'More at Home with Dementia' Effects of psychosocial interventions in the community and in nursing homes
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Study protocol of the more at home with dementia program. The effects of training of caregivers of people with dementia on the well-being of the caregiver and the person with dementia, a randomised controlled study.

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ABSTRACT

Background: Caring for a person with dementia (PwD) imposes a heavy burden on the caregiver especially for spouses. This prolonged burden can derail with symptoms of depression, anxiety and physical symptoms in the caregiver as well as early institutionalization of the PwD. An Australian study reported positive effects on the use of a residential caregiver training program, such as it delayed admission to a nursing home, lowered mortality, reduced caregivers’ psychological morbidity and lowered care costs. The principal aim of this replication study is to determine the effectiveness of this program after it is adapted and made fit for use in the Dutch health care system.

Methods and design: A randomized controlled trial study design will be used. The intervention will total five days and takes place in a holiday home. Data will be collected at three points: at baseline and after 3 and 6 months. Primary outcome is caregiver related quality of life after 3 months. The main secondary outcome constitutes PwD related neuro-psychiatric symptoms. Other secondary PwD related outcomes are activities of daily living and instrumental activities of daily living, use of health facilities and facilities for people with dementia, quality of life, agitation, dementia severity and use of psychotropic medication. Caregiver related secondary outcomes are experienced burden and objective burden, experienced health and use of health care facilities, use of psychotropic medication, depression and anxiety and perseverance time.

Discussion: The outcomes of the study will be used to determine the effectiveness of the intervention and, if confirmed, to introduce this program in usual care treatments. Furthermore, if shown to be successful, an effort will be made to further develop the training program based on experiences and recommendations of the participants after the study is completed.
BACKGROUND

People with dementia (PwD) prefer to live as long as possible at home in their community. Currently, approximately 70% of people with dementia in The Netherlands live in the community of which a large part is dependent on around the clock support from next of kin. This support is usually provided by caregivers such as spouses, children or other relatives. It is expected that the number of people with dementia will almost double the next 20 years, which means that even more relatives will be called upon to care for a relative with dementia. Caregivers of patients with dementia (PwD) are at risk of experiencing high levels of burden which may ultimately lead to mental illnesses, like depression or early institutionalization of the PwD.

A prospective cohort study reported that half of the caregivers experienced high levels of burden which increased over time leading to aggression, depression, anxiety and reduced physical health. Evidence also suggests that caregivers are at increased risk of developing serious illnesses and mortality. Research on the effect of long-term caregiving in general showed that some of its consequences may be long-term as well, i.e. caregivers’ psychological well-being did not improve to levels comparable to non-caregivers after nursing home admission or death of the person they cared for.

The high levels of burden the caregiver is exposed to can also enhance the risk of nursing home placement as was shown in a review on causes of nursing home placement, namely poorer cognition and neuropsychiatric symptoms (NPS) of the PwD. Caregiver psychological morbidity was also a predictor of mortality of the PwD.

These findings underpin the importance of developing effective interventions that are aimed at the caregiver because both the caregiver and the recipient are likely to benefit. There is extensive literature available on this issue but this literature is very heterogeneous with respect to interventions and outcomes which makes it difficult to determine the most effective and relevant interventions. In general, reviews of studies reported mild to moderate effects. Interesting were subgroup outcomes, which showed stronger positive effects. The interventions in these subgroups incorporate the following elements: group training programs, social support, cognitive interventions, intensive programs, multi-model programs with multiple components, programs which focus on dyad caregiver/PwD, training
the caregiver, involving family of the caregiver, adapting to the needs of the caregiver and giving psycho-education. Reviews focusing on the effects of respite care showed that this intervention generates no beneficial effect. A residential caregiver training program in Australia which incorporates most of the components that showed to be effective appears to be promising as it delayed admission to a nursing home, lowered mortality, reduced caregivers’ psychological morbidity and lowered care costs. This program is also being investigated in another study (entitled Going to Stay at Home program) which protocol was recently published.

