia at home for as long as possible.

Analyses of the intervention characteristics show that a combination of involvement and choice seems to be the main intervention characteristic that distinguishes effective support programs from ineffective ones. Effective support programs include counseling and personal assistance with problem solving, and they offer informal caregivers a choice of various support strategies and support services. This is consistent with previous findings.²⁸ One intervention^{23;27} that offered a wide range of support strategies and services but gave no choice as to which parts of the support program to follow was an exception.

Having so many choices or being able to choose one of several interventions might lead to satisfactory involvement. Such choices offer caregivers and people with dementia a sense of freedom that might result in a greater sense of personal control, more satisfaction with treatment, better adherence and transition to the daily routine, and consequently better outcomes.

This meta-analysis had some limitations. Cultural differences between and within countries in the presence, types, and preferences of institutional care, heterogeneity in the duration and severity of dementia, the follow-up periods, and the numbers of participants might have affected the treatment effects.

Concerning cultural differences, a common trend toward deinstitutionalization, less inpatient treatment, and improvement of community services characterizes the development of systems of mental health care in Western Europe and North America,^{29;30} although within and between countries, there are substantial differences in the design of organization and financing of health care (including longterm care), the

provision of informal and formal care (e.g., various types of residential accommodation), and cultural preferences concerning institutionalization.^{29–31} Italy, for example, continues to rely on the traditional provision of informal care by the family, a situation that not only economic factors, but also sociocultural factors, determines. National surveys show that families with some economic means who are caring for an elderly relative employ foreign migrant workers who assume the main burden of care for modest payment.^{31;32} The number of people aged 65 and older in residential homes in Italy is one of the lowest in Europe.³¹ To what extent this fact has affected the results about odds of institutionalization and time to institutionalization across countries is unclear. In general, the effects of these differences on participant outcomes are not reflected in outcome differences in a coherent way, the empirical evidence is limited, and further studies are required.³⁰

In six studies, there was heterogeneity in the mean time of care giving since the diagnosis of dementia or the commencement of the study; most studies did not report the duration of dementia. This might have affected the treatment effects. The same is true for the severity of dementia, which varied in most studies from mild to severe at baseline, and the heterogeneity in follow-up periods across studies. In all these cases, the odds of institutionalization were larger, and the time to institutionalization shorter, with cognitive decline over time. A combination of a study population that is more homogenous with respect to duration and severity of dementia at baseline and standardized follow-up periods might have limited the supposed heterogeneity and thereby the probable influence on treatment effects. By using the random-effects model, the statistical heterogeneity that is mainly caused by the different sample sizes of the studies was taken into account. Finally, it is unlikely that the different interventions contributed to the heterogeneity across studies. One study³³ distinguished different types of interventions beforehand and consequently pooled homogeneous interventions in its meta-analysis. The current meta-analysis had no such a priori subdivision, mainly because careful analysis of monocomponent support programs (psychoeducational interventions, case management, and general support) reveals that such programs have a multicomponent composition. It is unlikely that pooling homogeneous interventions adjusted for other causes of possible heterogeneity across studies, for example, cultural differences in the presence, types, and preferences of institutional care; differences in the duration or severity of dementia;

the follow-up periods; and the sample size. Nevertheless, it is still unknown which components of the support programs contributed to the treatment effects.

Owing to the lack of data in the studies analyzed, an estimation of the overall treatment effect on certain highrisk groups, such as women and spouse caregivers, could not be made, although in the present study, the most caregivers in the various support programs shared a household with the person with dementia.

The conclusions of this systematic review should be seen in the context of the methodological quality of the studies. In general, the methodological quality of most of the studies was good. Because of the nature of nonpharmacological intervention studies, it was not always possible to use a randomized, controlled trial design and to blind providers of the various support programs as to who was receiving the support program and who was not. Analysis of studies with the best methodological quality showed similar odds, so the analysis in the best methodological quality studies and the analysis in all 10 of the studies included in the meta-analysis showed that the odds of being institutionalized were lower for people with dementia involved in experimental interventions than people with dementia in control groups. However, for mean time to institutionalization, concentrating on the best-quality studies resulted in no difference between the experimental and control groups.

With respect to the recommendations, this systematic review shows that, if a support program is to be capable of delaying institutionalization, it must be intensive. The informal caregiver and the person with dementia are then actively involved in seeking solutions together and can try out and choose the support strategies or services that are best individualized to their needs. In addition, to meet future policies concerning efficiency, authors should evaluate their support programs on the net benefit or cost effectiveness. In this manner, the informal caregiver and person with dementia can be offered an efficient support program that will improve the quality of life of both parties and, most importantly, meet the wishes of both parties for the person with dementia to stay at home for as long as possible.

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Chapter 3

Systematic care for caregivers of people with dementia in the ambulatory mental health service: designing a multicentre, cluster, randomized, controlled trial

Anouk Spijker

Frans Verhey

Maud Graff

Richard Grol

Eddy Adang

Hub Wollersheim

Myrra Vernooij-Dassen

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Abstract

Background: Care for people with dementia and their informal caregivers is a challenging aim in healthcare. There is an urgent need for cost-effective support programs that prevent informal caregivers of people with dementia from becoming overburdened, which might result in a delay or decrease of institutionalization of the person with dementia. For this reason, we have developed the Systematic Care Program for Dementia (SCPD). The SCPD consists of an assessment of caregiver's sense of competence and suggestions on how to deal with competence deficiencies. The efficiency of the SCPD will be evaluated in our study.

Methods and design: In our ongoing, cluster, randomized, single-blind, controlled trial, the participants in six mental health services in four regions of the Netherlands have been randomized per service. Community mental health (CMH) professionals of the CMH services (psychologists and social psychiatric nurses) have been randomly allocated to either the intervention group or the control group. The study population consists of community-dwelling people with dementia and their informal caregivers (dyads) coming into the CMH service. The dyads have been clustered to the CMH professionals. The primary outcome measure is the admission of the person with dementia to a nursing home or home for the elderly at 12 months of follow-up. This measure is the most important variable for estimating cost differences between the intervention group and the control group. The secondary outcome measure is the quality of life of both the person with dementia and the accompanying informal caregiver.

Discussion: A novelty in the SCPD is the pro-active and systematic approach. The focus on the caregiver's sense of competence is relevant to economical healthcare, since this sense of competence is an important determinant of delay of institutionalization of people with dementia. The SCPD might be able to facilitate this with a relatively small cost investment for caregivers' support, which could result in a major decrease in costs in the management of dementia. Implementation on a national level will be started if the SCPD proves to be efficient.

Background

Estimates state that the rapidly aging western European population will peak at about 2040.¹ An aging population demands more healthcare and challenges the healthcare budget. Two-thirds of the people with dementia are cared for at home². Care at home is often intensive and burdensome. Informal caregivers of these people carry a greater burden than informal caregivers of other chronically ill people,³ and they are at a greater risk of depression.⁴⁻⁶ The institutionalized care of people with dementia is one of the three most expensive areas of healthcare.^{7;8} Furthermore, as a result of the growing elderly population, shortages within institutional care are expected. The resulting budgetary constraint necessitates the exploration of temporary alternatives, such as postponement of institutionalization and care at home. Without unpaid informal caregivers, the costs of professional care at home would double.⁹ Support is needed to prevent informal caregivers becoming overburdened and depressed. An informal caregiver's sense of being capable of giving care is a strong determinant of delaying institutionalization.¹⁰ Contemporary policies have therefore been designed to shape conditions to support caring for people with dementia at home and to minimize the risk of depression for informal caregivers.

Usual community mental health care

In the usual CMH care, in the Netherlands, the problems of informal caregivers often remain invisible until a crisis occurs. This happens partly because informal caregivers pay scant attention to their own problems, and professionals may not know how to support informal caregivers pro-actively.¹¹ When informal caregivers have become involved in care provided by the CMH services, they are rarely screened in a structured manner for the problems they may encounter. There is, for example, no systematic screening for the care burden or depressive symptoms. Informal caregivers suffering from depressive symptoms are either treated inadequately or not at all.^{12;13} Moreover, the available support of the CMH service varies from support groups for informal caregivers to case management for active support and organization of the care needed.¹⁴ This fragmented care is reflected in the different functions of the CMH services. The CMH services set their own standards for the care of people with dementia and their caregivers. This service is provided in collaboration and concurrence with other regional providers.

Effective support programs for caregivers of people with dementia

Usual care offers many opportunities to support informal caregivers that remain unused because of the late detection and the ad hoc identification and management of possible caregiver problems.¹²⁻¹⁵ Several support programs for these caregivers have been developed, some of which have proven to be effective.¹⁶ Most programs aim at reducing the caregiver's burden or enhancing feelings of competence in caring, and their purpose is to delay institutionalization of the person with dementia. Dutch examples of these programs are the Family Support Program,^{17;18} the Meeting Centres Support Program,¹⁹ and the Community Occupational Therapy Intervention for patients with dementia and their informal caregivers.^{20;21} These proven effective support programs found successively positive changes in caregiver depressive symptoms,²² problem behavior of the person with dementia and caregiver distress as related to problem behavior,²³⁻²⁶ sense of competence and feelings of competence being a female caregiver sharing the same household with the patient,^{18;27} as compared to changes in the controls. Moreover, proven effective support programs found a positive influence of the severity of dementia on delay of nursing home placement, as compared to the control groups.^{28;29} As part of the multicomponent intervention behavioral and cognitive strategies were used to train caregivers and people with dementia in the use of aids to compensate for cognitive decline and to cope with distressing behavior. Caregiving intervention studies appeared effective in improving caregiver psychological health and quality of life^{19;30-33} as well as patients' quality of life.³⁴

The Systematic Care Program for Dementia

We have transformed the Family Support Program into a Systematic Care Program for Dementia (SCPD) that can be used in the first consultation of a professional with a person with dementia and his/her informal caregiver (also referred to as "dyads" in this study protocol) entering the CMH service. The SCPD consists of an assessment of the caregiver's sense of competence and suggestions on how to deal with competence deficiencies. The SCPD has been chosen because of its potential to help diagnose and treat problems systematically and to cover a wide range of individual problems. The SCPD is flexible in connecting pro-active interventions to individual problems. Moreover, it is also connected to the positive effects found in our previous study.^{18;35} This program has been designed to fulfill the urgent need for effective and cost-effective support programs that can prevent overburdening the informal caregiver,

which might result in a delay or decrease of institutionalization of the person with dementia.

Objectives

The objective of this study protocol is to describe the design of a trial to determine both the effectiveness and the efficiency of the SCPD in comparison to regular CMH care. The aim of the program is to delay the institutionalization of the person with dementia and to improve the health-related quality of life of both the person with dementia and the informal caregiver.

Hypothesis

We expect a delay of institutionalization of the person with dementia in the intervention group as compared to controls at 12 months follow-up. In addition, we expect that time to institutionalization will be longer in the intervention group as compared to the control group.

Methods and design

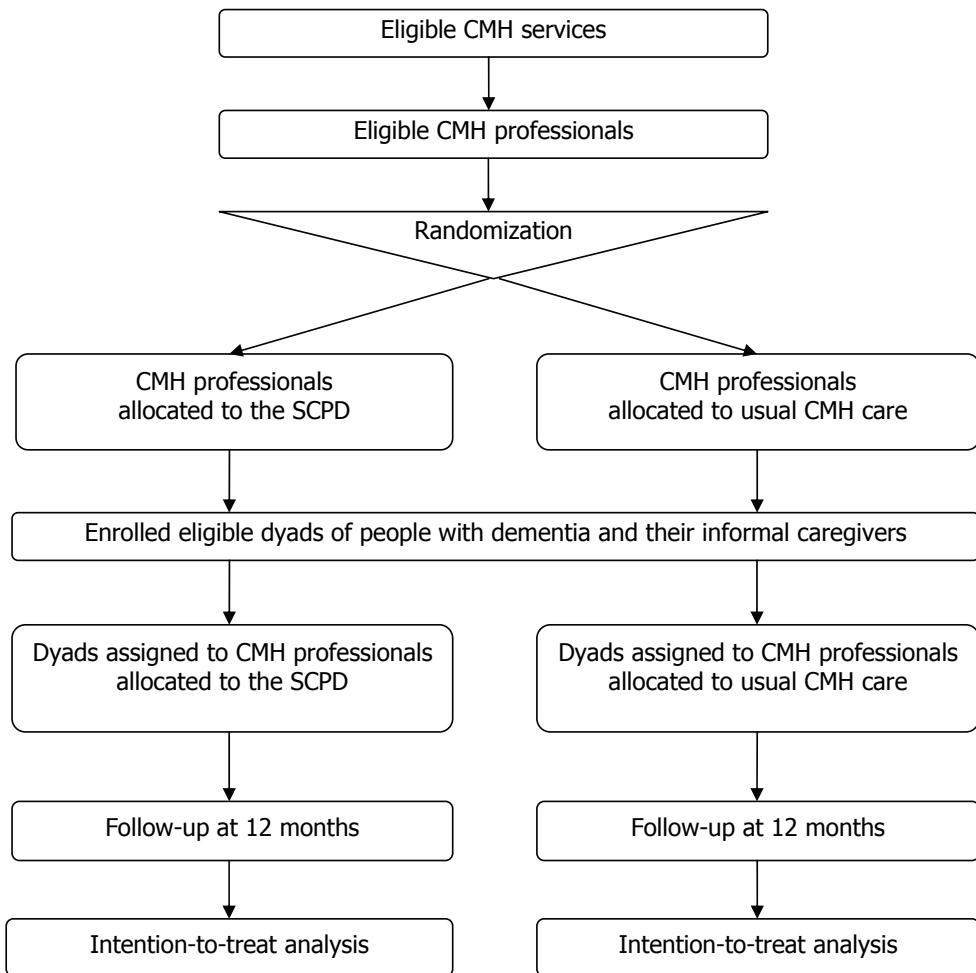
Study design and setting

The study design is a single-blind, multicentre, cluster, randomized, controlled trial. From September 2005 to February 2006, the research assistant enlisted and randomized CMH professionals (psychologists and social psychiatric nurses), initially from four CMH services, either to the intervention group or the control group. One service dropped out because of the interference with another clinical trial. In order to enroll dyads in due time three other CMH services were included. Altogether, CMH professionals from six health CMH services and four regions were randomized to either the intervention group or the control group. This setback in recruiting dyads prolonged the inclusion period by 4 months to a total of 17 months. The follow-up period has been set at 1 year. One year proved long enough for us to find significant effects in our previous study.³⁶ Figure 1 presents the flow of the participants through the trial at each randomization procedure.

The study cannot be double-blinded because all the CMH professionals involved are aware of the treatment allocation. To prevent contamination, the intervention group have been asked to keep the study intervention secret and to inform neither CMH professionals in the control group nor other colleagues nor field relations. The dyads have been blinded to the group allocation of the CMH professionals to whom they have

been assigned. The intervention group will be trained to integrate the SCPD in their treatment method. Moreover, we assume that CMH professionals will not be interested in telling dyads that they are using a new or presumably better treatment method.

Figure 1. Flow of the participants through the trial



Eligibility criteria

Community mental health services were considered eligible if they could enroll people with suspected dementia or with dementia. Furthermore, they had to be sure that they could recruit enough people with an accompanying informal caregiver. Community mental health professionals recruited by the CMH services were considered eligible if

they treated at least four of the dyads each year (see the section Power calculations). This is the minimum number required for reasons of continuity and routine. Moreover, this minimum is necessary so that the intervention CMH professionals can change their daily routine and become familiar with the SCPD method.

The eligibility criteria for the dyads were:

1. The person was referred to and entering the CMH service with (the suspicion of) dementia.
2. The person lives in the community.
3. The person has an informal caregiver living in the community.
4. The informal caregiver visits the person with (suspected) dementia at least twice a week.
5. The informal caregiver is willing to participate and gives written informed consent.

The exclusion criteria were:

1. The person with (the suspicion of) dementia has no informal caregiver.
2. The informal caregiver is a client of the CMH service her/himself.
3. The informal caregiver is seriously ill and unable to participate in the study.
4. The informal caregiver does not speak Dutch fluently.

Informed consent procedure

The informed consent procedure consisted of several steps. First, a psychologist or social psychiatric nurse provided written information for the informal caregiver. An informal caregiver who gave verbal consent and accepted the conditions was included in the next step. In this phase, the research assistant contacted the informal caregiver and made an appointment for the baseline interview, explained the assessment procedure, and answered questions. The informal caregiver was informed about the randomization procedure. After having given verbal consent, s/he received written confirmation of willingness to participate and the baseline questionnaire by post. An informal caregiver who was still willing to participate signed and returned the consent form and was included in the study.

Treatment in the intervention group: the Systematic Care Program for Dementia

The experimental intervention (training in the SCPD and its subsequent use) is based on the "Family Support Model" as developed by Gruenberg³⁷ and Bengtson and

Kuypers.¹⁷ Its purpose is to strengthen the caregiver's competence and sense of competence. Basically, the SCPD consists of an assessment of the caregiver's sense of competence and depressive symptoms, and suggestions about how to deal with deficiencies. It can begin in the first consultation between a CMH professional and a dyad.

The SCPD can be divided into three stages:

1. *Screening.* Community mental health professionals screen the caregiver's sense of competence and depressive symptoms with the SCPD screening tool (inventory and interpretation) as presented in Figure 2. This means that CMH professionals provide data about the Short Sense of Competence Questionnaire,³⁸ depressive symptoms,³⁹ and caregiver type.⁴⁰ They also provide their observations on the severity of dementia according to the Diagnostic and statistical manual of mental disorders, 3rd text revision (DSM-III-TR).⁴¹
2. *Psychosocial support.* The SCPD is flexible in connecting pro-active interventions to individual problems. Community mental health professionals use strategies aimed to support caregivers; for example, instructions on how to deal with the behavioral problems of the person with dementia. The clarification of the relation between the disease and the problematic behavior is a SCPD support strategy. One goal might be that the caregiver will not take difficult behavior personally, which can diminish mutual negative feelings considerably. Community mental health professionals provide data about their support and interventions (actions) during and after each contact with the dyad.
3. *Transfer to regular healthcare.* Along with psychosocial support, CMH professionals might negotiate or organize respite care, which is like home care or day care. If the screening for caregiver depression gives cause for further screening for clinical depression, the professional may also refer the caregiver or start treatment. Community mental health professionals provide data about the organization and management of care if the case is transferred to other institutions or health professionals.

Training in the Systematic Care Program for Dementia

The training to teach CMH professionals to use the SCPD consists of three sessions of 2 hours each. One meeting is for explaining the program, and two meetings are for the evaluation of the use of the program and for preparing suggestions on how to hand over the responsibility for care after the CMH service's work is completed.

Figure 2. Screening tool for the Systematic Care Program for Dementia

Screening for a sense of competence

1. CONSEQUENCES OF INVOLVEMENT IN CARE FOR THE PERSONAL LIFE OF THE CAREGIVER
 - a. Do you feel that the present situation with your ... does not allow you as much privacy as you would like?
 - b. Do you feel stressed by trying to do enough for your ... as well for other family responsibilities, job, etc.?
2. SATISFACTION WITH YOUR OWN PERFORMANCE AS A CAREGIVER
 - a. Do you wish that you and your ... had a better relationship?
 - b. Do you feel strained in your interaction with your ...?
3. SATISFACTION WITH THE PERSON WITH DEMENTIA AS A RECIPIENT OF CARE
 - a. Do you feel that your ... tries to manipulate you?
 - b. Do you feel that your ... behaves the way s/he does to annoy you?
 - c. Do you feel that your ... behaves the way s/he does to have her/his own way?

Support strategies

1. Define acceptable goals of involvement. Organize additional professional support.
2. Open a dialogue regarding expectations, resources, conflicts, stigmas and feelings of guilt. Dialogue about what the caregiver thinks s/he has to do and what s/he actually can do.
3. Clarify the relationship between the behaviour of the person with dementia and the dementia syndrome.

Screening for depression

1. During the past month have you often been bothered by feeling down, depressed, or hopeless?
2. During the past month have you often been bothered by little interest or pleasure in doing things?

Caregiver's management strategy

- *Nonadapters*: lack of understanding or acceptance of the situation; approaching the person with dementia with impatience, irritation, or anger.
- *Nurturers*: care and protection; parent-child approach in which the person with dementia is taken by the hand and is no longer regarded as an equal.
- *Supporters*: adapting to the level of functioning of the person with dementia and encouraging him/her in existing abilities.

Severity of dementia

Mild: the person can live independently for the most part, with adequate personal hygiene and relatively intact judgement, but social activities and employment are both significantly impaired.

Moderate: formal employment is no longer possible and independent living is fraught with hazard to the extent that limited supervision is required.

Severe: there is severe impairment of daily activities (like minimal personal hygiene), and continual supervision is needed. The patient is entirely dependent on the caregiver for survival. Recognizing familiar and unfamiliar people in the environment is often no longer possible.

Figure 3 summarizes the objectives and methods used in the three training sessions. Several aids have been developed to facilitate the use of the SCPD:

1. The SCPD screening tool. The questions for the screening a caregiver's sense of competence and depressive symptoms are printed on a handy plasticized pocket card.
2. The SCPD manual. The manual consists of the items to be discussed during the training sessions (i.e., background information and methods), and some supporting literature has been added.
3. The starter package and action list. Several forms have been developed for the requested data. The starter package contains the forms that CMH professionals need to gather these data. The action list contains 60 possible intervening and supportive actions that CMH professionals might undertake as a result of the screening. They are divided into nine categories: intake, diagnostics, psychoeducation, psychosocial care, medical care, how to hand over care, legal care, case management, and crisis management. The list was developed in collaboration with a staff member and a social psychiatrist from each of the original three participating health services. Each person involved listed potential intervention and support actions. Repeatedly mentioned actions were included in the action list. Consensus for including actions on this list was reached.

Treatment in the control group: usual community mental health care

Community mental health professionals randomized in the control group will continue their treatment for dyads as usual. During the study period they will not receive the training in the SCPD. Usual CMH care is characterized by late detection of caregiver problems and unsystematic support that differs among the health services.¹¹⁻¹⁴

Data collection at baseline and follow-up measurements

During the informed consent procedure, informal caregivers were asked to complete the baseline questionnaire. The research assistant and three trained interviewers collected baseline data and will collect follow-up data. If the caregiver cannot answer the questionnaire independently, assistance from the research assistant or the interviewer will be offered. Measurements take place at baseline (T0) and 3 (T1), 6 (T2), 9 (T3), and 12 months (T4) after inclusion. Table 1 presents the types of data to be collected at the various intervals. The completed questionnaires are to be returned to the IQ healthcare, Radboud University Nijmegen Medical Centre, by post, and the

research assistant will maintain caregiver anonymity while processing the data. The researcher and the research assistant are not involved in the assignment procedure, and they do not know the assignment decision. The blinding of the outcome assessor must remain intact until follow-up measurements are completed. The research assistant will process the CMH professionals' data after follow-up measurements are completed.

Figure 3. Training program for the Systematic Care Program for Dementia

First training session

Objective: the professional is able to assess caregivers sense of competence

Method

- Background and objective of the SCPD
- Sharing experience of obstacles to care for caregivers
- Instruction about how to apply the SCPD
- Role playing to assess the sense of competence
- Further reading, and the SCPD manual
- Preparation of the next training session and casuistic practical experience
- Evaluation

Second training session

Objective: professional is able to recognize deficiencies in caregivers sense of competence and brings up solutions for best practices

Method

- Sharing experiences of applying the SCPD
- Sharing experiences of using the SCPD screening tool
- Organizational obstacles, e.g., those involving caregivers at the first consultation
- Role playing best practices, finding solutions for deficiencies in competence
- Discussing what is needed for using the SCPD in practice
- Evaluation

Evaluation session

Objective: the professional is able to assess and to suggest solutions for deficiencies in caregivers' sense of competence

Method

- Sharing experiences of applying the SCPD
- Finding solutions for logistic, organizational, and emotional obstacles
- Sharing experiences of the tailor-made SCPD screening tool
- Discussing what is needed to use the SCPD in practice
- Evaluation

Outcome parameters

Table 1 presents the types of data used for the outcome parameters:

1. The primary outcome measure is the institutionalizing of the person with dementia in a nursing home or home for the elderly during the 12-month follow-up period.

Both the institutionalization rate and the time to institutionalization will be taken into account. Possible institutionalization will be assessed every 3 months with one item of the Resource Utilization in Dementia questionnaire.⁴²

2. The secondary outcome measure is the caregiver and person with dementia quality of life. The quality of the caregiver's life will be measured with the Sense of Competence Questionnaire,³⁵ the EuroQol-5D,^{43;44} the Center for Epidemiologic Studies Depression Scale,^{45;46} and the caregiver distress will be assessed with the Neuropsychiatric Inventory Questionnaire.^{47;48} The quality of life of the person with dementia will be measured with the Neuropsychiatric Problems Inventory Questionnaire and the Quality of Life in Alzheimer's Disease.^{49;50}

Baseline variables as well as sociodemographic characteristics of both the person with dementia and the informal caregiver are control variables. Sociodemographic characteristics are the severity of the dementia syndrome according the DSMIII-TR,⁴¹ and the caregiver's relation to the person with dementia and their living arrangements. The CMH service, gender, and job satisfaction^{51;52} of the CMH professional are also control variables.

Concerning the effect of the intervention on emotional functioning we expect positive changes on the secondary outcome quality of life – e.g. depressive symptoms, problem behavior of the person with dementia and caregiver distress as related to problem behaviour of the person with dementia, sense of competence, and both caregiver and person with dementia quality of life – at 12 months follow-up, in favor of caregivers and people with dementia involved in the intervention group, as compared to controls.

Process evaluation

A process analysis of the intervention will be carried out to gain insight into factors that might influence success or failure of the intervention.^{53;54} This process analysis is a description of the actual exposure of both the CMH professional and the caregiver to the SCPD as planned and the experience of the CMH professionals with the SCPD. For this purpose, the following questions will be examined retrospectively:

1. Were CMH professionals trained in the SCPD as planned?
2. Did the informal caregivers receive the care as planned?

3. What is the relationship between the results when the SCPD was carried out as planned and the outcome measures of institutionalization, time to institutionalization, and the quality of the caregivers' lives?
4. What are the CMH professionals' obstacles and facilitators for carrying out the SCPD as planned?

A triangulation of methods and data collection will be used to guarantee the internal validation of the process evaluation.^{55;56} First, content analysis^{57;58} will be used to determine whether the intervention group have been trained as planned. For this purpose, the data collected during the study period about the participation of CMH professionals in one or more parts of the training sessions will be scored. Second, content analysis of the starter packages and action lists returned to us will be used to determine whether the caregivers received care from the intervention group as planned. The 11 items of the SCPD screening tool must have a score of 100% before we can assume that the caregiver has received care from the CMH professional as planned. Because it is not possible to directly deduce whether the care received differs from the care planned, at least two items on the action list should be scored to make it credible that the caregiver received the care planned. We will present the results of both content analyses in tables of frequencies with cross tabulation.

These results will be the main input for the third question of the process evaluation, "What is the relationship between the results when the SCPD was carried out as planned and the outcome measures of institutionalization, time to institutionalization, and the quality of the caregivers' lives?" In answering this question, the carrying out of the SCPD as planned will be summarized as the product of two scores, namely, the score with CMH professionals trained as planned and the score with caregivers receiving the care as planned. Next, this score will be used as the input for multilevel logistic and multilevel linear regression analyses for the relationship of the carrying out of the SCPD as planned to the institutionalization, time to institutionalization, and the quality of the caregivers' lives. The gender of the CMH professional will be treated as a control variable to adjust for the characteristics of the CMH professional. All process evaluation analyses will be done with SPSS version 16.0 (SPSS, Chicago, Illinois) and MlwiN Version 2.0 (Centre for Multilevel Modelling, University of Bristol, Bristol, UK).

Semi-structured interviews will be used to explore CMH professionals' obstacles and facilitators in carrying out the SCPD as planned. Three key informants allocated to the intervention group from each CMH service will be interviewed. Purposive sampling⁵⁹ will be used to select a varied group of CMH professionals from each CMH service on the basis of scores pertaining to CMH professionals who carried out the SCPD as planned. In this approach, seven levels for exploring obstacles and facilitators are recognized: the intervention itself, the innovation itself, the individual CMH professional, the patient (e.g., the informal caregiver), the social context, the organizational context, and the economic and political context.⁶⁰ The records of the evaluation sessions with CMH professionals as part of their SCPD training, as well as information collected from two pilot interviews with CMH professionals, will be used as input for developing question sets at each level. The interviews will be audiotaped and transcribed. Two investigators will use the modified grounded theory approach to analyze them independently.⁶¹⁻⁶³ We assume that 18 interviews will be enough to reach the point of theoretical saturation. If not, the purposive sampling procedure will be repeated, and additional interviews will take place until no new information about the obstacles and facilitators appear. The software package SPSS version 16.0 will be used for the purposive sampling procedure, and Atlas.ti 5.2 will be used for the qualitative analysis.

Economic evaluation

The economics will be evaluated in parallel to the trial, which is compatible with the design presented earlier. The purpose of this evaluation is to determine the potential efficiency of the SCPD in the CMHcare setting versus usual care for the caregivers, from a societal perspective. The economic evaluation will be based on the general principles of a cost-effectiveness analysis, and the outcome measures will be costs, time to institutionalization of the person with dementia, and the quality adjusted life years (QALYs). These outcome measures will be combined in two incremental cost-effectiveness ratios (ICERs): cost per QALY gained and cost per unit of time-to-institutionalization gained. We will build up an empirical estimate of the sampling distributions of both ICERs by resampling with replacement from the original data (i.e., bootstrapping). A cost-effectiveness acceptability curve will summarize the evidence in support of SCPD being cost-effective for all potential values of the willingness to pay for a QALY, or a unit of time-to-institutionalization. We will explore the impact of uncertainty surrounding deterministic parameters (such as cost prices) on the ICER by means of one-way sensitivity analyses on the range of extremes.

The cost analysis will consist of two main parts. In the first part, on the dyad level, we will measure volumes of care prospectively, using the RUD questionnaire.^{42;64} This instrument contains questions about the use of community care services, type of accommodation, the employment status of the person with dementia and the primary informal caregiver, medical care, and informal care. Informal care-giving time will be categorized as a loss of production (friction-cost method) for an employed primary caregiver, and as a loss of leisure time in all other cases. The RUD instrument will be completed by the informal caregiver every 3 months from baseline to follow-up at 12 months. The time to institutionalization is the final event. In both treatment groups, SCPD and usual care, the people with dementia who are still not institutionalized at the end of 12 months are considered as censored observations. The second part of the cost analysis consists of determining the cost prices for each volume of consumption in order to be able to multiply the volumes registered for each participating caregiver and each person with dementia. The Dutch guidelines for cost analyses will be used.⁶⁵ If no guideline or standard prices are available for units of care/resources, we will determine real cost prices with the activity-based costing method.^{66;67}

The effect analysis will adhere to the design of a cluster, randomized, controlled trial. The relevant variables for the economic evaluation are the time to institutionalization and the quality of the caregiver's life. We will use QALYs computed with the trapezium rule for a cost-utility analysis of the two treatment groups. The time to institutionalization will be the final event, meaning that the quality of the caregiver's life will be researched until the time of the institutionalization of the person with dementia, with a maximum of 12 months. We will use the standard EQ-5D^{43;44} classification system developed by the EuroQol Group for the overall quantification of health status as a single index (utilities). The EQ-5D is one of three widely used multiattribute systems available to determine health state preferences (utilities). The arguments for choosing the EQ-5D are:

1. The five domains of the EQ-5D reflect aspects that are thought to be important for the population under consideration.
2. The system is relatively simple to administer.
3. The sensitivity of the instrument has proven satisfactory.
4. A reasonably sound algorithm has been published to compute utilities.

Power calculations

The difference in the expected effect is based on previous research in which 14% of the people with dementia in the intervention group and 28% in the control group were institutionalized.^{35;36} We need 132 dyads for each of the intervention and control groups to detect a 50% reduction in institutionalization rates with 80% power at the two-sided significance level of 0.05. We inflated this sample size with a design effect of 1.15 to 152 dyads for each group to allow for correlating dyads within the same cluster, assuming an average cluster size of four and an intracluster correlation coefficient of 0.05. Assuming a 25% dropout rate of dyads, the study needed a final enrolment of 190 dyads in each group, so that at least 48 CMH professionals needed to be randomized to each group.

Statistical analyses

Analyses will be performed at the level of the caregiver and the person with dementia. All available data will be analyzed on an intention-to-treat basis, i.e. dyads will remain in the group to which they are assigned. Descriptive analysis will be used to examine baseline comparability of both the intervention and control groups for sociodemographic characteristics, outcome parameters, and control variables. We will calculate the effect of the SCPD on the primary outcome measure (the number of institutionalizations) with Fisher's exact test. Multilevel logistic regression analyses will be used to correct for the design effect of clustering dyads with the CMH professionals (level 1), and CMH professionals in CMH services (level 2). Kaplan-Meier survival analysis will be used to quantify the effect of the SCPD on the primary outcome measure, time to institutionalization; and a Cox proportional hazard model, to correct for control variables. Analysis of the effect on the primary outcome and subgroup-analyses – adding the stratifying factor as a covariate and an interaction term of the stratifying factor with treatment group to the models – will be performed for shared household, age, and gender of the caregiver. Random coefficient regression analyses will be used to examine the effect of the SCPD on the secondary outcome measure (the quality of life of both the person with dementia and the caregiver) and also to correct for the clustering effect of the design, namely, dyads clustered with CMH professionals (level 1) and CMH professionals in CMH services (level 2). We will also perform per protocol analyses. Mean substitution will be used for missing values unless at least if two third of the other items of that particular scale was completed. The software SPSS 16.0 (SPSS, Chicago, Illinois) and MLwiN Version 2.0 (Centre for

Multilevel Modelling, University of Bristol, Bristol, UK) will be used for all statistical analyses.

Table 1. Outcome measures

Variable	PO	SO	EE	BG	Instrument/Source	T0	T1	T2	T3	T4
Professionals										
Job satisfaction	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Job satisfaction, subscale from the Consultants' Mental Health Questionnaire	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Gender	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	SPCD questionnaire	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Informal caregivers										
Sense of competence	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	SCQ	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Quality of life	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	EQ-5D	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Depressive symptoms	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	CES-D	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Caregiver distress	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NPI-Q	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Time spent giving care	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RUD	<input checked="" type="checkbox"/>				
Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gender	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethnicity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marital status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Living arrangement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Relation with the PWD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	SPCD questionnaire	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Shared household with the PWD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	SPCD questionnaire	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
People with dementia										
Housing conditions/residence	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>				
Quality of life	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	QoL-AD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Behavior problems	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	NPI-Q	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Healthcare services used	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	RUD	<input checked="" type="checkbox"/>				
Severity of dementia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	DSM-III-TR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Gender	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ethnicity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marital status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Living arrangement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Children	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Children living in	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	RUD	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PO, primary outcome; SO, secondary outcome; EE, economic evaluation; BG, background; T0, baseline measure; T1, 3-month follow-up measure; T2, 6-month follow-up measure; T3, 9-month follow-up measure; T4, 12-month follow-up measure; CES-D, Center for Epidemiologic Studies Depression Scale; DSM-III-TR, Diagnostic and statistical manual of mental disorders, 3rd text revision; EQ-5D, EuroQoL-5D; NPI-Q, Neuropsychiatric Problems Inventory Questionnaire; QoL-AD, Quality of Life in Alzheimer's Disease; RUD, Resource Utilization in Dementia; SCQ, Sense of Competence Questionnaire; SPCD, Systematic Care Program for Dementia; PWD, person with dementia.

Ethical principles

The Committee on Research Involving Human Subjects, Arnhem-Nijmegen Region, approved the study protocol on March 9, 2005. Participation in the study is voluntary. Written consent must be obtained from all participating informal caregivers (see the section Informed consent procedure). Informal caregivers must explicitly be informed about the fact that they can withdraw their consent any time, without any specific reason, and with no negative consequences with regard to healthcare treatment now or in the future. Dyads who withdraw from the study will continue to receive treatment from the CMH professional they are assigned to. If a person is institutionalized, or has died, the caregiver will no longer be invited to follow-up appointments.

Community mental health professionals from the CMH services allocated to the control group will not receive the SCPD training during the trial. However, they will be offered such training after the trial. This means that they can enter the SCPD, but with a 12-month delay.

Names of dyads and other confidential information will be treated with medical confidentiality, and data are always separated from the names of the dyads. Each participant is identified in the database by a number and an identity code. These codes are available only to the investigators and the research assistant.

The target groups are people with dementia, their informal caregivers, caregiver organizations, Alzheimer societies, professional healthcare workers, researchers of dementia care, and policy makers. The results of and information about the SCPD will be disseminated in publications and presentations at scientific and professional conferences and directly to family caregivers in Alzheimer cafes. The CMH services will also spread the results through their regional contacts.

Discussion

Strengths

A novelty in the SCPD for the caregivers is the pro-active and systematic approach, which involves informal caregivers in the support trajectory of the CMH service from the enrollment of the person with (suspected) dementia. Informal caregivers are systematically screened for a broad range of possible caregiver problems.

The use of an effective program to diagnose and systematically manage problems of these caregivers might improve the efficiency of the healthcare. Support for the

caregivers is very important because these caregivers have greater burdens than caregivers of other chronically ill people,³ and they are at a greater risk of depression.⁴⁻

⁶ The SCPD attempts to contribute to the quality of life of both the caregiver and the person with dementia by strengthening the caregiver's ability and sense of competence and by reducing behavioral problems of the person with dementia. The early detection and prevention of caregiver burden and depression may contribute to good results.

It is relevant to focus on the caregiver's sense of competence from the healthcare economic viewpoint, since a sense of competence is an important determinant of delaying institutionalization of the person with dementia.¹⁰ A relatively small cost investment for caregiver support from the SCPD would delay institutionalization, which is a major source of costs in the management of dementia. This is one of the three areas of greatest healthcare costs.⁷

Neither the pro-active elements nor the systematic elements of our study approach are usual in the management of dementia in the CMHcare setting. To our knowledge, there are no similar studies underway at this moment.

Limitations

Although a strong study design was used, some design characteristics might interfere with the reliability and validity of future results.

First, two forms of inclusion bias may have occurred. The first is the CMH services' method of recruiting CMH professionals: CMH professionals were free to decide whether they wanted to participate. This may mean that participating CMH professionals are more interested in care for the caregivers than their average colleagues. They may be more motivated to learn, and they might perform better than their non-participating colleagues. It is possible that they already take better care of caregivers than their colleagues. In practice, however, this form of inclusion bias is limited because almost all the available CMH professionals participated to generate the necessary number of CMH professionals. The second form of inclusion bias concerns the willingness of dyads to remain in the study until their end-point is reached. The informal caregiver's burden may be an influential predictor of their willingness to participate. It would be reasonable if caregivers with a great burden did not want to

participate because they could not handle any more work. Analyses of caregiver nonparticipation might be useful.

Second, the possibility of contamination arising due to a change of contacts and a possible knowledge exchange between CMH professionals in the intervention and control groups cannot theoretically be excluded. To overcome this problem in practice, any CMH professionals allocated to the intervention group were emphatically asked to keep the study intervention secret and not to give information about the intervention to the CMH professionals in the control group, other colleagues, or field relations. To evaluate the success or failure of this request, the intervention group will be evaluated at each training session for such knowledge. They will be asked if they have been questioned about the training by colleagues and whether they were able to keep the secret.

Third, CMH professionals were aware of the dissemination of a study about supporting caregivers of people with dementia beforehand, and participating CMH professionals are fully aware of their allocation. This may be a source of performance bias because the control group may treat dyads differently than they used to. However, verification of performance bias is difficult because the actual usual CMH care is still a black box. File investigation might determine whether CMH professionals treated dyads differently before, during, and after the study period.

Fourth, from an ethical point of view the question arises whether informed consent should be obtained from participating CMH professionals because randomization took place at this level. This topic will be discussed from the CMH professionals' point of view during the process analysis of the obstacles to and facilitators of the CMH professional's participation in the study.

Fifth, dyads were recruited from the CMH services, not from other institutions such as the outpatient clinics, the memory clinic, or directly from general practice. Thus our sample may not be representative of all dyads.

Policy implications

If the SCPD proves effective in the CMHcare setting, wider implementation might be recommended. In that case, the organization will be promoted on a national level to include the SCPD in usual care. Enhancement of the quality of life of the caregiver and the person with dementia and delaying or preventing institutionalization of the last-mentioned will benefit all the target groups. Generalization to other countries may be limited because there are substantial differences in the design of organizing and financing healthcare (including long-term care), the provision of both informal and formal care (e.g., various types of residential accommodation), and cultural preferences concerning institutionalization within and between countries.⁶⁸⁻⁷⁰

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Chapter 4

Systematic care for caregivers of people with dementia: a multicenter, cluster-randomized, controlled trial

Anouk Spijker
Hub Wollersheim
Steven Teerenstra
Maud Graff
Eddy Adang
Frans Verhey
Myrra Vernooij-Dassen

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Abstract

Objective: To evaluate the effectiveness of the Systematic Care Program for Dementia (SCPD) on institutionalization of the person with dementia and to determine the predictors of institutionalization.

Design: Single-blind, multicenter, cluster-randomized, controlled trial. Setting: Six community mental health (CMH) services across the Netherlands.

Participants: A total of 295 person with dementia–caregiver dyads referred to a CMH service with suspected dementia.

Intervention: Training of CMH professionals in the SCPD and its subsequent use. The SCPD consists of a systematic assessment of caregiver problems and alerts CMH professionals in flexible, connecting, proactive interventions to them. The intensity of the SCPD depends on the judgment of the CMH professional, based on individual caregiver needs.

Primary Outcome: Institutionalization in long-term care facilities at 12 months of follow-up.

Results: No main intervention effect on institutionalization was found. However, a better sense of competence in the control group reduced the chance of institutionalization but not in the intervention group. In both groups the caregiver's depressive symptoms, the severity of behavioral problems of the person with dementia and the dementia severity were the strongest predictors of institutionalization. The intensity of the program was low, even for dyads exposed to the SCPD.

Conclusions: Although no main effect was found, the results suggest that the SCPD might prevent a deterioration of the sense of competence in the intervention group. The intensity of a program is crucial and should be prescribed on the basis of evidence rather than left to the discretion of health professionals. Future controlled trials in daily clinical practice should use a process analysis to control for compliance.

Introduction

Two-thirds of the people with dementia are cared for at home.¹ Care at home is often intensive and burdensome. Informal caregivers of these people carry a greater burden than informal caregivers of other chronically ill people,² and they are at greater risk of depression.^{3;4} Contemporary guidelines and policies have been designed to shape conditions to support caring for people with dementia at home that, as a result, can delay institutionalization of the person with dementia.^{1;5}

Some caregiver support programs have been found effective.⁶⁻⁹ Such programs are most effective when they are tailor made, involve both the person with dementia and the caregivers, offer a choice of interventions, and are intensive.⁷ The caregiver's sense of competence¹⁰ or burden¹¹ is a strong predictor of institutionalization. Therefore, most programs aim at reducing the caregiver's burden or enhancing feelings of competence.

Caregivers' problems often remain invisible until a crisis occurs. In usual care in the Netherlands, the community mental health (CMH) services offer many opportunities for supporting caregivers that remain unused because of a lack of timely and systematic assessment of caregiver conditions. Caregivers suffering from a sense of inadequate competence and depressive symptoms are often undetected and are untreated.^{12;13} This contributes to the suffering of caregivers and the institutionalization of people with dementia. For these reasons, we developed the Systematic Care Program for Dementia (SCPD) for the CMH services. The SCPD consists of training CMH professionals in the systematic assessment and interpretation of the caregiver's sense of competence and depressive symptoms, as well as strategies about how to deal with deficiencies. The assessment covers a wide range of individual caregiver problems and triggers the awareness of CMH professionals in connecting proactive interventions to those problems. This is one of the tasks of the CMH service.

The main objective of this study was to evaluate the effectiveness of training CMH professionals in the SCPD and its subsequent use by CMH services in institutionalization in comparison to usual care. The second objective was to examine the strongest predictors of institutionalization of the person with dementia.

Methods

The study design was that of a single-blind, multicenter, cluster-randomized, controlled trial. The units of randomization were CMH professionals (psychologists and social psychiatric nurses) in the CMH services. The Committee on Research Involving Human Subjects in the Arnhem-Nijmegen Region approved the study. Written informed consent was obtained from all participating caregivers.

Sample

The researchers recruited seven CMH services for participation in the study. The CMH services recruited the CMH professionals, who were considered eligible if they treated at least four person with dementia–caregiver dyads each year, the minimum required for reasons of continuity and routine. The CMH services recruited the number of dyads needed to participate in the SCPD study. In addition to suspected dementia of people living in the community, the inclusion criteria required the informal caregiver to visit the person with dementia at least twice a week, be willing to participate, and give written informed consent. Dyads were excluded if the informal caregiver was a client of the CMH service itself, was too ill to participate in the study, or did not speak Dutch fluently.

Randomization procedures

Community mental health professionals from each participating CMH service were randomly assigned to the intervention group or the control group. Randomization was applied within CMH services. Sealed envelopes, each containing the code of one of the participating professionals, were used for random allocation. Subsequently the CMH services assigned the recruited dyads to a CMH professional in the SCPD or usual CMH care group respectively. The researcher, the research assistant, and four trained interviewers were not involved in the assignment procedure of the dyads, nor they did not know the assignment decision. Their blinding remained intact until the 1-year follow-up measurements were completed. Baseline assessments took place before assignment of the dyads. The study was single-blind because all the professionals involved were aware of the treatment allocation, but dyads were blinded to the group allocation.

Intervention

The SCPD was based on the home care introduced by the Family Support Program¹⁴ (FSP) and adapted for introduction to the CMH service. The FSP was effective, but quite intensive. Because it is important for implementation that the SCPD is embedded in usual care, we tried to reduce its intensity by adapting it to individual needs, thereby also reducing costs. Therefore, interventions that were already available in CMHcare were used. The intensity of the support and the actual use of interventions were left to the discretion of the CMH professional.

The SCPD can be used in the CMH professional's first consultation with a person with dementia–caregiver dyad entering the CMH service. It might prevent overburdening caregivers who have made no request for treatment of their own problems.

The intervention consisted of training CMH professionals in the systematic assessment and interpretation of the caregiver's sense of competence and depressive symptoms, and training in strategies to deal with deficiencies. The training program, three sessions of 2 hours each, described in detail elsewhere,¹⁵ were divided into three main components:

1. *Screening.* Community mental health professionals used validated scales to assess the caregiver's sense of competence¹⁶ and depressive symptoms.¹⁷ Professionals provided the researchers data from their results.
2. *Psychosocial support.* The assessment of caregiver problems alerted CMH professionals to flexibly connect, proactive interventions to them. The SCPD offered three possible intervention strategies to initiate support:
 - a. Define acceptable goals of involvement. Organize additional professional support.
 - b. Open a dialogue regarding expectations, resources, conflicts, stigmas, and feelings of guilt. Engage in a dialogue about what the caregiver thinks she/he has to do and what she/he actually can do.
 - c. Clarify the relationship between the behavior of the person with dementia and the dementia syndrome.

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The CMH professionals provided the researchers data from their supportive interventions as registered on the "action list" during and after each contact with the dyad. This list includes 60 possible supportive actions that CMH professionals might undertake and it is divided into nine categories: intake, diagnostics,

psychoeducation, psychosocial care, medical care, handover care, legal care, case management, and crisis management.

3. *Transfer to regular healthcare.* Along with psychosocial support, CMH professionals could organize medical, home, or respite care. After ending their contacts with the dyad, they handed the care over to the regular healthcare or home.

Outcomes and follow-up

Clinical outcomes. The primary outcome measure was institutionalization of the person with dementia in a long-term care facility during the 12-month follow-up. The institutionalization rate and date were assessed every 3 months with the Resource Utilization in Dementia Questionnaire.¹⁸ The caregiver's sense of competence, caregiver's depressive symptoms, distress due to the behavioral problems of the person with dementia, severity of the behavioral problems, and caregiver's quality of life were used as covariates (Table 1).

Table 1. Assessment scales based on the outcome measure and covariates

	Scale	Items and rating	Scores	Psycho-metrics
Primary outcome				
PWD Institutionalization	RUD ¹⁸	1	Institutionalized (yes or no)	Good ¹⁹
Covariates				
CG sense of competence	SCQ ¹⁴	27, rated on a 5-point –scale (1 "agree very strongly" to 5 "disagree very strongly")	27–135; a higher score indicates a better sense of competence	Good ^{14;20}
CG depressive symptoms	CES-D ^{21;22}	20, rated on a 4-point –scale (1 "seldom or never", to 4 "always or almost always")	0–60; a score ≥ 16 indicates clinically relevant depression	Good ^{22–24}
CG quality of life	EQ-5D ^{25;26}	5, rated as "no problems", "some problems" or "severe problems"	-0.33 (worst health) and 1.00 (perfect health) using the time trade-off method ²⁸	Good ^{25;28}
CG distress due to PWD behavioral problems	NPI-Q ^{29;30}	12, rated from 0 to 5, with 5 indicating the most severe level of distress	0–60; a higher score indicates more severe distress	Good ^{29;30}
Severity of PWD behavioral problems	NPI-Q ^{29;30}	12, rated from 0 to 3, with 3 being the most severe	0–36; a higher score indicates more severe behavioral problems	Good ^{29;30}

PWD = person with dementia; RUD = Resource Utilization in Dementia Questionnaire; CG = caregiver; SCQ = Sense of Competence Questionnaire; CES-D = Center for Epidemiologic Studies – Depression Scale; EQ-5D = EuroQol-5D; NPI-Q = Neuropsychiatric Problems Inventory Questionnaire

Assessed sociodemographics used as control variables were caregiver gender, caregiver's relation to the person with dementia, their living arrangement (i.e., sharing the same household), the severity of dementia as defined by the Diagnostic and statistical manual of mental disorders, 3rd text revision,³² and the CMH service.

Process outcomes. The actual exposure to the SCPD and the intensity of the SCPD were evaluated and used as covariates in the institutionalization analyses. The exposure was assumed to be adequately evaluated if the investigator knew that the CMH professional had participated in the three training sessions and had provided data from his/her screening of the caregiver's sense of competence and depressive symptoms for at least half of his/her dyads. The number of counseling sessions offered and the number of actions the CMH professionals took after the screening indicated the SCPD intensity.

Power calculations

The difference in the expected effect was based on previous research in which 14% of the people with dementia in the intervention group and 28% in the control group were institutionalized.^{14;32} For each of the intervention and control groups to detect a 50% reduction in institutionalization rates with 80% power at the two-sided significance level of 0.05 required 132 people with dementia–caregiver dyads. This sample size was inflated with a design effect of 1.15–152 dyads for each group to allow for correlating dyads within the same cluster, assuming an average cluster size of four and an intracluster correlation coefficient of 0.05. Assuming a 25% dropout rate of dyads, the study needed a final enrolment of 190 dyads in each group, so that at least 48 CMH professionals, each treating a minimum of 4 dyads, needed to be randomized.

Statistical analysis

Analyses were based on the principle of intention-to-treat. Unless otherwise stated, all dyads with complete data for the institutionalization outcome were analyzed according to their randomized condition, regardless of actual adherence to the assigned intervention. Baseline comparability between the intervention and control groups on sociodemographics, covariates, and control variables were tested with χ^2 tests and t-tests for categorical or numerical variables, respectively.

The effect of the SCPD on the institutionalization rate was calculated with Fisher's exact test. Multilevel logistic regression analysis was used to correct for clustering of dyads with the CMH professionals, and to correct for covariates and control variables. Kaplan-Meier survival analysis was used to quantify the effect of the SCPD on the time to institutionalization, and Cox regression analysis was used to correct for covariates and control variables. People with dementia who were not institutionalized at the end of 12 months were censored. For both analyses, interaction effects between group assignment and caregiver-and-people with dementia conditions were investigated, as were interaction effects between gender and living arrangements. P values less than 0.05 (two-tailed) were considered statistically significant.

A full model containing all interaction terms was built, then reduced by removal of nonsignificant interactions at the 0.10 level. For nonsignificant interactions, the corresponding main effects were removed if not significant at the 0.05 level. If no more than one-third of the items were missing from a dyad's data for a particular scale, the score for the completed items was extrapolated for the missing items. Missing data were deleted list wise. The software MLwiN Version 2.0 (Centre for Multilevel Modelling, University of Bristol, Bristol, UK) was used for multilevel analyses of the binary outcome measure of institutionalization rate,³³ and SPSS 16.0 (SPSS, Chicago, IL) was used for all other statistical analyses.

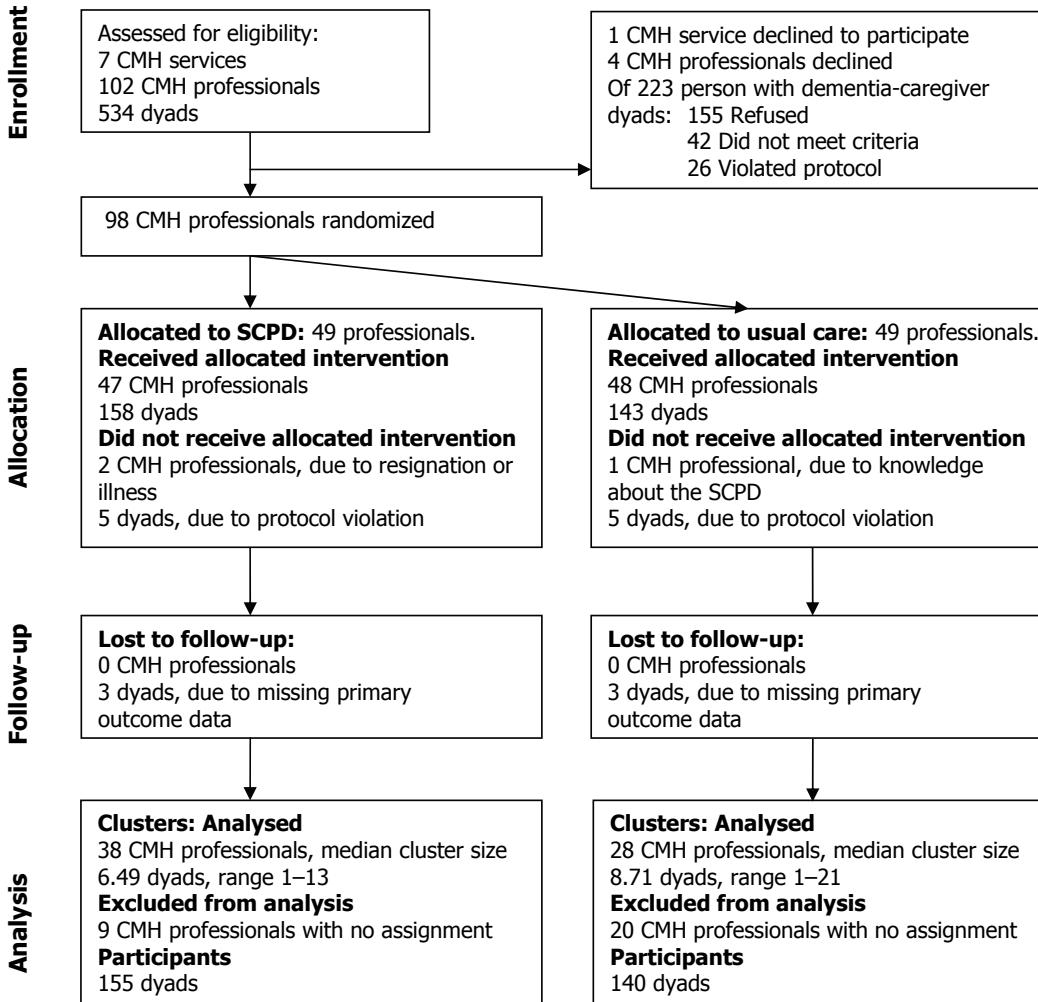
Results

Sample

People with dementia–caregiver dyads. Of the 534 enrolled people with (suspected) dementia, 223 dyads were excluded before baseline measurements: 155 dyads refused to participate, 42 dyads did not meet the inclusion criteria, and 26 dyads were excluded retroactively due to protocol violation (Figure 1). Initially, 311 dyads were included. Ten dyads were excluded because they received an intervention before baseline measurements. Finally, 301 dyads were included for baseline measurements. After 12 months of follow-up, data about the institutionalization of six dyads, three in each group, were missing. Altogether, 295 people with dementia–caregiver dyads were included in the study; 155 dyads were randomly assigned to a professional in the intervention group and 140 to the control group. Some eligible dyads who dropped out did provide data for baseline assessment. The sociodemographics of the dropouts (N=56) were comparable for the two groups. However, caregivers in the dropout group

experienced significantly more distress due to behavioral problems of the person with dementia ($t = 2.89$, degrees of freedom (df) = 68.17, $p=0.01$), and these people with dementia exhibited significantly more severe behavioral problems ($t = 3.92$, df = 349, $p=0.001$).

Figure 1. Flow of clusters and participants through the trial



Moreover, there were differences between the group baseline assessments concerning the caregiver–person with dementia relation ($\chi^2 = 47.88$, df = 3, $p=0.001$) and the severity of dementia ($\chi^2 = 9.20$, df = 2, $p = 0.01$; Table 2). Therefore, we used baseline-adjusted analyses to control for the effect of relationship and severity of dementia on institutionalization.

Table 2. Baseline comparison of the intervention and control groups

	SCPD	N=155	Usual care	N=140
Sociodemographics				
Mean (SD) age in years				
Caregivers	58.4 (12.2)	153	59.2 (12.9)	
People with dementia	80.1 (7.1)	154	80.1 (6.4)	
Women (%)				
Caregivers	114 (73.5)		105 (75.0)	
People with dementia	108 (69.7)		90 (64.3)	
Dutch ethnicity (%)				
Caregivers	153 (98.7)		137 (97.9)	
People with dementia	151 (97.4)		137 (97.9)	
Education (%)				
Caregivers				
Low	48 (31.0)		37 (26.4)	
Intermediate	70 (45.2)		71 (50.7)	
Higher	33 (21.3)		30 (21.4)	
Other	4 (2.2)		2 (1.4)	
People with dementia				
Low	100 (64.5)	153	85 (60.7)	
Intermediate	30 (19.4)	153	33 (23.6)	
Higher	12 (7.7)	153	14 (10.0)	
Other	11 (7.1)	153	8 (5.7)	
Relation (%)**				
Partner	41 (49.4)		42 (50.6)	
Child	75 (47.8)		82 (52.2)	
Other	39 (70.9)		16 (29.1)	
Living arrangement (%)				
Shared household	50 (32.3)		44 (31.4)	
Severity of dementia (%)**				
Mild	48 (31.0)		40 (28.6)	
Moderate	60 (38.7)		38 (27.1)	
Severe	20 (12.9)		11 (7.9)	
Not otherwise specified	3 (1.9)		48 (34.3)	
Not diagnosed	24 (15.5)		3 (2.1)	
Mean (SD) on assessment scales				
Caregiver				
SCQ	92.5 (16.3)	154	90.9 (13.8)	135
CES-D	12.4 (10.4)	154	13.5 (9.1)	135
EQ-5D	0.87 (0.20)	154	0.89 (0.14)	
NPI-Q (experienced distress)	12.7 (9.1)		14.4 (8.9)	
Person with dementia				
NPI-Q (severity behavior problems)	10.5 (7.1)		12.0 (6.3)	

SCPD = Systematic Care Program for Dementia; SCQ = Sense of Competence Questionnaire; CES-D = Center for Epidemiologic Studies – Depression Scale; EQ-5D = EuroQol-5D; NPI-Q = Neuropsychiatric Problems Inventory Questionnaire; ** Statistically significant difference ($p < 0.05$, two-tailed) between the intervention and control groups: relation of caregiver to patient (Chi-square test (χ^2) = 47.88, df = 3, $p = 0.001$); severity of dementia (χ^2 = 9.20, df = 2, $p = 0.01$)

Community mental health services and CMH professionals. Seven CMH services from four regions in the Netherlands, with 102 CMH professionals, were eligible to participate in the study (Figure 1). One CMH service and four CMH professionals withdrew from the study, leaving 98 CMH professionals from six CMH services to randomize. However, immediately after randomization, two CMH professionals in the intervention group and one in the control group dropped out. At 12 months of follow-up, 66 CMH professionals, of whom 38 were randomized to the intervention group and 28 to the control group, had treated 295 person with dementia–caregiver dyads. Nine CMH professionals in the intervention group and 20 CMH professionals in the control group treated no dyads.

Design effect

There were 295 dyads nested within 66 clusters of CMH professionals, giving an average of 7.54 dyads (range: 1–21; SD: 4.81) per cluster. Multilevel logistic regression analysis on institutionalization of the person with dementia, correcting for the clusters of CMH professionals, revealed no difference between clusters of CMH professionals (design effect virtually equal to 1), meaning that there was sufficient heterogeneity. Therefore, instead of multilevel logistic regression analysis in MLwiN, we used logistic regression analysis in SPSS to determine the effect of the SCPD on institutionalization.

Effects of the Systematic Care Program for Dementia on institutionalization

Institutionalization rate. No significant main intervention effect on the institutionalization rate was found [unadjusted: Fisher's exact test, $p=1.00$, Table 3; adjusted logistic regression analysis, odds ratio (OR): 0.98, 95% confidence interval (CI): 0.54–1.79, Wald $\chi^2 = 0.09$, df=1, $p=0.95$, Table 4]. There was a difference of four (3.6%) institutionalizations in the total number of 90 institutionalizations at the 12-month follow-up (Table 3). A total of 262 caregiver–patient dyads had complete data on the covariates and control variables and were included in the model. Logistic regression analysis revealed an interaction effect for group assignment and sense of competence [OR: 0.96, 95% CI: 0.92–0.99, Wald $\chi^2 = 4.60$, df=1, $p=0.03$; Table 5]. A better sense of competence significantly decreased the odds of institutionalization in the control group, while there was no relation between institutionalization and a sense of competence in the intervention group.

Table 3. Institutionalization at 12 months of follow-up and mean time to institutionalization

N= 295 dyads	SCPD	Usual care	Difference	Significance
Institutionalization rate				
Institutionalized: n (%)	47 (52.2)	43 (47.8)	4 (3.6)	1.00*
Not institutionalized: n (%)	108 (52.7)	97 (47.3)	11 (22.55)	
Time to institutionalization				
Mean days (SD)	306.67 (102.99)	300.25 (113.54)	6.42	0.87*
95% Confidence interval	290.50 to 322.83	281.50 to 318.99	-18.39 to 31.23	

SD = Standard deviation; SCPD = Systematic Care Program for Dementia

*Statistical test for institutionalization: Fisher's Exact Test

*Statistical test for time to institutionalization: Kaplan-Meier Log Rank (Mantel-Cox), $\chi^2 = 0.03$, df = 1**Table 4. Institutionalization at 12 months of follow-up and time to institutionalization, adjusted for relation and severity of dementia**

N= 295 dyads	Treatment effect	Significance
Institutionalization rate (OR)	(0.98), 95% CI 0.54 – 1.79, Wald 0.08, df = 1	0.95
Time to institutionalization (HR)	(0.93), 95% CI 0.57 – 1.53, Wald 0.08, df = 1	0.93

Institutionalization rate: Logistic regression analysis. The OR (odds ratio) is a relative measure of risk telling us how much more likely it is that a person whose caregiver has received the support program will be institutionalized than a person whose caregiver has not. The OR ranges from 0 to infinity. Values close to 1.0 indicate no relationship between the Systematic Care Program for Dementia (SCPD) and institutionalization. Values less than 1.0 suggest a protective effect, while values greater than 1.0 suggest a causative or adverse effect of the SCPD. An OR with $p \leq 0.05$ (two-tailed) was considered statistically significant.

Time to institutionalization: Cox regression analysis. The hazard ratio (HR) is equivalent to the odds that the time to institutionalization of a person whose caregiver has received the support program is less than the time to institutionalization of a person whose caregiver has not. Values close to 1.0 indicate no relationship between the SCPD and the time to institutionalization. Values less than 1.0 suggest delayed institutionalization. Values greater than 1.0 suggest an SCPD effect of shortening the time to institutionalization. A HR with $p \leq 0.05$ (two-tailed) was considered statistically significant.

95% CI = 95% confidence interval; Wald = Wald statistic; df = degrees of freedom

In both groups, the severity of dementia [Wald $\chi^2 = 9.80$, df=3, $p=0.02$], behavioral problems [OR: 1.06, 95% CI: 1.01–1.11, Wald $\chi^2 = 4.90$, df=1, $p=0.03$] and caregiver depressive symptoms [OR: 1.05, 95% CI: 1.01–1.09, Wald $\chi^2 = 6.18$, df=1, $p=0.01$, Table 5] were significant predictors of the odds of institutionalization. The rate of institutionalization increased with dementia severity as opposed to people whose condition was not otherwise specified, as well as with increased behavioral problems and with increased caregiver depressive symptoms.

Table 5. Influence of the Systematic Care Program for Dementia on the institutionalization rate at 12 months of follow-up

Variables in model with 262 dyads	OR	95% CI for OR		Wald statistic	df	P value
		Lower	Upper			
Group assignment (1)	54.33	1.21	2447.51	4.23	1	0.04
Gender	0.31	0.111	0.89	4.69	1	0.03
Living arrangement (1)	0.79	0.25	2.45	0.17	1	0.68
Severity of dementia				9.80	3	0.02
Mild	0.57	0.23	1.42	1.48	1	0.22
Moderate	0.97	0.40	2.39	0.00	1	0.95
Severe	2.66	0.87	8.07	2.97	1	0.09
Sense of competence	1.02	0.98	1.05	0.94	1	0.33
Behavioral problems	1.06	1.01	1.11	4.90	1	0.03
Caregiver depressive symptoms	1.05	1.01	1.09	6.18	1	0.01
Group assignment (1)*sense of competence	0.96	0.92	0.99	4.60	1	0.03
Gender*living arrangement (1)	3.92	0.97	15.82	3.69	1	0.06

Logistic regression analysis: OR = odds ratio; 95% CI = 95% confidence interval; df = degrees of freedom. Indicator variables: group assignment (0 = intervention, 1 = control group), gender (0 = female, 1 = male), living arrangement (0 = sharing the same household, 1 = not sharing the same household). For the severity of dementia, the reference group is the one with dementia not otherwise specified. An OR with p-value ≤ 0.05 (two-tailed) was considered statistically significant

Time to Institutionalization. No significant main intervention effect on the time to institutionalization was found (unadjusted: Kaplan-Meier log rank test, $\chi^2 = 0.03$, df=1, $p=0.87$, Table 3; adjusted Cox regression analysis, hazard ratio (HR): 0.93, 95% CI: 0.57–1.53, Wald $\chi^2 = 0.08$, df=1, $p=0.93$, Table 4). There was a mean difference of 6.42 days in the time to institutionalization, with people in the control group being institutionalized sooner (Table 3). The mean time to institutionalization was 303.62 days (SD: 6.28) from enrollment in the study. A total of 261 dyads had complete data on the covariates and control variables and were included in the model. Cox regression analysis revealed that in both groups the severity of dementia (Wald $\chi^2 = 15.10$, df=3, $p=0.002$) and behavioral problems (HR: 1.80, 95% CI: 1.18–2.75, Wald $\chi^2 = 7.49$, df=1, $p=0.01$, Table 6) were significant predictors of the time to institutionalization. People with more severe dementia, as opposed to people whose condition was not otherwise specified, and people with more severe behavioral problems were institutionalized sooner (Table 6).

Table 6. Influence of the Systematic Care Program for Dementia on the time to institutionalization after 12 months of follow-up

Variables in model with 261 dyads	HR	95% CI for HR		Wald statistic	df	P value
		Lower	Upper			
Group assignment (1)	0.97	0.59	1.60	0.02	1	0.90
Severity of dementia			15.10		3	0.002
Mild	0.64	0.32	1.30	1.51	1	0.22
Moderate	0.90	0.46	1.77	0.10	1	0.76
Severe	2.30	1.07	4.91	4.59	1	0.03
Sense of competence	0.99	0.97	1.00	3.15	1	0.08
Behavioral problems	1.80	1.18	2.74	7.49	1	0.01

Cox regression analysis: HR = hazard ratio; 95% CI = 95% confidence interval; df = degrees of freedom. Indicator variables: group assignment (0 = intervention, 1 = control group)

A HR with p-value ≤ 0.05 (two-tailed) was considered statistically significant

Intensity of the Intervention. Sixty-nine percent of the dyads were exposed to the intervention. They received an average of 3.09 (SD: 2.97) counseling sessions, including the assessment procedure. Fifty-six percent of these dyads received an average of 19.22 (SD: 16.65) supportive actions after the screening. After adjusting for the intensity (N=268), we found no significant effect on the institutionalization rate (logistic regression analysis: OR: 0.75, 95% CI: 0.32–1.75, Wald $\chi^2 = 0.45$, df=1, p=0.50) or the time to institutionalization (Cox regression analysis: HR: 0.86, 95% CI: 0.43–1.71, Wald $\chi^2 = 0.18$, df=1, p=0.67).

Conclusions

No main intervention effect on institutionalization was found. However, in the control group, a sense of better competence significantly decreased the chance of institutionalization, while there was no relationship between these measures in the intervention group. This might indicate that the SCPD prevented a deterioration of the sense of competence in the intervention group. For both groups, the severity of dementia, behavioral problems, and caregiver depressive symptoms were predictors of the institutionalization rate, as were the severity of dementia and behavioral problems for the time to institutionalization.

There may be several reasons why this study did not find a main effect of the SCPD on institutionalization:

1. The CMH professional did not systematically screen the caregivers. Thirty-one percent of the dyads in the intervention group had not received a systematic assessment. However, adjusting for the extent to which CMH professionals carried out the intervention as planned did not yield different effects on institutionalization.
2. It may be that the CMH professionals' systematic assessment was appropriate, but their proactive interventions as motivated by the assessment were not. However, it is impossible to produce evidence of this from our data.
3. The intervention might not have been intense enough. In most instances, there was relatively much emphasis on the assessment procedure and little room for extensive counseling. Screening programs for depression are only effective if subsequent coordinated mental health treatment and monitoring by health professionals are offered.³⁴ Adjustment of the intensity of the intervention did not yield different effects on institutionalization. However, compared to the literature^{6;7} and two previous successful interventions,^{14;35} the intensity, which proved to be an important ingredient that distinguishes effective programs from ineffective ones,^{6;7} was low. Only 69% of the dyads were exposed to the SCPD, and only 56% of this group received supportive actions. A reason for this was that the intensity of the SCPD was not standardized beforehand. The intensity of the intervention depended on the judgment of the health professional, optimization of the flexibility of the SCPD, and the acknowledgment of the expertise in the CMH services. Considering our prior successful trials,^{14;35} the SCPD should use CMH professionals that have already a high contact frequency. In this manner the presumed intensity of the SCPD is sustainable.

This study has some limitations related to dropouts. Around 40% of the dyads who were enrolled in the study dropped out, mainly because of refusal. The main reason for refusal was that little room was left for anything but caring for the person with dementia. Caregivers who dropped out experienced more distress due to behavior problems of the person with dementia, and the people with dementia related to those caregivers exhibited more severe behavior problems. This may have led to an underrepresentation of dyads with a heavy caregiver burden, which is the group that might have benefited most from our intervention.

Unlike some studies,^{6;7} there were more children of people with dementia than spouses of people with dementia among the caregivers in the SCPD. However, additional post-

hoc analyses showed that the caregiver's relationship to the person with dementia and their living arrangements did not affect the results.

The study could not be double-blinded, because active participation of the CMH professionals was necessary. Performance bias might have occurred and might have contributed to the results if awareness of CMH professionals in the control group eventuated in treating dyads differently; for example, with more attention than previously. However, verification of performance bias is difficult because actual usual CMH care treatment was not investigated.

Theoretically, the possibility of contamination due to a transfer of dyads and knowledge exchange between CMH professionals allocated to the different groups could have taken place. We checked whether the CMH professionals in the intervention group discussed the intervention with CMH professionals in the control group, and, given their answers, we conclude that they did not.

In summary, our study did not detect differences between the intervention group and the usual care group with regard to institutionalization, but we did detect a difference between the groups regarding the relation between the sense of competence and the institutionalization rate. Consistent with the literature, the caregiver depressive symptoms,³⁶⁻³⁸ behavioral problems of the person with dementia,³⁹ and the severity of dementia³⁹ were strong predictors of institutionalization in both groups. These results underline the importance of analyzing potential interaction effects, something that is not quite common in a research area driven by predefined analyses.

Future controlled trials in daily clinical practice should check the dropout phenomenon for key outcomes, and use a process analysis to control for compliance. Previous studies showed that the intensity of support programs proved to be a crucial factor in predicting the success of psychosocial interventions.^{6,7} The results of our study suggest that the intensity of the intervention should be prescribed on the basis of evidence rather than left to the discretion of CMH professionals. Policy and protocols for CMHcare should therefore include regulation of the expected intensity of the support programs. In this manner, systematic and timely assessment of caregiver problems will lead to effective proactive interventions that will relieve the caregivers of the subjective burden that can delay institutionalization of the person with dementia.

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Chapter 5

Influence of adherence to a systematic care program for caregivers of people with dementia

Anouk Spijker
Steven Teerenstra
Hub Wollersheim
Eddy Adang
Frans Verhey
Myrra Vernooij-Dassen

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Abstract

Objective: To evaluate the influence of adherence to the Systematic Care Program for Dementia (SCPD) intervention protocol on person with dementia and caregiver outcomes.

Design: Data were drawn from the SCPD study – a single-blind, multicenter, cluster-randomized, controlled trial. Multivariate regression analyses were used to assess the influence of adherence on person with dementia and caregiver outcomes.

Setting: Six community mental health (CMH) services across the Netherlands.

Participants: Forty-eight CMH professionals treating 125 person with dementia-caregiver dyads who were referred to the CMH service because of suspected patient dementia.

Intervention: Training of CMH professionals in the SCPD and its subsequent use. The SCPD consists of a systematic assessment of caregiver problems and consequent interventions.

Measurements: The dependent variables were caregiver's sense of competence, caregiver's depressive symptoms, caregiver's distress due to behavioral problems of the person with dementia, and the severity of behavioral problems of the person with dementia. The main independent variables were adherence to the SCPD intervention protocol and the intensity of the SCPD interventions. The follow-up lasted 12 months.

Results: Caregivers treated by adhering CMH professionals had a better sense of competence than caregivers treated by nonadhering CMH professionals at follow-up. No differences between intervention groups and controls were found for the other outcomes.

Conclusion: Nonadherence to the intervention protocol might be a reason for the difference found in the sense of competence between the intervention groups. Furthermore, the intensity of the SCPD might have been too low. Moreover, it might be that overburdened caregivers found it difficult to make effective use of the help offered to them. A qualitative process analysis should be executed to explore more in-depth clarifications.

Introduction

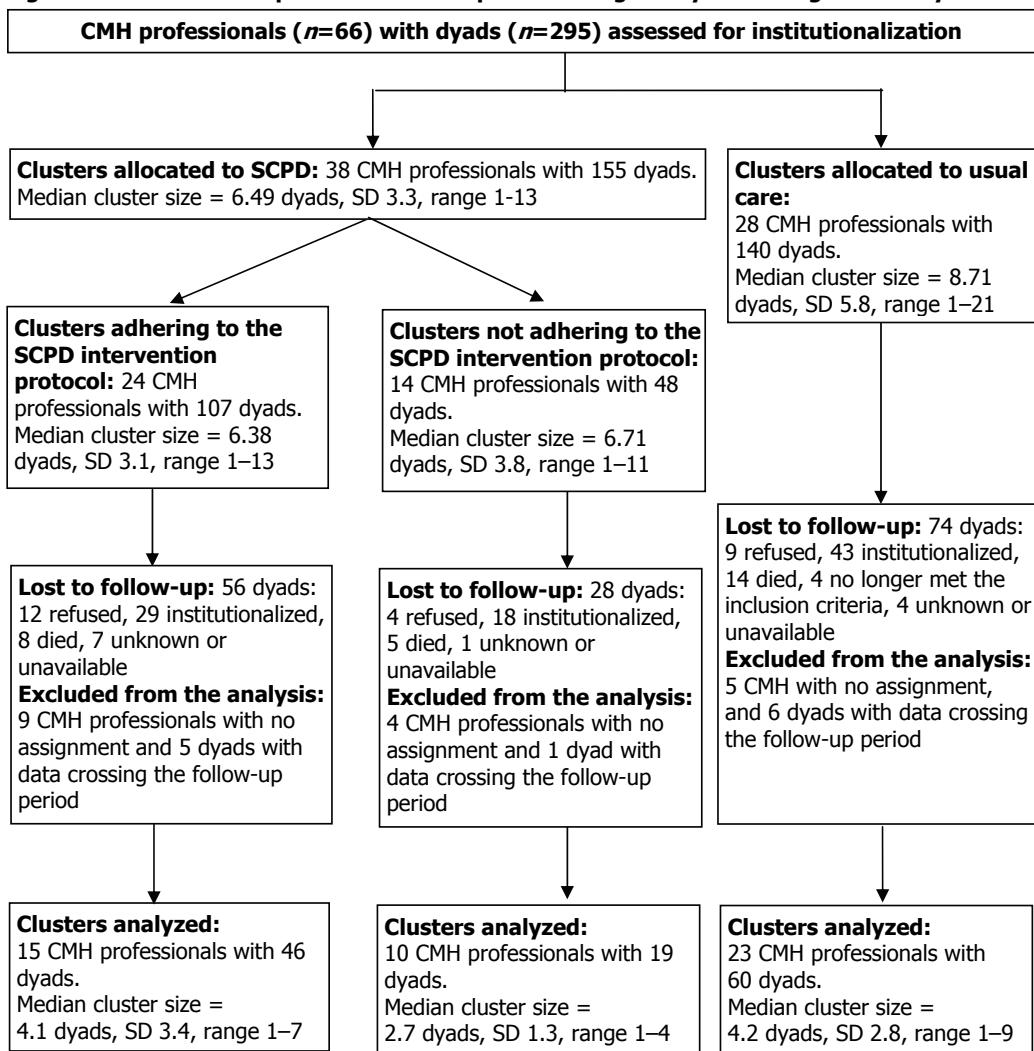
In usual community mental healthcare, the problems of informal caregivers often remain invisible until a crisis occurs because of a lack of timely and systematic assessment of caregiver conditions. The Systematic Care Program for Dementia (SCPD) has been developed to address this issue. Community mental health (CMH) services have been chosen to carry out the program because they are usually involved in dementia care for treatment of the person with dementia and they also have the expertise to support informal caregivers.

Preliminary analysis of the use of the SCPD in CMH services did not show any difference of effect between the SCPD and usual CMH care with regard to important clinical caregiver and person with dementia outcomes such as the caregiver's sense of competence,¹ caregiver's depressive symptoms,²⁻⁶ problem behavior of the person with dementia,⁷⁻⁹ and caregiver's distress as related to problem behavior of the person with dementia.^{10;11} This result is not compatible with the positive results of our previously introduced home care Family Support Program¹² and Community Occupational Therapy,^{13;14} and other support programs, which had similar intervention elements.^{15;16} We therefore investigated which factors might be responsible for the unexpected results of the SCPD regarding clinical outcomes in the CMHcare sector. We expect that CMH professionals' adherence to the SCPD intervention protocol is an important factor in the results, that is, whether CMH professionals actually carried out the planned improvement activities and whether the person with dementia-caregiver dyads were actually exposed to these activities.¹⁷ The aim of this study was to evaluate the influence of adherence to the SCPD intervention protocol on clinical outcomes.

Methods

Study design

Data were drawn from the SCPD study, a singleblind, multicenter, cluster-randomized, controlled trial.¹⁸ CMH professionals (n=66) with person with dementia-caregiver dyads (n=295) who were assessed for institutionalization were included in the analyses (Figure 1). The follow-up period was 12 months. The randomization procedure, the sample size calculations, the inclusion and exclusion criteria, and blinding are described in detail in our previous study.¹⁸ The Committee on Research Involving Human Subjects in the Arnhem-Nijmegen Region approved the study. Written informed consent was obtained from all the participating caregivers.

Figure 1. Flow of health professionals and patient-caregiver dyads through the analyses

Intervention

Basically, the SCPD consisted of training CMH professionals in the systematic assessment and interpretation of caregiver problems and in strategies to deal with deficiencies. The SCPD can be used in the CMH professional's first consultation with a dyad entering the CMH service. It might prevent overburdening caregivers who have made no request for treatment of their own problems.

The SCPD, as presented in Figure 2, can be divided into three stages:

1. *Screening*: Community mental health professionals used validated scales to assess the caregiver's sense of competence¹⁹ and depressive symptoms.²⁰
2. *Psychosocial support*: The assessment of caregiver problems alerted CMH professionals to flexibly connect pro-active interventions to them. The SCPD offered three possible intervention strategies to initiate support:
 - a. Define acceptable goals of involvement. Organize additional professional support.
 - b. Open a dialogue about expectations, resources, conflicts, stigmas, and feelings of guilt. Engage in a dialogue about what the caregiver thinks s/he has to do and what s/he actually can do.
 - c. Clarify the relationship between the behavior of the person with dementia and the dementia syndrome.

Supportive actions that CMH professionals might take as a result of the screening during and after each contact with the person with dementia–caregiver dyad were registered on the "action list". This list includes 60 possible intervening and supportive actions divided into nine categories: intake, diagnostics, psychoeducation, psychosocial care, medical care, hand-over care, legal care, case management, and crisis management.

3. *Transfer to regular healthcare*: Along with psychosocial support, CMH professionals could organize medical, home, or respite care. If the screening for caregiver depression is positive, the CMH professional may also refer the caregiver or start treatment. After ending their contacts with the dyad, they handed the care over to the regular healthcare or home.

The SCPD training consisted of three sessions of 2 hours each. One meeting was used to explain the program, and two meetings were used for evaluating the use of the program and for preparing suggestions about how to hand over the responsibility for care after the health service's work was completed. The objectives and methods used in the training sessions are described in detail in our study protocol.²¹

The SCPD is based on the effective but quite intensive Family Support Program¹² and adapted for introduction into the CMH services. Since it is important that the SCPD is embedded in usual care for implementation, we tried to reduce its intensity by adapting it more to individual caregiver needs.

Figure 2. Screening tool for the Systematic Care Program for Dementia**Screening for a sense of competence**

1. CONSEQUENCES OF INVOLVEMENT IN CARE FOR THE PERSONAL LIFE OF THE CAREGIVER
 - a. Do you feel that the present situation with your ... does not allow you as much privacy as you would like?
 - b. Do you feel stressed by trying to do enough for your ... as well for other family responsibilities, job, etc.?
2. SATISFACTION WITH YOUR OWN PERFORMANCE AS A CAREGIVER
 - a. Do you wish that you and your ... had a better relationship?
 - b. Do you feel strained in your interaction with your ...?
3. SATISFACTION WITH THE PERSON WITH DEMENTIA AS A RECIPIENT OF CARE
 - a. Do you feel that your ... tries to manipulate you?
 - b. Do you feel that your ... behaves the way s/he does to annoy you?
 - c. Do you feel that your ... behaves the way s/he does to have her/his own way?

Support strategies

1. Define acceptable goals of involvement. Organize additional professional support.
2. Open a dialogue regarding expectations, resources, conflicts, stigmas and feelings of guilt. Dialogue about what the caregiver thinks s/he has to do and what s/he actually can do.
3. Clarify the relationship between the behaviour of the person with dementia and the dementia syndrome.

Screening for depression

1. During the past month have you often been bothered by feeling down, depressed, or hopeless?
2. During the past month have you often been bothered by little interest or pleasure in doing things?

Caregiver's management strategy

- *Nonadapters*: lack of understanding or acceptance of the situation; approaching the person with dementia with impatience, irritation, or anger.
- *Nurturers*: care and protection; parent-child approach in which the person with dementia is taken by the hand and is no longer regarded as an equal.
- *Supporters*: adapting to the level of functioning of the person with dementia and encouraging him/her in existing abilities.

Severity of dementia

Mild: the person can live independently for the most part, with adequate personal hygiene and relatively intact judgement, but social activities and employment are both significantly impaired.

Moderate: formal employment is no longer possible and independent living is fraught with hazard to the extent that limited supervision is required.

Severe: there is severe impairment of daily activities (like minimal personal hygiene), and continual supervision is needed. The patient is entirely dependent on the caregiver for survival. Recognizing familiar and unfamiliar people in the environment is often no longer possible.

Therefore, the intensity of the support offered and the actual use of interventions were left to the discretion of the CMH professional to optimize the flexibility of the SCPD to individual caregiver needs. Furthermore, interventions that were already available in CMHcare were used. The "action list" was developed in collaboration with a staff member and a social psychiatrist from the participating CMH services. Consensus for including actions on this list was reached.

Adherence to the intervention protocol of the Systematic Care Program for Dementia

Each CMH professional allocated to the group that adhered to the SCPD intervention protocol had participated in the three SCPD training sessions and had provided data for all items of his or her screening of the caregiver's sense of competence and depressive symptoms for at least half of his or her dyads.

To assess the adherence to the SCPD intervention protocol, the researcher used a checklist to record whether intervention group CMH professionals had participated in all three SCPD-training sessions. This resulted in the measure referred to as "training", which was checked off as "yes" or "no".

Similarly, the measure "screening" was rated as "yes" for each intervention CMH professional who had provided data about all items of the screening of the caregiver's sense of competence and depressive symptoms for at least half of his or her dyads. If this criterion was not fulfilled, the CMH professional's screening was rated as "no".

The "training" and "screening" ratings resulted in the composite measure "adherence to the SCPD intervention protocol". A CMH professional adhered to the SCPD intervention protocol if she or he had both a "yes" for "training" and a "yes" for "screening". Community mental health professionals rated a "no" for "adherence to the SCPD intervention protocol" for all other possible combinations of "training" and "screening".

We evaluated not only adherence to the SCPD intervention protocol, but also the intensity of the SCPD intervention. We assessed the intensity of the SCPD intervention by counting the number of counseling sessions and the number of intervening and supportive actions. This resulted in the two variables "counseling sessions" and "actions", referred to in brief as "intensity".

Clinical outcomes

Validated clinical outcomes, as assessed at baseline before the intervention took place and at the 12-month follow-up, were the caregiver's sense of competence,¹² caregiver's depressive symptoms,^{22;23} caregiver's distress due to behavioral problems of the person with dementia, and the severity these behavioral problems^{24;25} (Table 1).

Table 1. Clinical outcomes

	Scale	Items and rating	Scores	Psychometrics
CG sense of competence	SCQ ¹²	n=27; rated on a 5-point scale of 1 (agree very strongly) to 5 (disagree very strongly)	27–135; a higher score indicates a better sense of competence	Good ^{12;26}
CG depressive symptoms	CES-D ^{22;23}	n=20; rated on a 4-point scale of 1 (seldom or never) to 4 (always or almost always)	0–60; S score ≥ 16 indicates clinically relevant depression	Good ^{23;27}
CG distress due to behavioral problems of the PWD	NPI-Q ^{24;25}	n=12; rated from 0 to 5, with 5 indicating the most severe level of distress	0–60; a higher score indicates more severe distress	Good ^{24;25}
Severity of behavioral problems of the PWD	NPI-Q ^{24;25}	n=12; rated from 0 to 3, with 3 being the most severe	0–36; a higher score indicates more severe behavioral problems	Good ^{24;25}

CG = caregiver; PWD = person with dementia; SCQ = Sense of Competence Questionnaire; CES-D = Center for Epidemiologic Studies – Depression Scale; NPI-Q = Neuropsychiatric Problems Inventory Questionnaire

Statistical analyses

Baseline differences between CMH professionals adhering to the SCPD intervention protocol, nonadhering CMH professionals, and controls were described and tested with the Pearson's χ^2 test or the Fisher's exact test in case 20% or more of the cells had expected values less than 5, and one-way analysis of variance for nominal and numerical variables at $p \leq 0.05$, respectively. The same analyses were used to compare dyads that dropped out with dyads that completed the follow-up. If the result of an analysis of variance was significant at $p \leq 0.05$, we used the least significant difference (LSD) test²⁸ in post-hoc analysis to get specific information about which groups differed significantly.

Since person with dementia-caregiver dyads were nested within the CMH professionals' groups, we performed multivariate regression in multilevel linear regression models to evaluate the influence of adherence to the SCPD intervention protocol on the sense of competence, caregiver depressive symptoms, caregiver distress due to problem

behavior of the person with dementia, and the severity of behavioral problems of the person with dementia. Variables that could confound the influence of adherence on clinical outcomes were included in the multivariate regression analyses as control variables.

Person with dementia-caregiver control variables that we presumed clinically relevant included baseline values for sense of competence, caregiver's depressive symptoms, distress due to behavioral problems of the person with dementia, the severity of these behavioral problems, caregiver gender and age, living arrangements (i.e., sharing the same household), and the severity of dementia, as defined by the Diagnostic and Statistical Manual of Mental Disorders, 3rd Text Revision.²⁹ The CMH professional-related control variables included gender, the CMH service (six locations), and work-related job satisfaction as assessed with a single item asking professionals, "How satisfying is your work overall", on a scale of 0 to 4 ("not at all" to "extremely") as derived from the Consultants Mental Health Questionnaire.^{30;31}

Including all the control variables in multivariate analyses would risk overfitting because of the large number of variables compared with the size of the data set: 25 variables in a data set of at most 125 participants, while the number recommended is at least 10 participants per variable.³² Therefore, we adopted the following selection and modeling strategy, and applied it separately for each clinical outcome:

5

Step 1. We used multivariate regression analysis to investigate whether the location of the CMH service influenced the outcome when the effects of adherence, intensity, and all patient–caregiver variables had already been accounted for. To this end, we compared a model with all of these variables including the CMH service (full model) with a reduced model without the CMH service. If the goodness of fit of this reduced model was significantly worse than that of the full model, the location of the CMH service had significant influence and we included it in step 4.

Step 2. We used the step 1 method to investigate whether the CMH professionals' gender, job satisfaction, and location of CMH service influenced the outcome when the effect of adherence and intensity had already been accounted for. If one or more of these CMH professional-related control variables had significant influence, we included them in step 4.

Step 3. First, we built a full model containing adherence, intensity, and all person with dementia-caregiver variables to adjust for the influence of adherence and intensity on the outcomes for all clinically relevant control variables. Next, we reduced this model to the smallest possible model with a goodness of fit that was not statistically different from that of the full model (i.e., $p > 0.05$), while retaining adherence and the baseline of the clinical outcome in the model.

Step 4. If step 1 or 2 showed that the location of the CMH service, CMH professionals' gender, or job satisfaction influenced the outcome, these factors were entered into the smallest model if the fit significantly improved.

We used the maximum likelihood method³³ to fit the full model and reduced models. In steps 1-3, we used the likelihood ratio test to compare the goodness of fit of the full model and a reduced model, as determined by the $-2 \log$ likelihood. In step 4, we used the Aikake information criterion³⁴ to determine whether the fit of the smallest model improved. After this final step, we refitted the ultimate model with the restricted maximum likelihood method³³ to obtain adjusted estimates and better standard errors of the regression coefficients.

Multilevel model assumptions, that is, normally distributed residuals and no correlation between residuals and predicted outcome, were checked in the full model and in the ultimate model. If these assumptions were violated, we used a log transformation of the outcome variable and/or the predictors and control variables to satisfy the model assumptions.³³ Outliers were only removed if they corresponded to errors in the data set. We used mean substitution for missing values unless at least two-thirds of the other items of the particular scale was completed. Missing data were deleted listwise. We used the software package SPSS 17.0 (SPSS, Chicago, IL) for all statistical analyses.

Results

Community mental health professionals' adherence to the SCPD intervention protocol

Sixty-three percent of the intervention group CMH professionals, treating 107 person with dementia-caregiver dyads, adhered to the intervention protocol (Figure 1). During the study period, 18 CMH professionals were excluded from the analysis because dyads

assigned to them were lost to follow-up (Figure 1). In total, 48 CMH professionals, treating 125 dyads, were included in the study evaluating the effectiveness of person with dementia and caregiver conditions (Figure 1). Of these CMH professionals, 15 adhered to the intervention protocol while treating their 46 dyads, 10 CMH professionals did not adhere to it while treating their 19 dyads, and the remaining 23 CMH professionals provided 60 dyads with usual care.

Baseline comparability

The baseline sociodemographics of the caregivers and people with dementia were well matched in the groups of caregivers and people with dementia treated by CMH professionals adhering and not adhering to the SCPD intervention protocol and the control group, with the exception of the severity of dementia. There were significantly more people with moderate or severe dementia in both intervention groups, as opposed to significantly more people whose dementia was not otherwise specified in the control group (Fisher's exact test, $p=0.00004$; Table 2).

Overall, there were significant differences in clinical outcomes between the groups at baseline for caregiver depressive symptoms ($F[2, 121] = 3.27, p=0.04$), distress due to the behavioral problems of the person with dementia ($F[2, 122] = 3.91, p=0.02$), and the severity of behavioral problems of the person with dementia ($F[2,122] = 3.33, p=0.04$; Table 2). Post-hoc analysis revealed that caregivers treated by CMH professionals not adhering to the SCPD intervention protocol had significantly more depressive symptoms than caregivers in the control group (LSD: mean difference = 5.97, $t=2.64$, $df=76$, $p=0.01$). The caregivers' distress caused by behavioral problems of people with dementia who were treated by nonadhering CMH professionals was significantly greater than that of caregivers treated by adhering CMH professionals (LSD: mean difference = 6.20, $t=2.83$, $df=63$, $p=0.01$). Furthermore, the behavioral problems of people treated by nonadhering CMH professionals and behavioral problems of people with dementia in the control group were significantly more severe than the behavioral problems of people with dementia treated by adhering CMH professionals (LSD: mean difference for nonadherence versus adherence = 3.61 , $t=2.10$, $df=63$, $p=0.04$; mean difference for the control group versus adherence group = 2.76, $t=2.25$, $df=104$, $p=0.03$).

Table 2. Baseline comparison of participants in the intervention and control groups

	Adhering to the SCPD profs	n=46	Nonadhering to the SCPD profs	n=19	Usual care	n=60
Sociodemographics						
Mean (SD) age in years						
Caregivers	58.9 (13.0)	45	56.0 (13.2)		60.4 (13.4)	
People with dementia	77.1 (8.0)		80.8 (6.5)		79.1 (4.8)	
Number of women (%)						
Caregivers	33 (71.7)		15 (78.9)		43 (71.7)	
People with dementia	31 (67.4)		16 (84.2)		36 (60.0)	
Dutch ethnicity (%)						
Caregivers	46 (100.0)		18 (94.7)		58 (96.7)	
People with dementia	46 (100.0)		19 (100.0)		59 (98.3)	
Education (%)						
Number of caregivers						
Basic	12 (26.1)		5 (26.3)		14 (23.3)	
Intermediate	21 (45.7)		9 (47.4)		35 (58.3)	
Higher	11 (23.9)		5 (26.3)		11 (18.3)	
Other	2 (4.3)		0 (0.0)		0 (0.0)	
Number of people with dementia						
Basic	24 (52.2)		14 (73.7)		37 (61.7)	
Intermediate	13 (28.3)		2 (10.5)		15 (25.0)	
Higher	5 (10.9)		2 (10.5)		7 (11.7)	
Other	4 (8.7)		1 (5.3)		1 (1.7)	
Relationship of CG to PWD (%)						
Partner	18 (39.1)		4 (21.1)		21 (35.0)	
Child	19 (41.3)		11 (57.9)		34 (56.7)	
Other	9 (19.6)		4 (21.1)		5 (8.3)	
Living arrangements (%)						
(shared household)	18 (39.1)		6 (31.6)		21 (35.0)	
Severity of dementia (%)^a						
Mild	17 (39.5)	43	5 (35.7)	14	20 (33.9)	59
Moderate	19 (44.2)	43	7 (50.0)	14	15 (25.4)	59
Severe	6 (14.0)	43	2 (14.3)	14	2 (3.4)	59
NOS	1 (2.3)	43	0 (0.0)	14	22 (37.3)	59
Means (SD) on assessment scales						
Caregiver						
SCQ	96.4 (15.1)		88.4 (19.4)		96.4 (11.6)	59
CES-D ^b	11.1 (9.3)		15.7 (12.9)		9.8 (6.7)	59
NPI-Q (distress) ^c	9.0 (6.7)		15.2 (10.6)		11.9 (8.9)	
People with dementia						
NPI-Q (behavior problems) ^d	7.8 (6.1)		11.4 (6.7)		10.5 (6.3)	

Statistical tests and test statistic: Pearson's χ^2 : χ^2 statistic; Analysis of variance (ANOVA): F (dfM, dfR) = F ratio and the degrees of freedom to assess the F ratio, e.g., the degrees of freedom for the effect of the model and the degrees of freedom for the residuals of the model. NOS: not otherwise specified; SCQ: Sense of Competence Questionnaire; CES-D: Center for Epidemiologic Studies-Depression Scale; NPI-Q: Neuropsychiatric Problems Inventory Questionnaire.

Statistically significant overall difference ($p \leq 0.05$) between people in the adherent, nonadherent, and usual care groups for: a: Severity of dementia: Fisher's exact, $p=0.00004$; b: Caregiver depressive symptoms: $F_{[2,121]} = 3.27$, $p=0.04$; c: Distress due to the behavioral problems of the person with dementia: $F_{[2,122]} = 3.91$, $p=0.02$; d: Severity of behavioral problems of the person with dementia: $F_{[2,122]} = 3.33$, $p=0.04$.

Intensity of the intervention

The 15 adhering CMH professionals offered each of their 46 dyads an average of 3.37 (SD: 2.79, range: 1–15) counseling sessions including the assessment procedure. Furthermore, they offered 65.2% of these dyads an average of 17.53 (SD: 11.57, range: 3–53) supportive interventions. The 10 nonadhering CMH professionals offered their 19 dyads an average of 1.05 (SD: 0.23, range: 1–2) counseling sessions.

Attrition

The main reasons for person with dementia–caregiver attrition were institutionalizations of the person with dementia, deaths, and refusal to participate in the study any longer (Figure 1). There were no statistically significant differences in the presumed clinically relevant sociodemographics between dyads that were lost to follow-up ($n=170$) and dyads included in the study ($n=125$). Concerning the clinical outcome measures, it revealed that dyads in the control group and those lost to follow-up were generally in worse condition at baseline (lower caregiver sense of competence, more caregiver depressive symptoms, more distress due to behavioral problems of the person with dementia, and more severe behavioral problems of the person with dementia) as compared with dyads included in the study. There were no significant differences between dyads treated by nonadhering CMH professionals. The baseline conditions of dyads treated by adhering CMH professionals and lost to follow-up were worse regarding caregiver distress due to the behavioral problems and severity of behavioral problems of people with dementia as compared with dyads included in the study.

The difference in the number of counseling sessions offered to dyads in the intervention groups and lost to follow-up versus the dyads that completed the follow-up measurements was clinically insignificant. Dyads treated by adhering CMH professionals and lost to follow-up ($n=61$) received on average 0.48 fewer consultations (mean: 2.89, SD: 3.11, range: 1–16) than dyads that completed the follow-up measurements (mean: 3.37, SD: 2.79, range: 1–15), including the assessment. Dyads treated by nonadhering CMH professionals and lost to follow-up ($n = 29$) received on average 0.02 fewer consultations (mean: 1.03, SD: 0.19, range: 1–2) than dyads that completed the follow-up measurements (mean: 1.05, SD: 0.23, range: 1–2).

Influence of adherence to the SCPD intervention protocol

The mean score for the sense of competence of caregivers assigned to adhering CMH professionals was statistically significantly higher than that of caregivers assigned to nonadhering CMH professionals at follow-up ($b=6.48$, 95% confidence interval 0.001-12.95, $t = 2.01$, $df = 47.81$, $p=0.05$; Tables 3 and 4). No statistically significant differences were found between dyads assigned to adhering CMH professionals versus nonadhering CMH professionals versus controls in caregiver depressive symptoms, caregiver distress due to the behavioral problems and the severity of behavioral problems of the person with dementia.

Table 3. Group means for patient and caregiver outcomes at 12 months follow-up

Outcomes	Unadjusted observed mean (SD)					
	Adhered to the SCPD	n	Not adhered to the SCPD	n	Usual care	n
Sense of competence	96.75 (11.05)	45	86.83 (17.42)	18	95.05 (12.39)	59
Caregiver depressive symptoms	9.5 (9.00)	45	14.78 (12.55)	18	9.80 (7.52)	59
Distress due to the patient's behavioral problems	11.02 (8.43)	44	15.59 (11.02)	17	13.83 (9.74)	58
Severity behavioral problems	9.16 (6.24)	44	11.76 (6.89)	17	10.72 (7.00)	58

Table 4. The influence of adherence on caregiver and patient outcomes at the 12-month follow-up, adjusted for the intensity of the intervention and control variables

	Adherence versus nonadherence to the SCPD					Adherence to the SCPD versus usual care					Nonadherence to the SCPD versus usual care				
	b	95% CI	t	df	p	b	95% CI	t	df	p	b	95% CI	t	df	p
Sense of competence	6.48	0.001 - 12.95	2.01	47.81	0.05	0.84	-3.71 to 5.38	0.37	37.48	0.71	-5.64	-12.04 to 0.76	-1.77	49.93	0.09
Caregiver depressive symptoms	-3.17	-7.24 to 0.90	-1.54	108	0.13	-0.88	-3.49 to 1.74	-0.67	108	0.51	2.29	-1.64 to 6.22	1.16	108	0.25
Distress due to patient's behavioral problems	-4.81	-10.05 to 0.44	-1.82	102	0.08	-2.24	-6.00 to 1.51	-1.18	102	0.24	2.56	-2.01 to 7.14	1.11	102	0.27
Severity of behavioral problems	-1.26	-4.62 to 2.10	-0.75	105	0.46	0.23	-1.96 to 2.43	0.21	105	0.83	1.50	-1.72 to 4.72	0.92	105	0.36

b = regression coefficient representing the change in the outcome resulting from a unit change in the predictor. A regression coefficient of 0 means: (1) a unit change in the predictor variable results in no change in the predicted values of the outcome (the predicted value of the outcome does not change at all); and (2) the gradient of the regression line is 0, which means that the regression line is flat; 95% CI = 95% confidence interval for b. If b is positive, then the relationship of this variable with the dependent variable is positive. If b is negative, then the relationship is negative; t = it tests the null hypothesis that the value of b is 0. Therefore, if t is significant ($p \leq 0.05$), then b is significantly different from 0, meaning that the predictor variable contributes significantly to the values of the outcome; p = the probability that the null hypothesis is true. The lower the p value, the less likely the null hypothesis is true, and consequently the more significant the result is. $p \leq 0.05$ is considered statistically significant.

We tested the influence of the intensity and the person with dementia-caregiver and professional control variables on clinical outcomes. With the exception of caregiver distress due to the behavioral problems of the person with dementia, the ultimate models did not contain the intensity of the interventions (i.e., the number of counseling sessions and the number of actions) and CMH professional-related control variables (i.e., professionals' gender and job satisfaction, and the CMH service), which means that these variables had not statistically influenced the clinical outcomes.

Discussion

Not much attention is usually given to an obvious reason why support programs are not effective: health professionals' adherence to the intervention protocol. Studying adherence to the SCPD intervention protocol revealed that, at follow-up, caregivers treated by adhering CMH professionals had a better sense of competence than caregivers treated by nonadhering CMH professionals. No differences were found between dyads assigned to adhering CMH professionals versus nonadhering CMH professionals versus controls in caregiver depressive symptoms, caregiver distress due to the behavioral problems and the severity of behavioral problems of the person with dementia.

These results show that CMH professionals' nonadherence to the SCPD intervention protocol might be one of the reasons why our study did not find a main effect in caregiver and patient outcomes. There might be other reasons. Compared with the literature^{15;35} and with two previous successful interventions,^{12–14} the intensity of the SCPD interventions was low. One reason for this was that the intensity was not standardized beforehand, and it depended on the CMH professionals' judgment, the optimization the flexibility of the SCPD to individual caregiver needs, and the acknowledgement of the CMH professionals' expertise.

The intensity proved to be an important element that distinguishes effective programs from ineffective ones.^{15;35;36} The number of sessions in the successful interventions was much higher: 4 hours of weekly meetings in 10 months¹² and 10 sessions of occupational therapy over 5 weeks^{13;14} versus 3.37 (SD: 2.79, range: 1–15) counseling sessions including the assessment procedure over 12 months. With the exception of caregiver distress due to the behavioral problems of the person with dementia, the intensity of the interventions had not influenced the outcomes, although we cannot

rule out that the level of intensity might have been too low for all dyads. Another reason might be that caregivers treated by nonadhering CMH professionals were depressed, struggling caregivers who found it difficult to make effective use of the help that was offered to them.

Our study has some limitations. The study sample consisted of a selective subgroup of person with dementia-caregiver dyads ($n=125$) and CMH professionals due to attrition (Figure 1). We did consider an intention to treat analysis ($n=295$) by imputation of missing outcomes at follow-up by multiple imputation.³⁷ In this situation, multiple imputation requires a regression model that estimates missing outcomes at follow-up from the available sociodemographics and outcomes at baseline. Dyads with missing follow-up outcomes were comparable in the presumed clinically relevant sociodemographics, but were generally in worse condition concerning the clinical outcomes at baseline, as compared with dyads that had completed the follow-up measurements. To reliably estimate the follow-up outcomes for dyads in such a "worse" condition requires that sufficiently similar dyads in such a "worse" condition with follow-up measurements were available. However, this was not the case. In the absence of a reasonable regression model to impute data, no imputation was performed and this has probably affected the results but it is unclear how much. Furthermore, we could not consider all control variables simultaneously because of the reduced sample size. We dealt with this problem by a stepwise model-building approach.

Theoretically, the possibility of contamination due to a transfer of dyads and knowledge exchange between CMH professionals in the intervention and control groups could have taken place. We checked whether the CMH professionals in the intervention group discussed the intervention with CMH professionals in the control group, and, given their answers, we conclude that they did not.

Our results provide possible reasons for not finding main effects of the SCPD. Nonadherence to the SCPD intervention protocol might be a reason for the difference found in the sense of competence between caregivers treated by adhering CMH professionals versus nonadhering CMH professionals. Furthermore, literature reviews suggest that high intensity interventions are needed to reach changes in the person with dementia and caregiver condition.^{15;35;36} Our intervention had a low intensity

which might have been too low. Another reason might be that depressed, struggling caregivers found it difficult to make effective use of the help that was offered to them. However, none of these reasons can totally explain the found results. Therefore, a qualitative process analysis exploring CMH professionals' barriers and facilitators using the SCPD for timely and systematic assessment of possible caregiver problems in caring for people with dementia in the CMHcare setting should be executed.

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Chapter 6

Adherence to a psychosocial intervention protocol: the hassles of ever-changing practice in community mental health services

Anouk Spijker

Emmelyne Vasse

Eddy Adang

Frans Verhey

Hub Wollersheim

Myrra Vernooij-Dassen

Submitted.



Abstract

Objectives: No significant effects of the Systematic Care Program for Dementia (SCPD) to support informal caregivers in community mental health (CMH) care have been found. However, the use of the program might be the very problem. Because we found that CMH professionals' adherence to the SCPD intervention protocol was limited, the aim of this study was to explore barriers and facilitators affecting adherence to the SCPD intervention protocol at six healthcare levels.

Methods: Qualitative thematic framework analysis at six healthcare levels, the SCPD innovation, CMH professionals using the SCPD, caregivers treated with the SCPD, the social context, the organizational context, and the economic and political context in which the SCPD innovation was embedded. Eleven purposely selected CMH professionals participated in semi-structured interviews in six CMH services in the Netherlands.

Results: Barriers and facilitators appeared at nearly all healthcare levels. The key themes that facilitated adhering to the SCPD intervention protocol when present and hindered adherence when absent were: appreciation of the intervention and training in the SCPD, involvement in deciding to participate in the SCPD study, and leadership and clerical assistance. Other themes affecting adherence to the SCPD intervention protocol were heavy workload, time constraints, high staff turnover, and policy changes like the introduction of the electronic patient record.

Conclusion: The results of the interviews opened the black box of the use and non-use of the SCDP. Overall, the competing challenges in the CMH services were a major barrier. Only strong motivation within all levels of the organization might overcome this barrier.

Introduction

The caring role provides satisfaction to many informal caregivers of people with dementia, but is stressful and burdensome to most of them. This can compromise their physical and mental health.¹ Usual community mental health (CMH) care offers many opportunities to prevent these problems in informal caregivers, but they remain unused because of the late detection of caregiver problems.² Therefore, the Systematic Care Program for Dementia (SCPD) has been developed. Training CMH professionals in the SCPD potentially helps CMH professionals to screen and treat caregiver problems systematically when people with dementia and their caregivers first enter the CMH service.

The SCPD is theoretically based on the Family Support Model,³ which suggests ways health professionals can reduce the families vulnerability and to increase the competency of families of older persons confronted with hazardous events or problems that they experience as threatening. The positive effects on caregivers and on institutionalisation of people with dementia in two previous studies using this model⁴⁻⁹ prompted us to this same model.

The Family Support Program⁴⁻⁶ was transformed into the SCPD² by making a concise version of the originally time consuming intervention program. The program fulfills the urgent need for effective and cost-effective support programs that can prevent overburdening the caregiver and may delay or decrease institutionalization of the person with dementia. Neither the proactive elements nor the systematic elements of the SCPD approach are routinely used in the management of dementia in the CMH care setting.

The results of our study regarding the effects of the SCPD on institutionalization¹⁰ and on relevant clinical outcomes for the caregiver and person with dementia¹¹ in CMH services did however not correlate with the positive results of the Family Support Program previously introduced in home care.^{4;6} This evoked new questions and required better insight into factors that might clarify our results.

Our process evaluation may throw light on the mechanisms behind the results obtained in the SCPD intervention group. It describes the intervention in detail, making it possible to check the actual exposure to the intervention. Process evaluation also

describes the experience of those exposed.^{12;13} In a previous paper, we described how CMH professionals' treatment variability in adhering to the SCPD intervention protocol might have negatively influenced the outcomes.¹¹ The aim of this current study was to describe the CMH professionals' experience with the SCPD intervention. We explore the barriers to and facilitators for adherence to the SCPD intervention protocol. This protocol aims at the timely and systematic assessment of possible caregiver problems in caring for people with dementia in CMH services. The results might help improve future interventions and reduce hassles.

Methods

The process evaluation was conducted alongside the effect study of the SCDP. We present the content of the SCDP intervention, the intervention training and protocol, the interview guide, the recruitment protocol and sampling, and data collection and analysis.

The Systematic Care Program for Dementia

The SCPD is based on the effective, but quite intensive, Family Support Program^{4;14} and is adapted for introduction into the CMH services.² Basically, the SCPD consists of training CMH professionals in the systematic assessment and interpretation of the caregiver's sense of competence¹⁵ and caregiver's depressive symptoms¹⁶ and in strategies to deal with deficiencies in competence. The SCPD, described in detail elsewhere,² can be divided into 3 stages:

1. *Screening.* Community mental health professionals screen the caregiver's sense of competence and caregiver's depressive symptoms with the SCPD screening tool (inventory and interpretation) as presented in Table 1.
2. *Psychosocial support.* The assessment of caregiver problems alerts CMH professionals to flexibly connect pro-active interventions to them. The SCPD offers three possible intervention strategies to initiate support:
 - a. Define acceptable goals of involvement. Organize additional professional support.
 - b. Open a dialogue about what the caregiver thinks she or he has to do and what she or he actually can do.
 - c. Clarify the relationship between the behavior of the person with dementia and the dementia syndrome.

Table 1. Screening tool for the Systematic Care Program for Dementia**Screening for a sense of competence**

1. CONSEQUENCES OF INVOLVEMENT IN CARE FOR THE PERSONAL LIFE OF THE CAREGIVER
 - a. Do you feel that the present situation with your ... does not allow you as much privacy as you would like?
 - b. Do you feel stressed by trying to do enough for your ... as well for other family responsibilities, job, etc.?
2. SATISFACTION WITH YOUR OWN PERFORMANCE AS A CAREGIVER
 - a. Do you wish that you and your ... had a better relationship?
 - b. Do you feel strained in your interaction with your ...?
3. SATISFACTION WITH THE PERSON WITH DEMENTIA AS A RECIPIENT OF CARE
 - a. Do you feel that your ... tries to manipulate you?
 - b. Do you feel that your ... behaves the way s/he does to annoy you?
 - c. Do you feel that your ... behaves the way s/he does to have her/his own way?

Support strategies

1. Define acceptable goals of involvement. Organize additional professional support.
2. Open a dialogue regarding expectations, resources, conflicts, stigmas and feelings of guilt. Dialogue about what the caregiver thinks s/he has to do and what s/he actually can do.
3. Clarify the relationship between the behaviour of the person with dementia and the dementia syndrome.

Screening for depression

1. During the past month have you often been bothered by feeling down, depressed, or hopeless?
2. During the past month have you often been bothered by little interest or pleasure in doing things?

Caregiver's management strategy

- *Nonadapters*: lack of understanding or acceptance of the situation; approaching the person with dementia with impatience, irritation, or anger.
- *Nurturers*: care and protection; parent-child approach in which the person with dementia is taken by the hand and is no longer regarded as an equal.
- *Supporters*: adapting to the level of functioning of the person with dementia and encouraging him/her in existing abilities.

Severity of dementia

Mild: the person can live independently for the most part, with adequate personal hygiene and relatively intact judgement, but social activities and employment are both significantly impaired.

Moderate: formal employment is no longer possible and independent living is fraught with hazard to the extent that limited supervision is required.

Severe: there is severe impairment of daily activities (like minimal personal hygiene), and continual supervision is needed. The patient is entirely dependent on the caregiver for survival. Recognizing familiar and unfamiliar people in the environment is often no longer possible.

An action list was developed in collaboration with a staff member and a CMH professional from participating CMH services. This list contains 60 possible intervening and supportive actions that CMH professionals might undertake as a result of the screening. This list includes 60 possible supportive actions that professionals might undertake, and it is divided into nine categories: intake, diagnostics, psychoeducation, psychosocial care, medical care, hand-over care, legal care, case management, and crisis management.

3. *Transfer to regular health care.* Along with psychosocial support, CMH professionals could organize medical, home, or respite care.

Intervention training and protocol

The training to teach CMH professionals to use the SCPD consists of three sessions of 2 hours each. One meeting is for explaining the program, and two meetings are for practicing, the evaluation of the use of the program, and for preparing suggestions on how to hand over the responsibility for care after the CMH service's work is completed. Table 2 summarizes the objectives and methods used in the three training sessions.

The training in the SCPD should guide CMH professionals through the three stages of the SCPD intervention starting with their first consultation with a dyad entering the CMH service. Community mental health professionals adhered to the SCPD intervention protocol if they had participated in the three training sessions in the SCPD and had the researchers provided data on all items from her/his screening of the caregiver's sense of competence and caregiver's depressive symptoms for at least half of his/her treated caregiver-person with dementia dyads. Table 3 summarizes what was expected from CMH professionals adhering to the SCPD intervention protocol as planned.

The intensity of the support and the intervention usage were left to the discretion of the CMH professionals. This optimized the flexibility of the SCPD for individual caregiver needs to prevent overburdening caregivers who had not requested treatment for their own problems.

Table 2. Objectives and training methods of the Systematic Care Program for Dementia***First training session****Objective: the professional can assess the caregiver's sense of competence*

Method

- Background and objective of the SCPD
- Sharing experiences of obstacles in care for caregivers
- Instruction about how to apply the SCPD
- Role-playing to assess the sense of competence
- Further reading and the SCPD manual
- Preparing the next training session and casuistic practical experience
- Evaluation

Second training session*Objective: professional can recognize deficiencies in the caregiver's sense of competence and names solutions for best practices*

Method

- Sharing experiences of applying the SCPD
- Sharing experiences of using the SCPD screening tool
- Organizational obstacles, e.g. those involving caregivers at the first consultation
- Role-playing best practices and finding solutions for deficiencies in competence
- Discussing what is needed for using the SCPD in practice
- Evaluation

Evaluation session*Objective: the professional can assess and suggest solutions for deficiencies in the caregiver's sense of competence*

Method

- Sharing experiences of applying the SCPD
- Finding solutions for logistic, organizational, and emotional obstacles
- Sharing experiences of the tailor-made SCPD screening tool
- Discussing what is needed to use the SCPD in practice
- Evaluation

SPCD, Systematic care program for dementia

The interview guide

The semi-structured interview guide was based on the theoretical, thematic framework of affecting change in clinical practice¹⁷ and was tailored to the SCPD. This framework included barriers and facilitators that could be met at six levels of healthcare: the SCPD innovation, CMH professionals using the SCPD, caregivers treated with the SCPD, the social context, the organizational context, and the economic and political context in which the SCPD innovation was embedded.

Table 3. The Systematic Care Program for Dementia: intervention and recruitment protocols

The intervention protocol	The recruitment protocol
<p>CMH professionals should participate in the three training sessions for the use of the SCPD with adherence to the intervention protocol. Then the CMH professionals should record the following data during the three stages of the intervention:</p> <ol style="list-style-type: none"> 1. Screening. Record your results of the assessment of the caregiver's sense of competence, depressive symptoms, and type, and the severity of dementia of the patient on the assessment form. 2. Psychosocial support. Record intervening and supportive actions on the action list, as indicated by the screening. 3. Transfer to regular healthcare. After ending your contacts with the dyad, you should hand the care over to the regular healthcare or home. Record the organization and management of care if the case is transferred to other institutions or health professionals on the action list. 	<p>Main CMH service activities of the SCPD recruitment protocol to facilitate CMH professionals' adherence to the intervention protocol:</p> <ol style="list-style-type: none"> 1. Recruit and enroll eligible dyads, each consisting of a caregiver and a person with suspected dementia. 2. Send aids to dyads who gave verbal consent to obtain written consent and the questionnaire with baseline measurements. 3. Assign dyads to CMH professionals randomized to the SCPD intervention or the usual care group. 4. Send data feedback about recruited, enrolled, and assigned dyads to the researchers. 5. Label medical records of dyads assigned to the CMH professionals randomized to the SCPD intervention group. 6. Include an assessment form and five action lists in medical records of dyads assigned to the CMH professionals randomized to the SCPD intervention group. 7. Collect the completed forms and action lists after dyads have been transferred to regular healthcare. 8. Hand over the collected forms and action lists to the researchers every 6 weeks.

SPCD, Systematic care program for dementia, CMH, community mental health

The preliminary version of the SCPD-adapted interview guide was first used in the evaluation sessions of the training of CMH professionals in the SCPD. After we analyzed these evaluations, we made adjustments and new questions came up, resulting in the final interview guide as presented in Table 4. A pilot interview with a CMH professional who adhered to the SCPD intervention protocol showed that no additional adjustments were necessary.

Table 4. Interview guide for the systematic care program for dementia

Level	Barriers and facilitators
Innovation	What were your expectations of the SCPD? To what extent did they come true? How well does the SCPD fit in with your usual working method for treating patients with dementia and their caregivers? To what extent might the SCPD be relevant to your clinical practice? And to the caregiver? What are the advantages and disadvantages of the SCPD assessment tool? What bottlenecks have you encountered while using the SCPD? How did you solve the problems? How could the SCPD be improved for implementation?
Health professional	To what extent did the training relate to your knowledge and skills? How relevant was the training to using the SCPD in daily clinical practice? And the evaluation session? To what extent do you think you have gained enough knowledge and skills to use the SCPD confidently in practice? To what extent did you manage to assess the sense of competence during the intake procedure? And the depressive symptoms? How well did you manage to keep track of the assessment forms and action lists during and after each contact with the dyad? What are the most important changes in using the SCPD compared to your usual practice? What motivated you to take part in the SCPD?
Social context	What kind of communication about the SCPD took place on the work floor? What topics did you discuss with your colleagues? To what extent did you feel that the management and team leader helped you use the SCPD in daily clinical practice? What doubts did you have while participating in the SCPD study? To what extent did you have a voice about participation?
Organizational context	How did the logistic organization around the execution of the SCPD appear to you? To what extent did the secretarial staff assist you? Please describe the workload within your organization during the study period. And now? How burdensome was the SCPD as an addition to your regular duties? Did you receive compensation for SCPD-related duties? How did your use of the SCPD relate to the treatment effects of the program?
Economic and political context	To what extent did the implementation of the electronic patient record and the diagnosis-treatment combination influence the use of the SCPD in daily clinical practice?

SCPD, Systematic care program for dementia

The Systematic Care Program for Dementia recruitment protocol and sampling

To facilitate CMH professionals' adherence to the SCPD intervention protocol a team leader from the circuit elderly, the secretariat, and an in the SCPD study involved CMH professional from each CMH service collaborated in developing a tailor-made recruitment protocol. The SCPD recruitment protocol was adapted to the specific procedures and working routines of each CMH service. It consisted of the logistic steps the CMH service needed, starting with the referral of a person with suspected dementia to the CMH service and continuing until the person was transferred to regular healthcare. The main activities of the CMH service stated in the SCPD recruitment

protocol to help CMH professionals adhere to the SCPD intervention protocol are summarized in Table 3.

At each logistic step of the SCPD recruitment protocol, the name of the responsible member of the CMH service was recorded. The researchers instructed and trained the secretariat and other CMH professionals responsible for the recruitment, enrollment of dyads, and equipping administration. Furthermore, the researchers were available for questions any time during the week.

We used purposive sampling¹⁸ to recruit CMH professionals randomly assigned to the intervention group of the SCPD study on the basis of two criteria: heterogeneity in the regions of the participating CMH services and heterogeneity in adherence to the SCPD intervention protocol. Adhering CMH professionals had participated in the three training sessions for the SCPD. They had provided data about all items from their assessments of the caregiver sense of competence¹⁵ and the caregiver depressive symptoms¹⁶ for at least half of their treated dyads.

Data collection and analysis

Three university master's students, who were trained in interview techniques, conducted all the semi-structured interviews, which lasted \pm 1.5 h each. The interviews were audiotaped and transcribed verbatim. Saturation, indicated by no new upcoming barriers and facilitators, was reached after ten interviews.

The transcripts were imported into Atlas-ti 6.1 (The ATLAS-ti Center, Berlin, Germany). We analyzed the data according the principles of the framework approach, a matrix-based method developed for policy research but increasingly used in applied health services research.^{19;20} This approach best suits our study because we started with predetermined aims and objectives, then we departed from the theoretical framework¹⁹ that effected changes in the clinical practice at different healthcare levels.¹⁷ Moreover, the framework approach is transparent about the analytical process that we needs. It involves a structured process of sifting, charting and sorting the transcribed data according to key themes²⁰ that hindered or facilitated adherence to the SCPD intervention protocol at the different levels of healthcare. Therefore, people other than the primary analyst can view and assess the analysis.¹⁹

Validity and reliability of the analysis

To provide a reliable analysis of the data and to improve the internal consistency of the analysis, two researchers (AS and EV) independently assigned the coded themes within the tentative framework and independently checked the thematic frame with indexed and charted data for 25% of the transcripts. To ensure that the interpretations were valid and contextualized in CMH professionals' broader accounts, the researchers moved back and forth between the full interview transcripts and the resulting thematic framework at six healthcare levels. Discrepancies between the original researcher's (AS's) analysis and that of the other researcher (EV) were resolved by discussion.

Ethical considerations

The Committee on Research Involving Human Subjects, Arnhem-Nijmegen Region, approved the study. Prior to each interview, the interviewer explained the study again, and gave CMH professionals the opportunity to ask questions. Written informed consent was obtained from participating CMH professionals before the interview.

Results

Participants

The researcher initially invited 18 CMH professionals from six CMH services by mail to participate in the interviews. The participating CMH professionals were rewarded with a book token in advance. Eleven CMH professionals from six CMH services were willing to participate; 8 of these CMH professionals had adhered to the SCPD intervention protocol and 3 had not. Those who did, of whom 5 were women, had 16.6 ± 7.54 years (range 6–29 years) of experience working with people with dementia and their caregivers. The nonadhering CMH professionals were all women and had averagely 21.1 ± 11.93 years (range 12–35 years) of experience working with people with dementia and their caregivers. The reasons that some initially invited CMH professionals did not participate were resignation, sickness/pregnancy leave, or inability to fulfill our request. This caused the unequal distribution of adhering and nonadhering CMH professionals willing to participate in the interviews.

Barriers and facilitators adhering to the SCPD intervention protocol

We ranked the emerged themes of our analysis by the healthcare levels given in the framework, starting with identified barriers and followed by identified facilitators as

summarized in Table 5. The results of our analysis are illustrated by quotations from the interviewed CMH professionals.

Table 5. CMH professionals' perceived barriers and facilitators at different healthcare levels

Level	Barriers	Facilitators
Innovation	The perceived non-innovativeness of the SCPD. Caregiver history-taking during the first contact between the person with dementia–caregiver dyad and the CMH professional. Assessment questions perceived as inadequate for an unequivocal clinical diagnosis.	Content of the SCPD and the intervention activities fitted into usual care practice. The systematic approach of the innovation. The adequate SCPD screening tool.
Health professional	Number of training sessions. Defensive attitude towards the SCPD. No intrinsic motivation to change habitual routines. Time investment. Administrative burden.	The perceived instructive training motivating a change of habitual routines. Adoption of time managing strategies to change habitual routines to promote adherence to the intervention protocol of the SCPD.
Social context	No perceived involvement in the decision to participate in the study. Inadequate local leadership facilitating and supervising the use of the SCPD in clinical practice.	The perceived involvement in the decision to participate in the study. Adequate local leadership facilitating and supervising the use of the SCPD in clinical practice.
Organizational context	Structurally high workload and clerical burden. No help from secretarial staff for the clerical and logistic organization. the logistic organization. A large turnover of staff. Non-adherence to the SCPD recruitment protocol.	A motivated and well-manned secretariat. Short communication lines with the researchers.
Economic and political context	The introduction of the electronic patient record and the diagnosis–treatment combination.	None.

SCPD, Systematic Care Program for Dementia

Innovation

A barrier regarding the innovation was the perceived non-innovativeness of the SCPD intervention. All CMH professionals said it did not require a working method other than their usual one. They already pay attention to the caregiver, take the caregiver's history and ask questions to determine whether the caregiver was overburdened and needed support.

CMH PROFESSIONAL6: Yes, the only difference was that you worked more according to the protocol because some questions were already fixed, but it was definitely not new.

Another barrier was the assessment of possible caregiver problems in the first contact. Some CMH professionals found it difficult to assess the caregiver's sense of competence and caregiver's depressive symptoms in their first contact with the caregiver-person with dementia dyad, because of the vulnerability in such a first contact. CMH professionals said this assessment might be too burdensome and might disrupt the trust relationship.

CMH PROFESSIONAL3: It (AS: history-taking) works in general, but some informal caregivers are less willing to allow it, and they are not ready at that time.... uh ...to allow it to be determined, and then it's more difficult to let them take part in the assessment.

Furthermore, some CMH professionals considered the assessment questions for the caregiver depressive symptoms, caregiver type, and dementia severity inadequate for an unequivocal clinical diagnosis. They hesitated to record their assessment results on the form because the assessment might be interpreted as an official, unequivocal, clinical diagnosis.

A facilitator regarding the innovation was CMH professionals experience that the intervention activities fitted in with usual care practice. All CMH professionals approved the design of the SCPD, which consisted of specific attention for possible caregiver problems in a systematic and structured approach. They said the SCPD made them more aware of giving systematic attention to caregivers of people with dementia.

CMH PROFESSIONAL9: I don't think there's so much wrong with the program, no. It's well coordinated. Yes, especially if you don't have much of the overall picture, I think it gives you a complete snapshot of what you can provide and how you can design the care for the informal caregiver.

These CMH professionals judged the screening tool as adequate for screening possible caregiver problems, easy to work with, and a good reminder to keep the intake

procedure systematic. The screening questions for caregiver depressive symptoms were particularly appreciated.

CMH PROFESSIONAL8: Just ask a little bit more about it. For example, feeling blue, that you give it a little more attention.

Community mental health professional

A barrier at the CMH professional level was that some CMH professionals disliked the number of training sessions, which could be reduced to one. Some did not like practicing the SCPD intervention in role play.

CMH PROFESSIONAL6: I thought the training meeting was OK. It was adequate for me. I thought the evaluation meeting was less relevant. It was more of the same. I didn't even do any more role-playing. I didn't think it useful, and it's as if you have to test the current competence all over again.

After the training, some CMH professionals did not change their defensive attitude towards the use of the SCPD in clinical practice. They said they had little motivation to participate. Some said they did not always adhere to the intervention protocol as a result of that. Another barrier was that all CMH professionals disliked the perceived extra time investment and administration. Most CMH professionals have a fixed amount of time for the intake procedure, in which many questions should be asked.

CMH PROFESSIONAL9: We have to do a lot of paper work already, and then another such list is added! That may sound silly, but it's the truth.

A facilitator was that most CMH professionals perceived the three training sessions as instructive. They said they gained enough knowledge and skills to execute the SCPD in practice. They appreciated the combination of the theoretical underpinning of the SCPD and practice with role-playing to execute the SCPD in daily clinical practice. Furthermore, most found the evaluation session very helpful because they and their colleagues could discuss solutions for barriers using the SCPD in practice.

CMH PROFESSIONAL7: Um, because it wasn't only theoretical, it was also practical. I mean, we really did practise. And yes, it showed that it can be done, I should be able to do it, and I can do it too.

After the training, most CMH professionals put aside their initial defensive attitude about the SCPD being nothing new, and started using it with a more open mind.

CMH PROFESSIONAL7: Now, there was a partial overlap. Indeed, the theory, but perhaps it had to do with the fact that I thought, hey, we do that already. But the training sessions were good to, well, to objectify it, to get it going.

Moreover, the perceived actuality and credibility of the SCPD was a facilitator that motivated CMH professionals to change their habitual routines. Some anticipated the extra attention for the caregiver and the notion that it is part of their job to support caregivers, their commitment to their job, or that it supports their personal learning process.

CMH PROFESSIONAL2: What I liked was the scientific foundation of some things. Why, then... and you can apply it with some people by dredging up the information. I mean, I don't spend so much time on scientific things, so for me it's... I'm very intuitive... it's really nice that I can provide it, so to speak. It complements what I have.

Another facilitator was that CMH professionals developed several strategies to deal with the felt time constraints. They changed their habitual routines for adhering to the SCPD intervention protocol by taking time at home visits or calling back later during the intake procedure, finding a chance to talk privately with a caregiver during the intake, or by gaining routine and discipline to act immediately.

CMH PROFESSIONAL8: Yes, you know, then one of my colleagues had to wait a bit, and when the colleague had finished, then they joined you in the kitchen, as if to say, I've finished. And then I said something like just 5 more minutes, or 10 more minutes, and then it was OK. So that seemed to fit in reasonably well. Or I phoned back afterwards, if I could find the time.

CMH PROFESSIONAL9: That (AS: taking caregiver history in the presence of the person with dementia) can be difficult. Informal caregivers sometimes simply don't want to say what they really think because they feel it's rather embarrassing. For example, if you have to do with daughters or so, even at the door and not in the presence of the person with dementia.

CMH PROFESSIONAL2: And once you had that first assessment form filled in, then there were action lists to fill in. It was not so difficult. Just needed a little handiness. In any case, I think I have quite a few people who participated. Yes.

Social context

A barrier regarding the social context was that CMH professionals felt they were not involved in deciding whether to participate in the SCPD study. Some felt that they could not refuse and that their involvement was forced, which strengthened a common shared resistance on the work floor.

CMH PROFESSIONAL5: All right, I think that it would help if you were to approach your personnel in a different way. Look, at a higher level, you can very pleasantly exchange thoughts with the management and the psychiatrist and the care home doctors who bear the final responsibility, but it has to be acceptable to all those on the work floor. I think it's important that you discuss it with your personnel and that you tell them they will be given time for it, and then don't worry about your production, because we will get production agreements. You have to produce as usual.

In case CMH professionals felt uninvolved in the study, an additional barrier was that there was no leadership from the management or the team leader to remedy it. Thus there was no one of the CMH service permanently reinforcing the study on the work floor, just some minor *ad hoc* attention in reaction to the external alerts of the researchers. This also meant that CMH professionals did not always assess caregiver problems and did not always record subsequent supportive interventions on the action list.

CMH PROFESSIONAL1: Now he (AS: the team leader) had been called to task with something like, 'Well boys, be sure that you do that'.

Shared decision-making about whether to participate in the SCPD study facilitated its use in daily clinical practice. A related facilitator was the presence of sufficient leadership regularly encouraging and reminding CMH professionals to fulfill their SCPD duties in CMH services that shared the decision to participate in the SCPD study.

CMH PROFESSIONAL10: The management, well. ... as the team leader and above him someone who, yes, that was indeed discussed. Whether time and people were made available, just as well as for this interview. And yes, you yourself could choose whether you wanted to invest time in it.

Organizational context

The bureaucratic product structure of the CMH services hindered the use of the SCPD in daily clinical practice. A barrier experienced by most CMH professionals were the continuously huge workload and administrative burden. There was a targeted output to keep the CMH service financially healthy. From this point of view, most CMH professionals and some team leaders did not endorse the management decision to participate in the SCPD study, and they were unmotivated to use the SCPD. The lack of adequate leadership in the CMH services aggravated the situation. A related barrier that aggravated this situation was the lack of time compensation for the secretaries, who were not excused from work that might interfere with the SCPD. CMH professionals in these CMH services reacted more vociferously to the question whether they received financial or time compensation for using the SCPD in daily clinical practice.

CMH PROFESSIONAL9: I know that if you, as a manager, decide to take part in a trial, then you must certainly also give the co-workers room to seriously participate, not just tag along, and that room was absolutely not there. The fact remains that asking all the questions systematically requires more time, and that time was absolutely not there.

Another barrier was that the CMH services dealt with mergers, acquisitions, relocations and a large staff turnover. Such organizational factors complicated the structural attention of the management or team leaders. It also caused discontinuation of the secretaries' attention to the SCPD study.

CMH PROFESSIONAL6: It is also true that, during the trial, there were many changes in the department for senior clients. A lot of personnel turnover, also caused by illness and death and suchlike. We have moved. I know for sure that that caused an administrative problem. And that is the way it was.

Furthermore, nonadherence to the SCPD recruitment protocol was another to the organizational context related barrier that hindered the continuity of the study and CMH professionals routine in using the SCPD. Nonadherence caused presumably eligible dyads to drop out. Potentially eligible dyads dropped out because the felt unease of the secretary or the CMH professional on duty to recruit or enroll dyads in the study because of suspected caregiver burden or caregiver age. Some dyads dropped out because they received interventions before the baseline measurements were complete, or they were not, or were belatedly, assigned to a CMH professional. Some dropped out because of crisis situations or immediate institutionalization of the person with dementia caused by long waiting lists due to capacity problems in long-term care. Thus, the time between the SCPD training and a chance for CMH professionals to practice their new skills in daily clinical practice was often too long. Moreover, the large turnover of CMH professionals during the study period complicated the adherence to the SCPD recruitment protocol and the continuity of the study. Other CMH professionals had to be recruited for allocation to either the intervention group or the control group to continue the study within the CMH service.

CMH PROFESSIONAL1: They were people you had to go to in a hurry. And then they couldn't have one of those assessment forms in advance.

CMH PROFESSIONAL5: Then family physicians referred people with a cognitive disorder to us. And when we got there, it turned out to be about a psychiatric patient. I have seen it happen that people died during the intake phase. I've had a number of drop-outs. And the result is that I have not seen so many people for whom I could apply this.

CMH PROFESSIONAL10: Not every client was suitable, not by a long shot. A lot of people dropped out. Because they already had contacts. And there was one drop-out who made me think: you can't do that to a caregiver. You knew that the caregiver would get an assessment form, and I can think of two situations where my opinion was: I just can't do that to her.

CMH PROFESSIONAL7: One bottleneck was that, during the trial, people changed jobs or new people appeared. Because then we had to ask somebody else for it. Start from the beginning all over again, because that person hadn't had the training and... yeah. The turnover of treatment staff on the work floor was a problem, absolutely.

A facilitator with regard to the organizational context was that CMH services that shared the decision-making for participation in the SCPD study had a stable and motivated secretariat because there was adequate supporting leadership that kept the secretaries free from other duties that might interfere with the logistics of the SCPD. The question whether they received any financial or time compensation for using the SCPD in daily clinical practice bothered CMH professionals in these CMH services less than those in other CMH services. In addition, adequate leadership and a stable secretariat facilitated the adherence to the SCPD recruitment protocol at the organizational level. There were sufficient recruitment and enrolment of dyads, and the logistic organization of the study was good. These factors contributed to the continuity of CMH professionals use of the SCPD in daily clinical practice.

CMH PROFESSIONAL7: We all had assessment forms and action lists in time, and when they were almost all gone, the secretarial office provided new ones; they were always replenished.

CMH PROFESSIONAL7: ...one secretary who had really sunk her teeth into the trial and knew everything about it. And the organization depended on her too, because, they said, whatever you need, you need.

Another facilitator was that CMH professionals appreciated the regular visits, the short and effective communication lines and the enthusiasm of the researchers, all of which motivated them to continue adhering to the SCPD recruitment protocol.

CMH PROFESSIONAL7: That was because of the enthusiasm of the people in Nijmegen, and um, yes, a mutual something like, well, you certainly got some results from that, and it was your idea too. OK, we have to keep on going, maybe we'll get there after all.

Economic and political context

One barrier was that government policy changes negatively affected the bureaucratic product structure of the CMH services at the time of the study. Such changes included the introduction of the electronic patient record and the 'diagnosis-treatment combination' (used as billing 'units'). For example, double recording of data frustrated their motivation to participate in the study. Furthermore, the waiting lists due to capacity problems in long-term care caused extra work and administrative burdens for CMH professionals.

CMH PROFESSIONAL8: Because you have to do so much already. We were in a hectic period, I think we had just merged here, uh, something like that. The implementation of the 'diagnosis-treatment combination'. Something that just breaks your neck, things like that.

Discussion

Barriers and facilitators in adhering to the SCPD intervention protocol for the timely and systematic assessment of possible caregiver problems in caring for people with dementia in CMHC appeared at nearly all healthcare levels. The same themes identified at different healthcare levels could be both barriers and facilitators. These were considered to be key themes and included appreciation of the SCPD intervention and training, involvement in the decision to participate in the study, leadership and clerical assistance. Overall, the competing challenges in the CMH services were a major barrier. Only strong motivation within all levels of the organization could possibly overcome this barrier.

A major barrier (which reflected the CMH professionals' lack of appreciation and motivation) was the claim that "we already do that", meaning that the caregiver already receives much attention, and the routine for dealing with caregiver problems is satisfactory. However, our previous study shows that CMH professionals in the intervention group helped only 39% of their caregiver-person with dementia dyads with one or more interventions.¹⁰ A major facilitator was that the intervention activities fitted in with the usual care practice of all the CMH professionals. Other CMH professionals liked the assessment tool and the training because it raised their awareness of caregiver depressive symptoms.

These results might reflect CMH professionals overestimation of CMH their own performance, or possible under-registration of help given might clarify this discrepancy in perception and performance.^{21;22}

Involvement in the decision to participate in the SCPD study and use of innovation,^{23;24} leadership style,²³⁻²⁸ and clerical assistance^{23;24;26;29} are crucial themes that facilitate or hinder behavioural change in implementation studies in CMH care. Leadership proved to be especially critical in situations with few external incentives for change.²⁸ Furthermore, to adhere to the SCPD innovation, CMH professionals had to face several structural organizational barriers. These barriers are well known in implementation

studies in CMH care: heavy workload,²³ time constraints²³ and high staff turnover.^{23;25-27}

Non-adherence to the SCPD recruitment protocol impeded the continuity of the study on many fronts. Recruitment problems or drop-out rates are hardly evaluated but come up in many intervention and implementation studies dealing with vulnerable participants^{30;31} or a lack of financial incentives.³⁰ The non-adherence to the SCPD recruitment protocol was one reason CMH professionals missed chances of developing SCPD routine in daily clinical practice. They hardly reached a mean number of four treated dyads annually.^{10;11} Four was the minimum number required for reasons of continuity and change in their usual daily routine.²

When we introduced our psychosocial intervention, we underestimated the influence of the economic and political context. The new electronic patient record and the diagnosis-treatment combination proved to be important barriers, causing high clerical burdens and pressure to produce to keep the CMH service financially healthy. Some CMH professionals argued that, during the study period, the CMH services paid more attention to implementing the diagnosis-treatment combination and the electronic patient record than to introducing the SCPD study. Some CMH professionals clearly stated, "It was too much at once".

The theoretical framework for barriers and facilitators at different healthcare levels¹⁷ proved feasible for developing our interview guide and analyses of the interview transcripts. We borrowed this framework from implementation science and found barriers and facilitators similar to those in implementation studies.^{17;32} With the addition of the theme 'adherence to the recruitment protocol' that emerged at the organizational level, the framework proved adequate for future evaluation of psychosocial interventions in CMH care.

The interviews showed that all CMH professionals had to cope with the same barriers and facilitators while adhering to the SCPD intervention protocol. They not only provide a convincing clarification for the nonadherence to the SCPD intervention protocol, but also a clarification why our study did not find a main effect of the SCPD on institutionalization¹⁰ and on relevant clinical outcomes for the caregiver and person

with dementia¹¹ in CMH services. Problems in adhering to the intervention protocol might prevent intervention studies from being effective.

This study has several limitations. The under-representation of non-adhering CMH professionals might have affected the results. However, given that CMH professionals adhering to the SCPD intervention protocol encountered the same barriers and facilitators as non-adhering CMH professionals, we believe that the saturation requirements for barriers and facilitators have been met. Data analysis identified no barriers or facilitators at the caregiver level because we did not ask CMH professionals about caregiver attitudes or caregiver adherence to the SCPD intervention.

Conclusion

To sum up, the results of the interviews suggest that the CMH services and their personnel were not ready to adopt and use the SCPD intervention in daily clinical practice. The use of the SCPD has not been prioritized within the competing challenges they have to deal with. To increase the chances of successful improvement and future implementation, the readiness for change (consider staff expectations, the perceived need for the innovation, its compatibility with existing routines, leadership, and clerical assistance) should first be assessed. Furthermore, our study reveals that policy changes like the introduction of the electronic patient record and the diagnosis-treatment combination might impede the attention for quality-improvement research without financial incentives. Therefore, future studies should avoid introducing psychosocial interventions concurrently with other major organizational changes.³³ Furthermore, although the study of barriers and facilitators is usually reserved for the implementation phase of effective interventions, this study shows that they already occur in the intervention phase of intervention studies. Therefore, barriers and facilitators should be studied before the intervention is applied in order to take into account the context of the intervention and to adapt the intervention to daily practice.

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Chapter 7

General discussion

Prevention of social breakdown syndrome requires a reorientation of working patterns in our mental health agencies--more than it requires additions of services or trained professionals! In fact, almost every community with a mental health association already has the personnel and services to achieve the prevention of social breakdown syndrome as one of the objectives of its mental health program. This prevention is an achievable goal if high enough priority is given it and when services are organized to provide continuity of care. – Gruenberg and Huxley, 1970

We almost never see people who just have dementia and no behavioral problems. They are all taken care of by physicians and the Care Needs Assessment Center and home care. So when we arrive, the patients have been cherry-picked. – Interviewed CMH professional

Research questions and main findings

The research aim of this thesis was to investigate the effectiveness and efficiency of training care professionals in the Systematic Care Program for Dementia (SCPD) in community mental health (CMH) care services in the Netherlands, as compared to usual CMH care. The general research questions were: What are the effects of the SCPD on institutionalization of people with dementia (primary outcome) and on the quality of life of the caregiver and the person with dementia (secondary outcome) at the 12-month follow-up, as compared to usual CMH care? What are the costs and benefits of the SCPD at the 12-month follow-up, as compared to usual care?

Chapter 2 addressed these questions: What support programs are available, and what is known about their overall effectiveness in preventing or delaying institutionalization of people with dementia? And which intervention characteristics distinguish effective psychosocial interventions from ineffective ones? Analyses revealed that support programs can significantly decrease the odds of institutionalization and significantly increase the time to institutionalization. Analyses of the intervention characteristics revealed that the most effective interventions are individualized, intensive, tailor-made ones that actively involve caregivers and people with dementia (also referred to as "the dyad") and that give care recipients the opportunity to choose from different interventions. These interventions may offer dyads a sense of freedom that provides a greater sense of personal control, more satisfaction with treatment, better compliance and transition to the daily routine, and consequently better outcomes.

Chapter 4 questioned: What is the effect of the SCPD on institutionalization of the person with dementia at the 12-month follow-up, as compared to usual CMH care? The results of our analysis revealed no significant intervention effect of the SCPD on the number of institutionalizations or time to institutionalization at the 12-month follow-up, as compared to usual CMH care. This means that we cannot confirm that training CMH professionals in the SCPD and subsequent use of the SCPD are more effective than usual care on the primary outcome of institutionalization of the person with dementia. However, an interaction effect was found between the treatment group and the caregiver's sense of competence on the change of institutionalization at the 12-month follow-up. In the usual care group, a low sense of competence at baseline was associated with a high risk of institutionalization, and a better sense of competence at baseline was associated with a lower risk of institutionalization. This means that the SCPD study sample seems to be representative of the group of dyads we wanted to include and examine. In the SCPD group, there was no association between sense of competence and institutionalization. The risk of institutionalization was the same for people with dementia having a caregiver with either a low or a high sense of competence at baseline. This suggests that the SCPD intervention prevented a deterioration of the sense of competence of caregivers with a low sense of competence at baseline and whose care recipients were in principle at high risk of institutionalization. The SCPD might have lifted up the level of sense of competence to a level associated with a lower risk of institutionalization of the person with dementia.

Preliminary analysis revealed no significant intervention effect of the SCPD on quality-of-life measures – the caregiver's sense of competence, depressive symptoms, and distress due to problem behavior of the person with dementia and its severity – at the 12-month follow-up, as compared to usual CMH care. This means that we cannot confirm that training CMH professionals in the SCPD and subsequent use of the SCPD are have more effect than usual care on the secondary outcome measures of quality of life.

Chapter 5 raised the question: What is the influence of CMH professionals' adherence to the SCPD intervention protocol on the quality-of-life measures at the 12-month follow-up? Analysis of adherence to the SCPD intervention protocol versus the quality of the caregivers' lives did not yield different results at the 12-month follow-up. However, at that time, we did find that caregivers treated by CMH professionals

adhering to the SCPD intervention protocol had a better sense of competence than caregivers treated by nonadhering CMH professionals. This suggests that such nonadherence may be one of the reasons our study did not find a main effect of the SCPD on the caregiver and person with dementia outcomes.

The unexpected results of the SCPD for the primary and secondary outcomes evoked new questions and required better insight into factors that might clarify the results. Therefore, as **Chapter 6** verifies, we performed a qualitative process evaluation. We questioned: What barriers to and facilitators for the systematic and timely use of the SCPD intervention protocol in daily clinical practice occur at different levels of healthcare? Analysis revealed that involvement in the decision to participate in the SCPD study and use of the innovation, leadership style, and clerical assistance emerged as crucial key themes. These key themes were both a barrier and a facilitator at different healthcare levels. They hindered CMH professionals' adherence to the SCPD intervention protocol when absent and facilitated its use when present. A heavy workload with time constraints, policy changes [such as the electronic patient record (EPR) causing a high clerical burden] and the pressure to produce were perceived as barriers hindering the adherence to the SCPD intervention protocol.

The interviews revealed that all CMH professionals had to cope with the same barriers and facilitators while adhering to the SCPD intervention protocol as planned. The evaluation of the barriers and facilitators they encountered provided some convincing clarifications for the results of the SCPD about institutionalization the person with dementia and the quality of life of the dyad.

Because we did not find a main effect of the SCPD on the primary and secondary outcomes, we did not consider economically evaluating the SCPD with a cost-effectiveness analysis. Therefore, the potential efficiency of the SCPD was not tested.

In the next sections, we put these results in a broader perspective and discuss possible clarifications for the main findings as well some methodological considerations that might have affected the results, possible adverse events of the intervention study, and implications for future study, policy, and practice.

Clarifications

The SCPD intervention does not comprise effective treatment modalities

In line with the literature,¹ our systematic review and meta-analysis revealed that the most effective interventions are individualized, intensive, tailor-made interventions that actively involve dyads and give care recipients choices out of different interventions.

Reflecting on the SCPD from the viewpoint of the systematic assessment of the caregiver's sense of competence and depressive symptoms proved a good starting point for targeted actions of possible caregiver problems.

CMH PROFESSIONAL9: I don't think there's so much wrong with the program, no. It's well coordinated. Yes, especially if you don't have much of the overall picture, I think it gives you a complete snapshot of what you can provide and how you can design the care for the informal caregiver.

However, to implement the SCPD in usual care routines of CMH services, two program modalities of the SCPD, based on the effective Family Support Program (FSP) introduced in home care,^{2;3} were purposely changed, namely, the intensity of the program and the use of accepted and available supportive interventions. In the next sections, we discuss whether these modified FSP treatment modalities affected the results.

The SCPD intervention was not intense enough. Unlike the FSP^{2;3} the number of counseling sessions was not standardized beforehand. The intensity of the SCPD intervention depended on the judgment of the CMH professionals, optimization of the flexibility of the SCPD, and acknowledgment of the expertise in the CMH services. Although adjustment of the intervention intensity did not yield different outcomes,^{4;5} we think that the SCPD intervention package was not intense enough for all caregivers. There were many more sessions in successful interventions³: 4 hours of weekly meetings in 10 months in the FSP^{2;6} and 10 sessions in 5 weeks in the Community Occupational Therapy Intervention^{7;8} versus 3.37 (SD 2.79) counseling sessions, including the assessment, in the 12 months of our study. These results also indicate that using the SCPD there put relatively much emphasis on the assessment procedure and left little room for extensive counseling. In contrast, effective interventions^{2;3;6-8} offered an intensive intervention package during the whole treatment trajectory and

not only at the beginning. Therefore, the low intensity level of the SCPD intervention for all caregivers might have negatively influenced the results.

No effective interventions available. Like the FSP,^{2;3} the SCPD offers three possible intervention strategies to initiate support:

- 1) Define acceptable goals of involvement. Organize additional professional support.
- 2) Open a dialogue about expectations, resources, conflicts, stigmas, and feelings of guilt. Engage in a dialogue about what the caregiver thinks she or he has to do and what she or he actually can do.
- 3) Clarify the relationship between the behavior of the person with dementia and the dementia syndrome.

Contrary to the FSP,^{2;3} only listed supportive interventions already available in CMH care were used. However, before the first training session, CMH professionals were asked to provide a social chart consisting of 10 regional service providers – i.e., support groups, Alzheimer café, meeting centers, and home care – to whom dyads could be referred in case a service was not available within the CMH service. Considering the needs of caregivers,⁹⁻¹¹ this package of intervening supportive actions and services that CMH professionals could offer caregivers was a good choice of the available interventions that would serve their specific needs. Therefore, it is unlikely that this treatment modality, based on the successful FSP,^{2;3} affected the results of the SCPD.

The SCPD intervention protocol was not carried out as planned

Nonadherence to the SCPD intervention protocol may be one reason our study did not find a main effect of the SCPD on the outcomes.^{5;12} Caregivers treated by adhering CMH professionals had a better sense of competence than caregivers treated by nonadhering CMH professionals at the 12-month follow-up.⁵ However, CMH professionals perceived that they already paid attention to the caregiver, took the caregiver's history, and asked questions to determine whether the caregiver was overburdened and needed support.¹²

One reason for this discrepancy might be an overestimation of CMH professionals' own performance or an under-registration of the help given.^{13;14} Two other reasons might be: no guidance to proactive supportive interventions and no systematic assessment of

the caregiver condition during the intake. In the next sections, we discuss whether these reasons can clarify the discrepancy and whether it affected the results.

No guidance for proactive supportive interventions. Perhaps the CMH professionals' systematic assessment was appropriate, but their guidance to effective, proactive, supportive interventions as the assessment indicated was not. As already mentioned, the SCPD intervention was probably not intense enough for all caregivers. Furthermore, there was relatively much emphasis on the assessment procedure and little room for extensive counseling during the whole treatment trajectory, as compared to effective psychosocial interventions.^{2;3;6-8} This suggests that CMH professionals might not know how to involve and guide overburdened caregivers in making a well-considered choice from the available treatment options.¹⁵ Barriers to counseling – difficulty making a connection with the family, feeling like an unwanted intruder, and denial and reluctance to be helped and deal with denial¹⁶ – might hinder this.^{15;17} However, we did not observe the CMH professionals' actual caregiver involvement and guidance in making the well-considered choice. Therefore, we cannot confirm or deny that this clarification affected the results.

No systematic assessment of caregiver problems during the intake. Barriers to counseling and gaining trust made some CMH professionals feel uneasy about systematically assessing the caregiver's condition during the intake as a starting point for further guidance and treatment. They foresaw losing the trust of caregivers.

CMH PROFESSIONAL9: R1: Well, I've always felt that it is important that you already have a trust relationship with the caregiver, so it's not the first time that this has come up, yes. And that they really will not tell you everything the first time. If you have already been there several times, then, then people are more... R2: But in itself it was not difficult to take in the information, I must say. R1: Absolutely not, no, I think it has a lot more to do with... R2: How you normally methodically go to work... yes, absolutely. R1: And how you notice things in the caregiver yourself, eh.

From the literature, we know that caregivers often focus on the care recipient's needs and neglect their own health needs,^{18;19} or give in and give this care despite their needs when the person with dementia refuses some services.¹⁷ Focus groups have

shown that it is difficult for caregivers to admit their reluctance to be helped with the problems they face. Nonetheless, they want CMH professionals to do something about the refusal of the person with dementia to accept help.¹⁷ A lack of acceptance to be helped significantly hampers the decision-making process with regard to treatment and care for caregivers and care recipients.¹⁵

The literature²⁰ characterizes the communication process in which both the caregiver and CMH professionals have a reserved attitude as a "double taboo" or the "conspiracy of silence". It describes a barrier to counseling for both the care recipients and CMH professionals. The risk of a reserved attitude resulting in a delayed systematic assessment of the caregiver condition may leave caregivers by the wayside. One example is the intake procedure being subject to an internal evaluation in health services as a start- or end-point.

We do not know if CMH professionals in intervention and usual CMH care groups differed in the reservation of their attitude to care recipients. An open attitude towards a timely diagnosis of dementia and subsequent care is more pronounced among health professionals younger than our interviewees.^{20;21} This clarification for not finding an effect of the SCPD might therefore be limited to the interviewed CMH professionals.

Community mental health services were not ready to adopt and use the SCPD

In line with the literature,²²⁻²⁷ involvement in the decision to participate in the SCPD study and use of the innovation, leadership style, and clerical assistance emerged as crucial key themes. These themes facilitated adherence to the SCPD intervention protocol when present and hindered the adherence when absent. Furthermore, CMH professionals had to cope with several well-known organizational barriers mentioned in the literature,^{22;23;25;26} namely, a structurally heavy workload, time constraints, and high staff turnover. Moreover, simultaneously with our intervention study, the Dutch national healthcare system required the implementation of the diagnosis-treatment combination and the new EPR. This caused extra clerical burdens. Community mental health professionals were urged to maintain production to keep the CMH service financially healthy.

The interviews showed that all CMH professionals had to cope with the same barriers and facilitators while adhering to the SCPD intervention protocol. Overall, the competing challenges in the CMH services were a major barrier. These results of the interviews suggest that CMH services and their personnel were not ready to adopt and use the SCPD intervention in daily clinical practice. This not only provided a convincing clarification for the nonadherence to the SCPD intervention protocol, but also a clarification why our study did not find a main effect of the SCPD on institutionalization and the quality of life of the dyad.

Overburdened caregivers are under-represented

Unfortunately, around 40% of the 534 dyads enrolled in the study dropped out, mainly because of withdrawal of consent, according to the caregivers. Potential caregivers also dropped out because they felt the unease of the secretary or the CMH professional on duty while recruiting or enrolling caregivers because of suspected caregiver burden or age.

From a select group of 30% of the 534 dyads that dropped out, we know that caregivers experienced significantly more distress due to behavior problems of the people with dementia, and that these people exhibited significantly more severe behavior problems than the care recipients of the 295 caregivers included for baseline measurements and subsequent analysis.

After baseline measurements, 58% of the 295 dyads were lost to follow-up, mainly because of institutionalization of the person with dementia, deaths, and refusal to participate in the study any longer. Table 1 presents the in-depth analysis that reveals that dyads in the usual care group who were lost to follow-up were generally in worse condition at baseline (lower caregiver sense of competence, more caregiver depressive symptoms (mean score 16.39, SD 9.74 – close to clinical depression), more distress due to behavioral problems of the person with dementia, and more severity of behavioral problems) than dyads who were present at follow-up. Furthermore, the baseline conditions of dyads treated by adhering CMH professionals and lost to follow-up were worse regarding caregiver distress due to behavioral problems of the care recipient and its severity, as compared to dyads who were still present at the 12-month follow-up.

The literature reports that cognitive decline¹⁷ and burden of care (particularly due to the care recipient's problems of activities in daily living and increased behavioral problems) are associated with more service use.^{28;29} Furthermore, nonspousal caregivers, who are over-represented in our study, are more likely to use services than spouse caregivers.^{28;29} From this point of view, it is a pity that these caregivers experiencing distress due to severe behavioral problems of the care recipient were unable to fully utilize the available treatment options.

Table 1. Score differences between groups for dyads lost to follow-up (attrition) and dyads who completed the study

Treatment group	Subgroup	n	Mean (SD)	Mean Difference (SE)	Test Statistic	Df	P
Sense of competence							
Adherence	<i>Attrition</i>	60	91.01 (16.19)	5.41 (3.09)	<i>t</i> = -1.75	104	0.08
	<i>Completed</i>	46	96.41 (15.13)				
Nonadherence	<i>Attrition</i>	29	92.14 (15.55)	0.43 (1.93)	<i>t</i> = 3.72	46	0.47
	<i>Completed</i>	19	88.42 (19.45)				
Usual care	<i>Attrition</i>	76	86.62 (13.82)	9.78 (2.24)	<i>t</i> = -4.37	133	0.0001*
	<i>Completed</i>	59	96.40 (11.63)				
Caregiver depressive symptoms							
Adherence	<i>Attrition</i>	60	12.72 (10.61)	1.65 (1.97)	<i>t</i> = 0.84	104	0.40
	<i>Completed</i>	46	11.07 (9.30)				
Nonadherence	<i>Attrition</i>	29	11.59 (9.60)	4.15 (3.26)	<i>t</i> = -1.28	46	0.21
	<i>Completed</i>	19	15.74 (12.94)				
Usual care	<i>Attrition</i>	76	16.39 (9.74)	6.62 (1.48)	<i>t</i> = 4.68	131.04	0.0001*
	<i>Completed</i>	59	9.77 (6.66)				
Caregiver distress due to patient behavioral problems							
Adherence	<i>Attrition</i>	61	14.38 (9.74)	5.42 (1.59)	<i>t</i> = 3.40	104.24	0.001*
	<i>Completed</i>	46	8.96 (6.71)				
Nonadherence	<i>Attrition</i>	29	13.76 (8.77)	1.40 (2.82)	<i>t</i> = -0.50	46	0.62
	<i>Completed</i>	19	15.16 (10.64)				
Usual care	<i>Attrition</i>	80	16.21 (8.52)	4.28 (1.48)	<i>t</i> = 2.89	138	0.01*
	<i>Completed</i>	60	11.93 (8.89)				
Severity of behavioral problems							
Adherence	<i>Attrition</i>	61	11.15 (7.31)	3.39 (1.33)	<i>t</i> = 2.54	105	0.01*
	<i>Completed</i>	46	7.76 (6.13)				
Nonadherence	<i>Attrition</i>	29	12.93 (7.07)	1.56 (2.04)	<i>t</i> = 0.77	46	0.45
	<i>Completed</i>	19	11.37 (6.68)				
Usual care	<i>Attrition</i>	80	13.06 (6.00)	2.55 (1.05)	<i>t</i> = 2.43	138	0.02*
	<i>Completed</i>	60	10.52 (6.33)				

n = number; SD = standard deviation; SE = standard error for the mean difference; Df = degrees of freedom; * p ≤ 0.05

The drop-out and attrition phenomenon might have biased the effects of the SCPD because of an under-representation of these caregivers who might have benefited most from our intervention. In line with our previous clarification, this might be a result of CMH professionals' unease in systematically assessing caregiver conditions during the intake or the inability to guide caregivers to proactive supportive interventions. However, we cannot produce evidence from our data that these clarifications were or were not the case, and if they were, whether they affected the main findings of the SCPD study.

Visual inspection of the scatter plots did not indicate smaller than normal variability in the incidences of caregiver symptoms between baseline and follow-up scores of the 125 dyads who completed the 12-month study period. Therefore we found no indication of ceiling effects. However, strictly ruling out the presence of ceiling effects affecting the results due to the drop-out and attrition phenomenon is problematic because there are no normative standards (cut-off points) for evaluating clinically meaningful change.³⁰

Methodological considerations

Strengths of the SCPD study

Theoretically driven design. The SCPD study was adapted to psychosocial intervention studies that were theoretically driven but effective. The strong foundation of the SCPD intervention design, who to target, the development of specific hypothesis and goals, and therefore clarity about the outcome measures to be used made the SCPD study promising in practice.

The use of evidence-based outcome measures. We used the evidence-based outcome measures that are recommended by European consensus for evaluating the effectiveness of psychosocial interventions in dementia care.³¹ This contributes to meaningful comparisons of the SCPD study with other studies and interventions in dementia care.

Mixed method study. The SCPD study fits in with the growing interest for studies evaluating a process in or alongside the cluster randomized controlled trial of complex health care interventions like the SCPD.^{32;33} The intrinsic value of integrating these study methods was explicitly covered in our study protocol.³⁵ The performance of both quantitative and qualitative process evaluations gave us a chance to open up the black

box a little. We were able to determine whether the SCPD intervention was delivered as intended, determine whether variations in adherence to the SCPD intervention protocol yielded other results in outcomes and explore clarifications for the unexpected results.

Weaknesses of the SCPD study

Randomization at the level of CMH professionals. Because randomization took place at the level of the CMH professionals and not at the level of CMH services, several forms of bias and challenging methodological rigors might have occurred. First, inclusion bias may have occurred because the presumed voluntary character of the participation of the CMH professionals in the study. Voluntary CMH professionals may be more interested or may already take better care of caregivers, and may perform better in research than their colleagues. In practice, however, this form of inclusion bias was limited. To be able to include the necessary number of dyads and to deal with a high turnover of CMH professionals treating these dyads, CMH services had to pull out all the stops and include almost all their available CMH professionals in the study. Many CMH professionals even felt forced to participate.¹³

Second, the possibility of contamination due to knowledge exchange or a transfer of dyads between CMH professionals allocated to the different groups could have taken place. Community mental health professionals allocated to the intervention group told us they did not discuss the content of the SCPD intervention with CMH professionals allocated to the usual care group. However, treatment proposals were discussed in consultations with CMH professionals allocated to both groups. Therefore, it is not unlikely that CMH professionals allocated to the control group learned skills about possible SCPD treatment strategies from CMH professionals allocated to the intervention group. This is even more likely due to the fact that the study could not be double-blinded because active participation of the CMH professionals was necessary. The awareness of allocation might have caused CMH professionals' in the control group to treat dyads differently; for example, with more attention than previously. However, verification of contamination is difficult because usual mental health care before the start of the study and actual mental health care treatment during the study were not investigated.

The disadvantages of randomization at the level of the CMH professionals may be prevented by randomization at a higher level, that is at the level of CMH services. In principle, this would have been the preferred study approach if feasible. Considering the with strain recruited six health services this would have meant a randomization of three versus three health services which, however, would result in a severe loss of power. Roughly 48 versus 48 CMH services would have been needed to detect a 50% reduction in institutionalization rates with 80% power at the two-sided significance level of 0.05.³⁴ For reasons of feasibility, it was therefore acceptable to accept a certain degree of contamination, this is a biased downward estimate of the effect,³⁵ because it was compensated by a substantial gain in power.

Selection bias due to nonadherence to the recruitment protocol and drop-out of caregivers. Recruitment problems or drop-out rates are hardly evaluated but appear in many intervention and implementation studies dealing with vulnerable participants³⁶⁻³⁸ or with a lack of financial incentives.³⁷ In line with successful recruitment strategies,³⁹ the researchers communicated the study methods, and trained secretaries and CMH professionals to correct misunderstandings of study methods, and reinforced knowledge of the potential benefits of the study, for both health professionals and their clients. All caregivers newly referred to the CMH service were assessed for eligibility for participating in the SCPD study to prevent caregiver inclusion bias. However, as already mentioned, nonadherence to the recruitment protocol caused presumably eligible dyads to drop out because they felt the unease of the secretary or the CMH professional on duty in recruiting caregivers with a presumably heavy burden or great age. Furthermore, a large proportion of caregivers were lost to follow-up. This disrupted the study timetable added several months, and created selection bias. It caused an under-representation of overburdened caregivers, the group that might have benefitted most from the SCPD intervention, and this reduced the chances of detecting treatment differences.⁴⁰

The lack of the caregiver perspective. Unfortunately, we could not carry out one or more caregiver case studies due to time constraints, which definitely resulted in a less nuanced perception of what happened in the black box. Investigating different perspectives of interested parties is important because caregivers and CMH professionals may have divergent views⁴¹ of preferences, expectations, level of involvement, and the treatment offered and received in CMH services. Such information

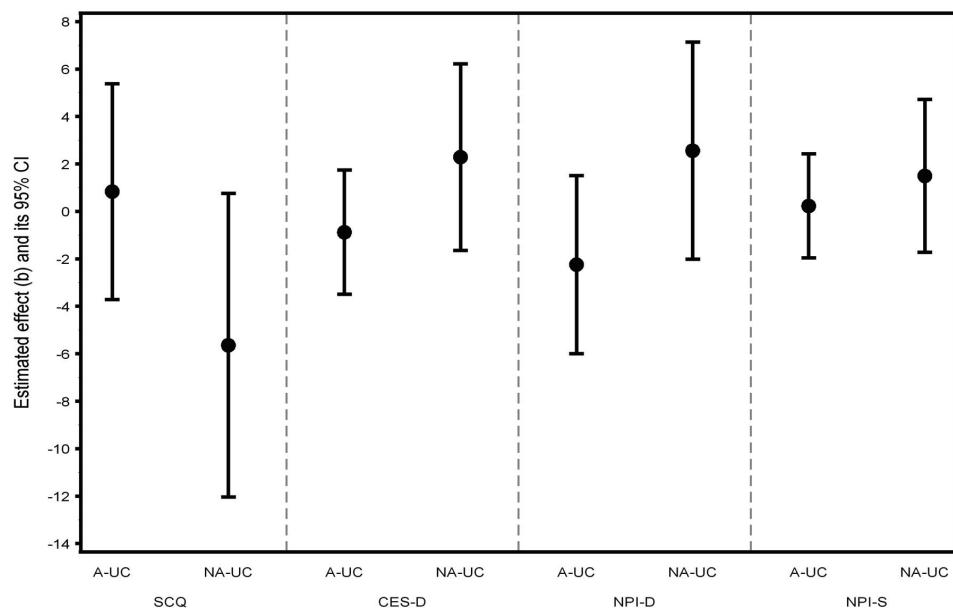
might have contributed to a better understanding of our study results and the quality improvement of the SCPD intervention in CMH services.

Generalizability. Caregivers were recruited from the CMH services, not from other institutions such as the outpatient clinics, the memory clinic, or directly from general practice. Thus our sample may be representative of neither all community-dwelling caregivers of people with dementia nor other CMH services, e.g., respite care or home care, in the Netherlands. Furthermore, our sample consisted mainly of Caucasian people, although the second- and third-generation caregivers, whose parents or grandparents were born and raised outside the Netherlands, are catching up with their access to CMH services⁴². It is unclear whether the SCPD and CMH professionals are sensitive to caregivers with diverse cultural beliefs about and preferences for formal support and the institutionalization of their loved one with dementia.

Adverse effects of the SCPD due to treatment variability

No others than the expected adverse events were reported during the SCPD study. However, CMH professionals' treatment variability (compliance) might have had adverse effects on the well-being of caregivers. As already discussed, we found that caregivers treated by adhering CMH professionals had a better sense of competence than caregivers treated by nonadhering CMH professionals at the 12-month follow-up.⁵ Our study also revealed that, with the exception of the severity of behavioral problems, dyads assigned to adhering CMH professionals or to usual care were numerically in better condition than dyads assigned to nonadhering CMH professionals at the 12-month follow-up (Figure 1; **Chapter 5**, Table 4). Although not statistically significant caregivers treated by CMH professionals adhering to either the SCPD intervention protocol or usual care were less overburdened over a range of outcome measures than caregivers treated by nonadhering CMH professionals. In other words, the first group of caregivers had numerically a better sense of competence, fewer depressive symptoms, and less distress about behavioral problems. The SCPD and daily routine usual care seems to prevent a deterioration of the caregiver's condition. Caregivers assigned to CMH professionals not adhering to the SCPD or usual care pay a price for these professionals' nonadherence to evidence-based practices.

Figure 1. Comparison of estimated treatment effects (*b*) on outcomes for dyads treated by adherent and nonadherent CMH professionals versus usual care



A-UC = estimated effect on dyads treated by adhering CMH professionals versus dyads treated by CMH professionals in the usual care group; NA-UC = estimated effect of dyads treated by nonadhering CMH professionals versus dyads treated by CMH professionals in the usual care group; SCQ = caregiver sense of competence; CES-D = caregiver depressive symptoms; NPI-D = caregiver distress due to behavioral problems of the person with dementia; NPI-S = severity of behavioral problems of the person with dementia as experienced by caregivers.

Note. The estimated *b*'s for groups (A, NA, UC) are the *b*'s for groups adjusted for all covariates and control variables

These unexpected adverse treatment effects for caregivers assigned to nonadhering CMH professionals relative to usual care may be due to the mechanisms of the process of change. Starting a process of change disturbs the daily routine and makes CMH professionals initially conscious of what should be changed and raises the issue of incompetence.⁴³ This may have resulted in a feeling of being stuck between what they were used to and what they were asked to change. The non-action resulting from this may have worsened their daily practice.

The many statistical tests might have increased the risk of a chance finding (type 1 error). However, because the results for caregivers assigned to adhering CMH professionals versus nonadhering CMH professionals versus usual care were consistent

for almost all clinical outcomes, we believe that the results are not a chance finding. Furthermore, the results were derived from a select group of caregivers who completed the 12-month study period; many caregivers in worse condition had already been lost to follow-up.

Implications for future research

Readiness assessment before the intervention phase of intervention studies

We underestimated possible hassles in introducing a complex psychosocial intervention like the SCPD study in CMH services' working patterns and routines. Our study shows that testing a complex psychosocial intervention in daily practice can encounter problems similar to those in large-scale implementation. Therefore, as in large-scale implementation, a substantial amount of time should be spent on introducing and testing the intervention research. This means that the readiness for change⁴⁴⁻⁴⁶ and possible barriers to and facilitators of adherence to the intervention protocol should be explored before the intervention phase of complex psychosocial intervention studies. Some matters to be considered are staff expectations, the perceived need for the innovation, its compatibility with existing routines, and leadership. Only strong motivation within all levels of the organization might overcome competing challenges in healthcare organizations. The used framework for hindering or facilitating change in clinical practice at different levels of healthcare⁴⁷ proved to be suitable for this. Attention in advance to possible barriers to health professionals adapting evidence-based practices might lead to more successful results.

Assessment and evaluation of adherence

Our study reveals that CMH professionals' treatment variability might have affected caregiver treatment outcomes. Therefore, the influence of health professionals' adherence to the intervention protocol on outcome measures should not be overlooked. The assessment of adherence might help clarify the results and also detect adverse treatment effects. To prevent possible adverse treatment effects, future researchers should stress the possible negative consequences for caregivers as a result of health professionals' nonadherence to evidence-based practices.

Implications for future policy and practice

Family policy: acknowledgement of the caregiver as a partner in care

The implementation of involving the caregiver as a partner in care in CMH care is ongoing.⁴⁸ Many elements of caregiver and care recipient involvement are adopted to satisfactory levels – e.g., the level of information – while other elements are scarcely realized.⁴¹ In our study, we noticed that the referral to CMH services was not accompanied by caregiver data in many cases. This invisibility of the caregiver as a partner in care hindered the recruitment of presumably eligible dyads to participate in the SCPD study. The secretariat of the health services spent much time getting basic data about the caregiver, including simple contact details, before the intake procedure.

Once caregivers were involved in the help trajectory, CMH professionals had difficulty systematically assessing possible caregiver problems during the intake procedure. However, a reserved attitude that delays systematic assessment of possible caregiver problems might leave caregivers by the wayside.

In both cases just described, the caregiver seems to remain invisible until a crisis occurs. Therefore, formal registration of the primary caregiver is an important requirement to empower him/her and to acknowledge his/her indispensability as an equal partner in care. Reducing invisibility might prevent undertreatment of caregivers and help prevent or delay institutionalizing the care recipient.

Monitoring the caregiver condition during the course of the dementia disease

Effective interventions^{2;3;6-8} for people with dementia and their caregivers offer an intensive intervention package, not only at the beginning, but also throughout the whole treatment trajectory. This is important, considering the various caregiver problems and needs during the dementia course. Screening programs for depression are only effective if subsequent coordinated treatment and monitoring by health professionals are offered.⁴⁹ Notwithstanding the fact that we were unable to decisively prove the effectiveness of the SCPD screening tool it can be used as a caregiver monitoring tool to prevent or delay institutionalizing the person with dementia.

Attention for caregiver distress

Behavioral problems associated with dementia, which include depression, agitation, apathy, wandering, and incontinence, are among the most challenging stressors for caregivers and are a major cause of institutionalization of people with dementia.^{4;50} They are also among the most important predictors of high levels of caregiver distress.⁵⁰ From this point of view, it is a pity that many caregivers suffering such distress dropped out of the SCPD study and then could not benefit fully from the treatment options available. Community mental health professionals should pay timely and systematic attention to the presence and treatment of caregiver distress, which might help prevent or delay institutionalizing the person with dementia.

The guarantee of a very intensive supportive intervention package

Compatible with the literature,^{1;3;51} our study suggests that high-intensity interventions are needed to change the dyad condition. The SCPD intervention package might not have been intense enough for all caregivers. Caregivers who received less formal help and were more dissatisfied with the amount of formal help offered found the behavioral and psychological symptoms of dementia more stressful.⁵² Policy and protocols for CMH care should therefore regulate the intensity of support programs. The support program should prescribe a minimum number of counseling sessions on the basis of evidence to guarantee that caregivers are offered the care they need. A more pragmatic solution would be to use only CMH professionals who already see their clients often.

Integration of the SCPD and the electronic patient record

The SCPD screening tool and assessment forms were printed on handy plasticized pocket cards and papers, respectively. In retrospect, it might have been more suitable to hand over these aids as a user-friendly, web-based application.

In line with the literature,⁵³ CMH professionals commented during the retrospective interviews that the EPR was being used with a great satisfaction. Notwithstanding the fact that we were unable to decisively prove the effectiveness of the SCPD screening tool, it could be integrated with the EPR system to assess, treat, and monitor possible caregiver problems during the course of the dementia. Alternatively, the tool could be integrated with the development and implementation of routine outcome monitoring (ROM) in CMH care.⁵⁴ Integrating the SCPD with the EPR or embedding it in the ROM

(accessible on their own iPads for home visits) might help CMH professionals work more efficiently, systematically, transparently, and in an evidence-based way. It might prevent under-treatment of caregivers and improve caregiver treatment, which, in turn, might prevent or delay institutionalizing people with dementia.

CMH PROFESSIONAL9: It's all well put together. R1: But how can you make that for the CMH professionals in a friendly, approachable way? That it can be used as efficiently as possible. Soon we'll have the EPR, then you might imagine that you have a handy computer system in which you can quickly check off those things and that it will be faster than now. But I'm just making that up on the spot, you know. R2: It would be nice, just for clarity and transfers, and it would also be nice to have an external system in which that sort of thing is very transparent. R1: Because, of course, we are all soloists here. Everybody does it his own way. And that in itself is not bad, but you have to be able to find it all again. R2: A combination of more systematic and method gives just a little more guidance, and then you show others what you're doing better. Then you can, imagine that you lose something, then you don't lose it as quickly. It's all a bit sharper, less volatile, more obligatory. Then you can work in a more evidence-based way, I think. That can still be improved, but some time must be freed up for it! Here we have so much workload and production, and then we do extra on top.

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Summary

The impact of dementia urgently exhorts us to shape conditions that favor caring for people with dementia at home as long as possible and to minimize the risks of undue burden and depression for caregivers. Such action may even delay the institutionalization of people with dementia.

Because of their expertise, the community mental health (CMH) care services can play prominent roles in both the diagnosis and management of dementia. The CMH services offer many opportunities for supporting caregivers. Unfortunately, these opportunities are currently not routinely taken because of a lack of timely and systematic assessment of caregiver problems. As a consequence, caregivers accompanying people with dementia often remain invisible until a crisis occurs.

To optimally benefit from the expertise and opportunities in CMH services and to fulfill the urgent need for proactive and cost-effective support programs, the effective in-home care Family Support Program was adapted for the Systematic Care Program of Dementia (SCPD). Basically, the SCPD consists of training CMH professionals in the timely and systematic assessment and interpretation of the caregiver's sense of competence and depressive symptoms. **Chapter 1** describes in detail:

1. The theoretical foundation of the SCPD in response to the Social Breakdown Syndrome and problems of aging.
2. The content of the SCPD, the training and training methods, and the aids developed to facilitate the use of the SCPD.

To our knowledge, neither the proactive elements nor the systematic elements of the SCPD approach are routinely used in dementia management in the CMH care setting. Publicizing firmer evidence of its effectiveness and efficiency might encourage the adoption of the SCPD in the Dutch setting. Therefore, our research aim was to investigate the potential effectiveness and efficiency of SCPD training for care professionals working in CMH services in the Netherlands. The research questions were: What are the effects of the SCPD on institutionalization of people with dementia (primary outcome) and on the quality of life of the caregiver and the person with dementia (secondary outcome) at the 12-month follow-up, as compared to usual CMH care? What are the costs and benefits of the SCPD at the 12-month follow-up, as compared to usual care?

Exploration of the literature revealed that studies about the effectiveness of support programs intending to prevent or delay institutionalization of people with dementia are contradictory. Therefore, we performed a systematic review and a meta-analysis. The results as presented in **Chapter 2** revealed that support programs can significantly decrease the odds of institutionalization and can significantly increase the time to institutionalization. Analyses of the intervention characteristics revealed that individualized, intensive, tailor-made interventions, which actively involve caregivers and people with dementia, and give care recipients the opportunity to choose from different interventions, are most effective. These interventions might offer caregivers and people with dementia a sense of freedom, resulting in a greater sense of personal control, more satisfaction with treatment, better adherence and transition to the daily routine, and consequently better outcomes.

Chapter 3 describes the SCPD intervention and our design for evaluating the effectiveness and efficiency of the SCPD as compared to usual CMH care. We used a process evaluation to gain insight into factors that might affect the success or failure of the SCPD intervention.

Chapter 4 evaluates the effect of the SCPD on institutionalization people with dementia (primary outcome) at the 12-month follow-up, as compared to usual CMH care. The results of our analysis revealed no significant intervention effects of the SCPD on the number of institutionalizations and the time to institutionalization at the 12-month follow-up, as compared to usual CMH care. This means that we cannot confirm that training CMH professionals in the SCPD and the subsequent use of the SCPD have more effect than usual care on the primary outcome of institutionalization. However, an interaction effect was found between the treatment group and caregiver's sense of competence on the change of institutionalization at the 12-month follow-up. In the usual-care group, a low sense of competence at baseline was associated with a high risk of institutionalization; and a better sense of competence at baseline, with a lower risk of institutionalization. In the SCPD group, there was no association between sense of competence and institutionalization. The risk of institutionalization was the same for people with dementia having a caregiver with either a low or a high sense of competence at baseline. This suggests that the SCPD intervention prevented a deterioration of the sense of competence among caregivers with a low sense of competence at baseline and their care recipients that were in principle at high risk of

institutionalization. This suggests that the SCPD intervention might have lifted up the level of sense of competence to a level associated with a lower risk of institutionalization of the person with dementia.

Preliminary analysis revealed no significant intervention effect of the SCPD on the quality-of-life measures (secondary outcome)– e.g., the caregiver's sense of competence, depressive symptoms, and distress as related to the problem behavior of the person with dementia and its severity – at the 12-month follow-up, as compared to usual CMH care. This means that we cannot confirm that training CMH professionals in the SCPD and the subsequent use of the SCPD are more effective than usual care for the secondary outcome measures of quality of life. **Chapter 5** determines whether CMH professionals' treatment variability influenced the relationship of treatment group to caregiver quality-of-life outcomes. Analysis of the adherence to the SCPD intervention protocol as related to the quality of the caregivers' lives did not yield different results at the 12-month follow-up. However, at that time, caregivers treated by CMH professionals adhering to the SCPD intervention protocol had a better sense of competence than caregivers treated by nonadhering CMH professionals. This suggests that nonadherence to the SCPD intervention protocol might be one of the reasons our study did not find a main effect of the SCPD on caregiver and person-with-dementia outcomes.

Because we did not find a main effect of the SCPD on the primary and secondary outcomes, we did not consider economically evaluating the SCPD with a cost-effectiveness analysis. Therefore, the potential efficiency of the SCPD was not tested.

The unexpected SCPD results for the primary and secondary outcomes evoked new questions and required better insight into factors that might clarify these results. Therefore, **Chapter 6** presents our qualitative process evaluation. We explored CMH professionals' barriers to and facilitators for adhering to the SCPD intervention protocol as planned. Involvement in deciding to participate in the SCPD study and using the innovation, leadership style, and clerical assistance emerged as crucial key themes. These key themes were both barriers and facilitators at different healthcare levels. They hindered CMH professionals' adherence to the SCPD intervention protocol when absent and facilitated its use when present. A heavy workload with time constraints and policy changes (such as using the Electronic Patient Record, which caused a high

clerical burden and pressure to produce) were perceived as barriers hindering adherence to the SCPD intervention protocol.

The interviews showed that all CMH professionals had to cope with the same barriers and facilitators while adhering to the SCPD intervention protocol as planned. The evaluation of barriers and facilitators they encountered provided some convincing clarifications of the results of the SCPD for the institutionalization of people with dementia and the quality of life of both the caregiver and the person with dementia.

Chapter 7 summarizes the results and puts them in a broader perspective. Clarification of the main results, some methodological considerations that might have affected the results, possible adverse events of the intervention study, and implications for future study, policy, and practice are discussed.

Samenvatting

Systematische zorg voor mantelzorgers van mensen met dementie in instellingen voor de GGZ: een psychosociaal interventieonderzoek

"R2: Ik denk dat er met het programma niet zo veel mis is, nee. R1: Het zit allemaal goed in elkaar. R2: Ja, zeker als je daar niet zo veel zicht op hebt, denk ik dat het een heel compleet plaatje geeft van wat je allemaal kunt leveren en op welke manier je de zorg voor de mantelzorger kunt vormgeven."

"R1: Ik denk dat we er onvoldoende energie in hebben gestopt. Dat dat gewoon niet goed... Maar ook het begin, de manier waarop het gegaan is, geïntroduceerd is, daar begint het al.

R2: Dat denk ik ook.

R1: Onze baas heeft ja gezegd, maar zijn mensen die het moeten uitvoeren die hadden zo iets van 'hallo, hoe doen we dit, krijgen we er tijd voor, nee dus'. En daar hebben jullie dan last van en dat vind ik zonde. Ik denk ook dat je daar als onderzoeker best kritisch op mag zijn. De organisatie zegt wel ja, maar wie zegt er eigenlijk ja? Ik denk jullie inspanningen zijn ook best groot geweest en als je dan in een organisatie komt die ja zegt om dan wel goed af te stemmen hoe zit het eigenlijk met de motivatie. Wie zegt er eigenlijk ja? Is dat alleen de baas of de mensen die het moeten doen? Daar hebben jullie nu last van."

Geïnterviewde zorgprofessional R1 en R2-

De impact van dementie

Dementie heeft een enorme weerslag op het persoonlijk leven van mensen met dementie en hun mantelzorgers¹. Zorgen voor een naaste met dementie is een zware opgave. Professionele ondersteuning van de mantelzorgers is belangrijk, zodat zij de zorg beter volhouden en hun naasten met dementie zo lang mogelijk thuis kunnen blijven wonen. Bovendien zijn de maatschappelijke kosten van dementie aanzienlijk, uitstel van opname in een verpleeghuis helpt om die hoge kosten te beheersen.

Van de mensen met dementie wordt 70% thuis verzorgd. Hun dagelijks functioneren hangt met name af van de zorg die hun mantelzorgers kunnen geven. Mantelzorgers geven aan dat ze veel voldoening halen uit de waardering die ze krijgen voor hun zorg, maar dat de zorgverantwoordelijkheid zwaar op hun schouders drukt. Dit kan ten koste

¹ Mantelzorgers zijn mensen die onbetaald zorgen voor een chronisch zieke, gehandicapte of hulpbehoefende ouder, kind of ander familielid, vriend of buur. Zij geven die zorg omdat ze een persoonlijke band hebben met die persoon. Die zorg is langdurig, intensief en afhankelijk van de behoeftte van de zorgbehoefende. We spreken over mantelzorg als het gaat om zorg die de 'gewone' zorg qua duur, intensiteit of zwaarte overstijgt.

gaan van hun eigen fysieke gezondheid en mentale welbevinden. In Nederland blijkt dat partners van mensen met dementie vier keer zoveel risico hebben op een depressie dan partners van mensen zonder dementie. Voorts blijkt dat ongeveer de helft van alle mantelzorgers van mensen met dementie lijdt aan een depressie, terwijl slechts 20% hiervoor wordt behandeld.

Ondersteuning van mantelzorgers in instellingen voor de GGZ

Een tijdige diagnose en management van dementie kan (overmatig) gebruik van dure zorgvoorzieningen voorkomen. Het geeft mensen bovendien de tijd om zich voor te bereiden op komende medische, financiële en emotionele uitdagingen die dementie met zich meebrengt. De behoeften van mantelzorgers zijn tweeledig. Op medisch en educatief gebied hebben zij met name behoefte aan de helderheid over de diagnose en prognose, meer kennis van de gevolgen van de ziekte, het aanleren van communicatieve vaardigheden en het leren omgaan met geheugen- en gedragsveranderingen. Op psychologisch gebied geven mantelzorgers aan voornamelijk behoefte te hebben aan ondersteuning bij het leren hanteren van emotionele stress en de verwerking van angst, woede en schuldgevoelens.

Vanwege hun expertise kunnen instellingen voor de GGZ een prominente rol spelen in de diagnose en management van dementie en in de ondersteuning van mantelzorgers. Helaas worden deze mogelijkheden momenteel niet structureel gebruikt omdat in de huidige werkwijze mogelijke problemen van mantelzorgers niet tijdig en systematisch in kaart gebracht worden. Als gevolg hiervan blijven mantelzorgers van mensen met dementie vaak onzichtbaar totdat er een crisis uitbreekt. Reactief crisismangement gepaard met een opname van de persoon met dementie in een verpleeghuis is dan vaak nog de enige optie. De huidige werkwijze typeren wij in ons onderzoek als gebruikelijke zorg.

Het Systematisch Zorgprogramma Dementie

Om optimaal gebruik te maken van de expertise en ondersteuningsmogelijkheden van instellingen voor de GGZ én om te voorzien in de dringende behoefte aan proactieve kosteneffectieve ondersteuningsprogramma's is het Systematisch Zorgprogramma Dementie (SZP-Dementie) ontwikkeld. Het programma is gebaseerd op het in de Thuiszorg effectief bevonden Gezinsondersteuningsprogramma Dementie en aangepast voor introductie in de GGZ. Het accent ligt op het vergroten van het gevoel van

competentie van de mantelzorger om te kunnen zorgen voor een naaste met dementie. Uit de literatuur blijkt dat dit gevoel van competentie van de mantelzorger een belangrijke voorspeller is voor opname van mensen met dementie in het verpleeghuis.

Het SZP-Dementie bestaat uit drie trainingssessies voor zorgprofessionals (sociaal psychiatrisch verpleegkundigen en psychologen) in het tijdig en systematisch inventariseren en interpreteren van het gevoel van competentie om te zorgen voor een naaste met dementie en depressieve symptomen van mantelzorgers (Figuur 1). De inventarisatie van het gevoel van competentie beslaat een scala van mogelijke problemen binnen drie domeinen: 1) Consequenties voor het persoonlijk leven van de mantelzorger; 2) Tevredenheid over zichzelf als mantelzorger; 3) Tevredenheid over de persoon met dementie als verzorgde. De SZP-Dementie screening tool is op een handzaam plastic kaartje gedrukt dat zorgprofessionals bij zich kunnen dragen.

Als blijkt dat de mantelzorger zich onvoldoende competent voelt om te zorgen voor zijn naaste en/of depressieve gevoelens heeft, zal de zorgprofessional proactief ondersteunende interventies inzetten. Dit gebeurt in overleg met de betrokkenen en wordt afgestemd op de behoeften van de mantelzorger. Het SZP-Dementie voorziet in een aantal ondersteuningsstrategieën die zorgprofessionals kunnen toepassen om het gevoel van competentie van de mantelzorger te verbeteren. Een voorbeeld is uitleggen wat de relatie is tussen dementie en de gedragsveranderingen van de persoon met dementie. Een behandelingsdoel kan zijn dat de mantelzorger het gedrag van de persoon met dementie niet persoonlijk opvat, waardoor wederzijds negatieve gevoelens kunnen verminderen, wat ten goede komt aan hun relatie.

De inventarisatie en interpretatie van het gevoel van zorgcompetentie en mogelijke depressieve symptomen kan plaatsvinden tijdens de intakeprocedure, waarin het eerste contact tussen een zorgprofessional de persoon met dementie en diens mantelzorger gelegd wordt. Dit bereikt ook mantelzorgers die aanvankelijk geen hulpvraag hebben, omdat zij als vanzelfsprekend de verantwoordelijkheid om voor hun naaste te zorgen op zich nemen en zichzelf niet als mantelzorger zien. Deze mantelzorger kan al wel overbelast zijn, maar herkent dit niet bij zichzelf.

Figuur 1. Screeningtool SZP-Dementie

Inventarisatie gevoel van competentie:

1 Consequenties voor persoonlijk leven mantelzorger

- a. Heeft u door de huidige situatie met uw... het gevoel dat u minder privacy heeft?
- b. Drukken de verantwoordelijkheden voor uw gezin, familie, werk en de persoon waar u voor zorgt, zwaar op u?

2 Tevredenheid over zichzelf als mantelzorger

- a. Bent u ontevreden over hoe het tussen u en uw.... gaat?
- b. Voelt u zich gespannen in uw contacten met uw.....

3 Tevredenheid over de persoon met dementie als verzorgde

- a. Is het gedrag van uw veranderd? Is dat gedrag zo omdat uw... u wil manipuleren, u dwars wil zitten of omdat uw... zijn/haar zin wil krijgen?

Strategieën voor ondersteuning:

1. Haalbare doelen stellen en aanvullende ondersteuning bieden
2. Dialoog over wat de mantelzorger denkt te moeten en wat deze in feite kan doen
3. Verklaar relatie tussen gedrag en ziekte

Vragen naar mogelijke gevoelens van depressiviteit:

1. Heeft u zich de afgelopen maand terneergeslagen, depressief of hopeloos gevoeld?
2. Heeft u de afgelopen maand weinig interesse of plezier in dingen gehad?

Observeren type mantelzorger:

Niet adaptieven: geen begrip, wel irritatie

Verzorgenden: zorg en protectie

Supporters: aanpassen aan niveau cliënt, supervisie en stimuleren van bestaande capaciteiten

Inventariseren ernst van dementie:

Mild: Het werk en sociale activiteiten zijn significant beperkt, maar de capaciteit om zelfstandig te leven blijft, met adequate persoonlijke hygiëne en een relatief intact beoordelingsvermogen

Matig: Zelfstandig wonen is gewaagd, en een beperkte mate van supervisie is noodzakelijk

Ernstig: Activiteiten in het dagelijkse leven zijn zo beperkt dat continu supervisie nodig is, bijv. niet in staat minimale persoonlijke hygiëne te handhaven; voornamelijk incoherent of doofstom

Doelstelling, onderzoeks vragen en verwachtingen

Het doel van deze studie was de effectiviteit en kosteneffectiviteit van het SZP-Dementie in instellingen voor de GGZ te onderzoeken. Een 'mantelzorger-persoon met dementie' paar dat toegewezen is aan een zorgprofessional getraind in het behandelen volgens SZP-Dementie, bevindt zich in de interventiegroep. Een 'mantelzorger-persoon met dementie' paar dat toegewezen is aan een zorgprofessional, die behandelt volgens

de gebruikelijke zorg, bevindt zich in de controlegroep. De onderzoeks vragen en bijbehorende verwachtingen zijn:

1. Wat zijn de effecten van het SZP-Dementie op het aantal opnamen en de tijd tot opname van de persoon met dementie in een verzorgings- of verpleeghuis bij 12 maanden onderzoek (primaire uitkomstmaat), vergeleken met gebruikelijke zorg? De verwachting is een vermindering van het aantal opnamen van mensen met dementie in een verpleeg- of verzorgingshuis in de interventiegroep, in vergelijking met mensen met dementie in de controlegroep na 12 maanden onderzoek. Aansluitend wordt verwacht dat de tijd tot opname van de persoon met dementie in de interventiegroep langer is dan in de controlegroep na 12 maanden onderzoek.
2. Wat zijn de effecten van het SZP-Dementie op de kwaliteit van leven van de mantelzorger en de persoon met dementie na 12 maanden (secundaire uitkomstmaat), vergeleken met gebruikelijke zorg? Er worden positieve veranderingen verwacht in de volgende maten van kwaliteit van leven – gevoel van competentie van de mantelzorger, depressieve symptomen van de mantelzorger, door de mantelzorger ervaren belasting door gedragsproblemen van de persoon met dementie, de ernst van gedragsproblemen en de kwaliteit van leven van zowel de mantelzorger als de persoon met dementie – in mantelzorgers en mensen met dementie in de interventiegroep, in vergelijking paren in de controlegroep na 12 maanden onderzoek.
3. Wat is de kosteneffectiviteit van het SZP-Dementie vergeleken met gebruikelijke zorg? We verwachten dat het SZP-Dementie kosteneffectief is – gemeten als kosten per gewonnen QALY (Quality Adjusted Life Year), oftewel een voor kwaliteit gecorrigeerd levensjaar en als kosten per vermeden opname van de persoon met dementie – ten opzichte van gebruikelijke zorg over een periode van 12 maanden vanuit een maatschappelijk perspectief.

Hoofdstukindeling en voornaamste resultaten

Hoofdstuk 1, de algemene inleiding van het proefschrift, bevat een gedetailleerde beschrijving van de theoretische uitgangspunten van het SZP-dementie voortgekomen uit het Gezinondersteuningsprogramma Dementie. Details over de inhoud van het SZP-Dementie, de training en de trainingsmethoden in het SZP-Dementie, als wel de ontwikkelde materialen om het gebruik van het SZP-Dementie te faciliteren zijn hier beschreven.

Een eerste verkennung van de literatuur naar de effecten van ondersteuningsprogramma's met de intentie om opname van mensen met dementie te voorkomen of uit te stellen laten conflicterende onderzoeksresultaten zien. Daarom is in **Hoofdstuk 2** een systematisch literatuuroverzicht gemaakt om te inventariseren welke ondersteuningsprogramma's met welke interventiekenmerken met de intentie om opname van mensen met dementie te voorkomen of uit te stellen er zijn. Daarnaast is een meta-analyse² uitgevoerd om te bepalen wat het overkoepelende effect is van deze programma's op het aantal opnamen en de tijd tot opname van mensen met dementie.

Uit de meta-analyse blijkt dat ondersteuningsprogramma's de potentie hebben om de kans op een opname significant te verminderen en de tijd tot opname significant uit te stellen, ten opzichte van gebruikelijke zorg of een alternatieve interventie. De analyse van de interventiekenmerken laat zien dat deze multicomponente (meerdere onderdelen, brede aanpak), intensieve, op maat gesneden programma's voorzien in de (unieke) behoeften van mantelzorgers en mensen met dementie op het juiste moment. De combinatie van een actieve betrokkenheid in de behandeling en een ruime keuze uit mogelijke behandelstrategieën en -opties blijkt het werkzame interventiekenmerk te zijn dat effectieve van niet-effectieve ondersteuningsprogramma's onderscheidt. Mogelijkerwijs biedt dit mantelzorgers en mensen met dementie een gevoel van controle over de behandeling wat resulteert in meer tevredenheid met de behandeling, betere naleving en inpassing van de behandeling in de dagelijkse routine en dus betere uitkomsten – minder opnamen en uitstel van opname.

Hoofdstuk 3 beschrijft het onderzoeksontwerp, de verwachtingen (hypothesen), de uitkomstmatten, controlematen³ en meetmomenten van het SZP-Dementie onderzoek. Daarna volgt een globale beschrijving van de onderzoeksmethoden en de statistische analyses om de effectiviteit en kosteneffectiviteit van het SZP-Dementie te evalueren.

² Een meta-analyse is een overkoepelende analyse van de gevonden onderzoeksresultaten van verschillende reeds uitgevoerde onderzoeken op eenzelfde onderzoeksmaat, in ons geval: opname van de persoon met dementie. Door de resultaten uit eerdere afzonderlijke onderzoeken gezamenlijk te analyseren kunnen inzichten verkregen en uitspraken gedaan worden die op basis van de resultaten van elk afzonderlijk onderzoek niet mogelijk waren.

³ Controlematen zijn variabelen die ook van invloed kunnen zijn op het effect van het SZP-Dementie ten opzichte van gebruikelijke zorg. Ze kunnen de relatie tussen de onafhankelijke variabele (behandelgroep) en de afhankelijke variabele (opname van de persoon met dementie) mede verklaren maar ook versturen. Daarom worden deze variabelen, zoals bijvoorbeeld de ernst van dementie, vaak opgenomen in de effectanalyse.

Een procesevaluatie is uitgevoerd om inzicht te krijgen in factoren die van invloed zijn op het vinden van (g)een effect van het SZP-Dementie op de primaire en secundaire uitkomstmaat. Voor de procesevaluatie werden de volgende vragen geformuleerd:

- Zijn zorgverleners getraind in het SZP-Dementie zoals beoogd?
- Hebben mantelzorgers de zorg ontvangen zoals beoogd met het SZP-Dementie?
- Wat is de samenhang tussen de mate waarin het SZP-Dementie is uitgevoerd zoals beoogd en de uitkomstmaten 'opname van de persoon met dementie' en 'kwaliteit van leven de mantelzorger'?
- Wat zijn belemmerende en bevorderende factoren van zorgprofessionals voor de uitvoer van het SZP-Dementie zoals beoogd?

Zorgprofessionals zijn getraind in het SZP-Dementie zoals beoogd als zij de drie trainingen in het SZP-Dementie volledig gevuld hebben. Mantelzorgers hebben de zorg ontvangen zoals beoogd indien zorgprofessionals getraind in het SZP-Dementie, van minimaal de helft van de door hun behandelde mantelzorgers, de volgende resultaten aan de onderzoekers aangeleverd hebben: 1) de inventarisatie van het gevoel van competentie van de mantelzorger om te kunnen zorgen voor een naaste met dementie; 2) de inventarisatie van mogelijke gevoelens van depressiviteit van de mantelzorger. Zorgprofessionals getraind in het SZP-Dementie hebben het SZP-Dementie uitgevoerd zoals beoogd indien zij voor 100% voldaan hebben aan beide eisen.

In **Hoofdstuk 4** wordt het effect bepaald van het SZP-Dementie op 'opname van de persoon met dementie', de primaire uitkomstmaat van het onderzoek, in vergelijking met gebruikelijke zorg na 12 maanden onderzoek. Bijna 100 zorgprofessionals werkzaam in zes instellingen voor de GGZ in vier regio's in Nederland hebben meegedaan aan het onderzoek. Deze zorgprofessionals zijn willekeurig toegewezen aan de groep die training in het SZP-Dementie krijgt (de interventiegroep) of aan de groep die doorgaat met het verlenen van gebruikelijke zorg (de controlegroep). Over deze twee groepen zorgprofessionals zijn bijna 300 mensen met dementie en hun mantelzorger verdeeld door de instellingen voor de GGZ.

Uit de resultaten blijkt dat er geen significant verschil is in het aantal opnamen en de tijd tot opname tussen mensen met dementie in de interventiegroep en mensen met dementie in de controlegroep na 12 maanden onderzoek. Dit bevestigt niet dat het

trainen van zorgprofessionals in het SZP-Dementie effectiever is dan gebruikelijke zorg wat betreft het aantal opnamen en de tijd tot opname na 12 maanden.

Wel is er een interactie-effect⁴ tussen de behandelgroep en het gevoel van competentie van mantelzorgers op de kans van opname na 12 maanden. In lijn met de literatuur blijkt dat in de controlegroep een gering gevoel van competentie van de mantelzorger bij aanvang van het onderzoek samenhangt met een grote kans op opname van de persoon met dementie na 12 maanden. Vice versa hangt in de controlegroep een sterk gevoel van competentie van de mantelzorger bij aanvang van het onderzoek samen met een kleine kans op opname van de persoon met dementie na 12 maanden. Bij mantelzorgers uit de interventiegroep is er geen samenhang tussen het gevoel van competentie en opname van de persoon met dementie. Dit suggereert dat het SZP-Dementie een verslechtering van het gevoel van competentie van mantelzorgers met een gering gevoel van competentie bij aanvang heeft voorkomen. Behandeling in de interventiegroep volgens het SZP-Dementie lijkt ervoor te zorgen dat het gevoel van competentie van mantelzorgers opgetild wordt naar een niveau dat samenhangt met een kleinere kans op opname van de persoon met dementie.

Tot slot is in dit hoofdstuk geëvalueerd of de mate waarin zorgprofessionals in de interventiegroep het SZP-Dementie hebben uitgevoerd leidt tot andere resultaten? Behandeling volgens het SZP-Dementie kan een effect hebben op opname van de persoon met dementie als onderscheid wordt gemaakt tussen zorgprofessionals, die wel en niet het SZP-dementie hebben uitgevoerd zoals beoogd, in vergelijking met de controlegroep. Door deze 'splitsing' van de interventiegroep, ontstaan als het ware drie behandelgroepen: 1) de interventiegroep waarin de zorgprofessional het SZP-Dementie heeft uitgevoerd zoals beoogd; 2) de interventiegroep waarin de zorgprofessional het SZP-Dementie niet heeft uitgevoerd zoals beoogd; 3) de controlegroep die gebruikelijke zorg heeft ontvangen. Bovendien is in deze analyse de variatie in intensiteit van de geboden behandeling meegenomen als een indicatie van de mate waarin mantelzorgers zorg ontvangen hebben zoals beoogd. De intensiteit is gemeten

⁴ In de statistiek spreken we van interactie als het effect van een variabele afhangt van de waarde van andere variabelen. In dit geval, of de uitkomstmaat opname van de persoon met dementie in een verzorgings- of verpleeghuis afhangt van de behandelgroep waarin het mantelzorg-persoon met dementie paар is toegewezen in wisselwerking met de waarde van het gevoel van competentie van de mantelzorger.

als het aantal behandelsessies en het aantal ondersteunende acties door zorgprofessionals na hun inventarisatie van het gevoel van competentie en gevoelens van depressiviteit bij de mantelzorger.

Uit de vergelijking van de drie groepen blijkt dat de mate waarin zorgprofessionals, getraind in het SZP-Dementie, het programma hebben uitgevoerd niet tot andere uitkomsten in het aantal opnamen en de tijd tot opname van de persoon met dementie leidt. De variatie in intensiteit van de geboden zorg aan mantelzorgers is evenmin van invloed op het aantal opnamen en de tijd tot opname van de persoon met dementie.

In **Hoofdstuk 5** wordt het effect bepaald van het SZP-Dementie op 'kwaliteit van leven' van zowel de mantelzorger als de persoon met dementie, de secondaire uitkomstmaat van het onderzoek, in vergelijking met gebruikelijke zorg na 12 maanden onderzoek. Slechts 48 zorgprofessionals, die tezamen 125 paren van mantelzorgers en mensen met dementie behandelden, zijn meegenomen in deze effectanalyses. Het betreft een selecte groep omdat gedurende het onderzoek een aanzienlijk aantal zorgprofessionals uitgevallen zijn door uitval van 'mantelzorger-mensen met dementie' paren. Deze uitval werd vooral veroorzaakt door: opname of overlijden van de persoon met dementie, en het niet langer willen deelnemen aan het onderzoek door de mantelzorger.

Uit een eerste effectanalyse blijkt dat er geen verschil is in de kwaliteit van leven – zoals vastgesteld door het gevoel van competentie, depressieve symptomen, ervaren belasting van de mantelzorger door gedragsproblemen en de ernst van gedragsproblemen van de persoon met dementie - tussen mantelzorgers en mensen met dementie behandeld door zorgprofessionals getraind in het SZP-Dementie en mantelzorgers die gebruikelijke zorg ontvangen hebben. Met andere woorden, dit bevestigt niet dat het trainen van zorgprofessionals in het SZP-Dementie effectiever is dan gebruikelijke zorg wat betreft de secondaire uitkomstmaat kwaliteit van leven van de mantelzorger en de persoon met dementie na 12 maanden onderzoek.

Na deze bevinding is ook geëvalueerd of de mate waarin zorgprofessionals het SZP-Dementie hebben uitgevoerd zoals beoogd leidt tot andere resultaten in de maten van kwaliteit van leven van zowel de mantelzorger als de persoon met dementie? Uit de resultaten blijkt geen effect van het SZP-Dementie op 'kwaliteit van leven' tussen de

drie groepen mantelzorger-persoon met dementie paren. De variatie in intensiteit van de geboden zorg aan mantelzorgers is evenmin van invloed op de kwaliteit van leven tussen de drie behandelgroepen. Echter mantelzorgers wiens zorgprofessional het SZP-Dementie heeft uitgevoerd zoals beoogd hebben wel een beter gevoel van competentie dan mantelzorgers wiens zorgprofessional het SZP-Dementie niet heeft uitgevoerd zoals beoogd. Dit suggereert dat het niet uitvoeren van het SZP-Dementie zoals beoogd één van de redenen kan zijn waarom we geen verschil in de maten van kwaliteit van leven gevonden hebben tussen paren behandeld door zorgprofessionals getraind in het SZP-Dementie en paren die gebruikelijke zorg ontvangen hebben.

Het is opmerkelijk dat de variatie in intensiteit van de geboden behandeling – aantal behandel sessies en aantal ondersteunende acties – niet leidt tot andere resultaten op de primaire en secundaire uitkomstmaat (**Hoofdstuk 4; Hoofdstuk 5**). Uit het literatuuronderzoek blijkt namelijk dat de intensiteit van de geboden behandeling een belangrijk kenmerk is dat effectieve van ineffectieve ondersteuningsprogramma's onderscheidt (**Hoofdstuk 2**). Echter het aantal behandel sessies in deze effectieve ondersteuningsprogramma's is vele malen groter als het aantal behandel sessies in het SZP-Dementie onderzoek. Zo beslaat de behandeling van het Gezinsondersteuningsprogramma Dementie, waarop het SZP-Dementie is gebaseerd, 4 uur per week ondersteuning over een periode van 10 maanden. Zorgprofessionals getraind in het SZP-Dementie hebben mantelzorgers gemiddeld 3 behandel sessies aangeboden over een periode van 12 maanden (**Hoofdstuk 4; Hoofdstuk 5**). We kunnen niet uitsluiten dat de intensiteit van de behandeling mogelijk te laag is geweest voor *alle* in ons onderzoek behandelde mantelzorgers. Dit suggereert dat een lage behandelintensiteit één van de redenen is waarom we geen verschil hebben gevonden in 'opname' en 'kwaliteit van leven' tussen mantelzorgers behandeld door zorgprofessionals getraind in het SZP-Dementie en mantelzorgers die gebruikelijke zorg ontvangen hebben.

Omdat we geen hoofdeffect hebben gevonden van het SZP-Dementie op de primaire en secundaire uitkomstmaat ligt het niet voor de hand een kosteneffectiviteitanalyse uit te voeren. De hypothese dat het SZP-Dementie kosteneffectief is ten opzichte van gebruikelijke zorg is dan ook niet getoetst.

De onverwachte resultaten van het SZP-Dementie op de primaire en secundaire uitkomstmaat roepen nieuwe vragen op en vereisen een beter inzicht in verklarende factoren. Daarom zijn semigestructureerde interviews met zorgprofessionals gehouden om te exploreren welke belemmerende en bevorderende factoren zij ondervonden hebben in het uitvoeren van het SZP-Dementie zoals beoogd. In **Hoofdstuk 6** blijkt dat de waardering voor het SZP-Dementie en de training, medezeggenschap in het besluit deel te nemen aan het onderzoek en het gebruik van het SZP-Dementie, leiderschapsstijl, en secretariële ondersteuning cruciale thema's zijn. Deze thema's kunnen zowel een belemmerende als bevorderende factor voor de uitvoer van het SZP-Dementie zijn. Als zorgprofessionals geen waardering hebben voor het SZP-Dementie en (onderdelen van) de training, ervaren dat zij geen medezeggenschap hebben gehad in het besluit tot deelname, er op de werkvloer geen ondersteuning en aansturing is om het SZP-Dementie uit te voeren, en er geen ondersteuning is vanuit het secretariaat bij het uitvoeren van hun taken, dan belemmeren deze factoren de uitvoer van het SZP-Dementie zoals beoogd. Als er wel aan deze factoren is voldaan, dan bevorderen zij de uitvoering van het SZP-Dementie zoals beoogd. Naast deze factoren speelden ook andere belemmerende factoren in de GGZ als organisatie een rol, namelijk een structurele hoge werkdruk, tijd nood en een groot verloop onder zorgprofessionals en secretaresses. Daarnaast veroorzaakte ten tijde van de introductie van het SZP-Dementie de implementatie van de Diagnose Behandel Combinatie en het Elektronisch Patiënten Dossier een extra administratieve belasting voor zorgprofessionals. De 'noodzaak te produceren' teneinde de instelling voor de GGZ financieel gezond te houden werd hierdoor nog meer evident. In de meeste instellingen had dit beleid, aldus de zorgprofessionals, prioriteit boven de uitvoer van het SZP-Dementie. De belemmerende factoren voor de uitvoer van het SZP-Dementie zijn tezamen dan ook een overtuigende verklaring voor het niet vinden van een effect van het SZP-Dementie op de primaire en secundaire uitkomstmaat in vergelijking met gebruikelijke zorg.

In **Hoofdstuk 7** worden de resultaten van de voorgaande hoofdstukken samengevat en in een breder wetenschappelijk en maatschappelijk perspectief geplaatst. Verklaringen voor de gevonden resultaten als wel enige methodologische overwegingen die de resultaten mogelijk hebben beïnvloed, mogelijke neveneffecten van het SZP-Dementie onderzoek en implicaties voor toekomstig onderzoek, beleid en praktijk worden hier besproken.

Conclusie

Ondersteuningsprogramma's voor mantelzorgers van mensen met dementie kunnen de kans op opname van de persoon met dementie significant verminderen en de tijd tot opname significant uitstellen. Voorwaarde hiervoor is dat de aangeboden behandeling intensief is, mantelzorgers en mensen met dementie actief betrokken worden in de behandeling en zij een ruime keuze hebben uit mogelijke behandelstrategieën en -opties.

Tegengesteld aan de geformuleerde verwachtingen kan niet bevestigd worden dat training van zorgprofessionals in het gebruik van het SZP-Dementie effectief is in vergelijking met de gebruikelijke zorg in instellingen voor de GGZ op de uitkomstmaten 'opname van de persoon met dementie' en 'kwaliteit van leven van de mantelzorger en de persoon met dementie' na 12 maanden onderzoek. Mogelijke verklaringen voor dit onverwachte resultaat zijn: 1) het beperkt uitvoeren van het SZP-Dementie zoals beoogd door zorgprofessionals en 2) een te geringe intensiteit van de geboden behandeling aan mantelzorgers van mensen met dementie. De belemmerende factoren hierbij zijn: a) onvoldoende waardering voor het SZP-Dementie en de training, b) geen medezeggenschap in het besluit deel te nemen aan het onderzoek en het gebruik van het SZP-Dementie in de dagelijkse praktijk, c) onvoldoende leiderschap, d) onvoldoende secretariële ondersteuning, e) een hoge werkdruk en, f) een extra administratieve belasting als gevolg van veranderingen in beleid. Over het algemeen kan gesteld worden dat de concurrerende uitdagingen en belangen op de verschillende niveaus van de organisatie een enorme belemmering waren voor het inbedden en uitvoeren van het SZP-Dementie in de dagelijkse praktijk.

Voor toekomstig onderzoek is het aan te bevelen de "readiness for change", de bereidheid en mogelijkheden voor verandering, te inventariseren vóór de introductie van ondersteuningsprogramma's voor mantelzorgers van mensen met dementie in een organisatie als de GGZ. Aandacht voor belemmerende factoren voor verandering van de dagelijkse praktijk dient onderdeel te zijn van de interventie. Alleen een sterke motivatie op alle organisatieniveaus heeft in beginsel de potentie de introductie van kwaliteitsverbeterende innovaties voor mantelzorgers van mensen met dementie in de praktijk te faciliteren.

Dankwoord

"Niet bestemd voor de elektronische versie"

"Niet bestemd voor de elektronische versie"

"Niet bestemd voor de elektronische versie"

“Niet bestemd voor de elektronische versie”

"Niet bestemd voor de elektronische versie"

"Niet bestemd voor de elektronische versie"

Curriculum Vitae

"Het is zo gegaan dat ik hier ben en kijk."

- Wislawa Szymborska

Anouk Spijker werd op 15 januari 1974 geboren te Nijmegen. Zij groeide op in Twente en doorliep het basisonderwijs aan de RK basisschool Heeckeren te Goor. Na het afronden van het VWO aan het Twinkelcollege te Hengelo, startte zij in 1993 met de studie Pedagogische Wetenschappen aan de Radboud Universiteit Nijmegen (RUN). Daarnaast genoot zij onderwijs bij het Instituut voor Genderstudies (RUN). Voor haar wetenschappelijke stage werkte zij mee aan het onderzoeksproject "Gezinsfunctioneren van gezinnen met een kind met een hersentumor" aan het Kinderoncologisch Centrum en het toenmalige Interdisciplinair KinderNeurologisch Centrum van het UMC St Radboud (UMCN). Voor haar doctoraal examen, dat zij in 2003 succesvol afsloot, heeft zij het project "ICT en gezin: een samenlevingscontract" opgezet en uitgevoerd. Het onderzoek beschrijft hoe gezinnen nieuwe ICT's domesticeren en hoe nieuwe ICT's de machtsrelaties binnen gezinnen mede reproduceren en/of transformeren conform een onderhandelingsgerichte gezinscultuur. Anouk heeft als magazijnmedewerker bij Kijkshop B.V. en als postbode bij het toenmalige PTT Post/TPG Post gewerkt, totdat zij in 2005 bij IQ healthcare (UMCN) aan de slag kon op het project "Systematic care for informal caregivers of dementia patients: an efficient approach?". Dit project vormde de basis voor het promotieonderzoek waarvan in dit proefschrift verslag wordt gedaan. De uitvoering van dit promotieonderzoek heeft zij altijd gecombineerd met medewerking aan andere onderzoeksprojecten en begeleiding van studenten en junioronderzoekers. Daarnaast heeft zij bij het IOWO (RUN) het *Traject basiskwalificatie onderwijs* (Traject BKO) gevolgd voor docentprofessionalisering in onderwijsuitvoering, onderwijsontwikkeling en onderwijsorganisatie. In 2011 startte Anouk als postdoctoraal onderzoeker bij de sectie Biostatistiek, afdeling Health Evidence (UMCN), op het project "Cluster trials in Quality of Healthcare". Dit project had als primair doel de ad hoc samenwerking van de sectie Biostatistiek met de afdeling IQ healthcare om te zetten in een structurele samenwerking, door de ontwikkeling van efficiënte en praktische designs en analysemethoden voor cluster trials in Quality of Healthcare. Met het onlangs door beide partijen bekragtigde besluit om de sectie Biostatistiek een structurele formatie aan te bieden binnen de afdeling IQ healthcare is het project geslaagd. Momenteel werkt Anouk mee aan de ontwikkeling van de Mantelzorgacademie, een initiatief van Thuisverpleging Rijk van Nijmegen.

Publications

This thesis

- Adherence to a psychosocial intervention protocol: the hassles of ever-changing practice in community mental health services. *Spijker A, Vasse E, Adang E, Verhey F, Wollersheim H, Vernooij-Dassen M.* Submitted.
- Influence of adherence to a systematic care program for caregivers of dementia patients. *Spijker A, Teerenstra S, Wollersheim H, Adang E, Verhey F, Vernooij-Dassen M.* Am J Geriatr Psychiatry 2013;21(1):26-36.
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- Effectiveness of nonpharmacological interventions in delaying the institutionalization of patients with dementia: a meta-analysis. *Spijker A, Vernooij-Dassen M, Vasse E, Adang E, Wollersheim H, Grol R, Verhey F.* J Am Geriatr Soc 2008;56(6):1116-28.

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- Wilhelmus, M.M.M. (2006). *Small heat shock proteins and apolipoprotein E in Alzheimer's disease*
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- Graff, M.J.L. (2008). *Effectiveness and efficiency of community occupational therapy for older people with dementia and the caregivers*
- Claassen, J.A.H.R. (2008). *Cerebral hemodynamics in aging: the interplay between blood pressure, cerebral perfusion, and dementia*
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Seventy percent of the people with dementia are cared for at home so their daily functioning depends mainly on the care provided by informal caregivers. The caring role provides satisfaction to many informal caregivers, but is stressful and burdensome to most of them. This can compromise their physical and mental health. Moreover, the strain of caring for people with dementia is not just a social issue, but also an economic one. It places a growing burden on the working population and health systems. Contemporary policies are therefore designed to develop proactive, cost-effective support programs for informal caregivers and people with dementia at home that can prevent overburdening the caregiver which, as a result, may delay or decrease institutionalization of the person with dementia.

In this thesis Spijker describes which psychosocial interventions for caregivers and people with dementia are available and what is known about their effectiveness in preventing or delaying the institutionalization of the person with dementia. Subsequently, Spijker describes the results of the introduction of a psychosocial intervention in community mental health services, a systematic care program for informal caregivers of people with dementia. This program has the potential to prevent overburdening the informal caregiver and may delay or decrease institutionalization of the person with dementia.

This thesis is recommended for family physicians, geriatricians, psychiatrists, psychologists, gerontologists, health managers, case managers, community mental health professionals and other professionals that regularly deal with the management and support of people with dementia and their informal caregivers.

Anouk Spijker (1974) is a certified family educator and currently involved in the establishment of the Caregiver Academy, an initiative of Thuisverpleging Rijk van Nijmegen.