In the Netherlands, dementia is commonly diagnosed at geriatric outpatient clinics by general practitioners (GPs) or elderly care physicians. Following diagnosis patients are referred to a case manager specialized in dementia who supports the caregiver, but also gives advice concerning e.g. home care, day care and admission to nursing homes. However, there are significant local differences with regard to availability of and accessibility to these health services.

After adapting the program, when necessary, to the Dutch practice, this study aims to determine its effectiveness based on the following outcomes:

1. Primary outcome; caregiver related quality of life after 3 months.

**METHODS AND DESIGN**

**Study design**

A randomized controlled trial study design will be used. Participants can apply for participation by returning a signed informed consent. After receipt of this consent participants are randomly assigned to the intervention or the control group. This will take place by means of block randomization. The randomization sequence is recorded in a separate document unavailable for the research assistant who is
enrolling the participants. Data will be collected at three points in time: at baseline and during meetings at 3 and 6 months after the intervention. Additionally, information on the use of care and health facilities is collected by telephone after six and eighteen weeks. People who drop out of the intervention or control group will be contacted at regular times by phone to request information, if applicable, on the date of admission to a nursing home or death. The study is registered at the Dutch Trial Register; trial ID is NTR5775.

**Control group**

Participants in the control group receive care-as-usual. They are visited by a research assistant at baseline and after 3 and 6 months and contacted by telephone at six and eighteen weeks to collect data.

**Recruitment of participants**

Participants will be recruited following a referral by professionals and by self-referral. To arouse interest and promote participation, the public will be informed about this study via public and social media. Likewise, by also promoting the project under geriatricians, case managers, day care centers, mental health institutions for elderly and general practitioners, participation rates should benefit. Publicity, targeting directly at potential participants, will be generated by a radio interview, an advertorial, Facebook, a website and by the website of the Dutch Alzheimer Association (Alzheimer Nederland).

**Inclusion criteria for people with dementia**

- confirmed diagnosis of dementia according to Diagnostic and Statistical Manual of Mental Disorders (DSM IV criteria)
- living at home with primary caregiver
- able to understand and communicate in Dutch

**Exclusion criteria for people with dementia**

- refusal to participate verbal or by behavior
- aggression or wandering behavior
**Inclusion criteria for caregivers**
- able to understand and communicate in Dutch

**Intervention**

We will use the course material and facilitators guide of the ‘Going to Stay at Home’ program both for structure and content of the sessions. The content will be adapted only when necessary e.g. when not applicable in the Dutch situation.

**Setting**

The intervention will total five days and takes place in a holiday home in the vicinity of Rotterdam with accommodation to host six couples, each of them having their own bedroom. Groups will consist of three to six PwD-caregiver dyads.

**Program for caregivers**

The caregivers will attend 14 psycho-educational sessions. These will be delivered in an informal setting by a psychologist, physiotherapist, occupational therapist, elderly care physician, speech therapist, dietician and social worker. Sessions include didactic elements, group work, modeling and role play.

**Sessions**

1. Combating social isolation: participants will be stimulated to share their experiences and will be stimulated to explore their social contacts and support and their social needs. Also, an open and supportive relationship between caregivers can be established during the intervention and the following meetings.
2. Medical aspects of dementia: relevant information will be provided about dementia. Different types of dementia and changes in behavior as well as accompanying symptoms like apraxia, aphasia will be discussed. Furthermore, frequently occurring complications like delirium and depression will be explained.
3. Planning for the future: In this session, the need to plan for future emergencies and unforeseen events will be discussed. Also issues like driving, legal and financial matters and Advance Care will be discussed. These issues will be
explored in the session and participants are advised to explore this further at home preferably together with their partner and if necessary with help of relatives or professionals.

4. Re-roling: This session will explore issues regarding changing roles and responsibilities between the caregiver and the PwD: caregivers will be assisted in considering ways to take over tasks from the PwD while maintaining his or her dignity. Then attention will be paid to the new responsibilities of caregivers and to how to deal with these.

5. Reminiscence and orientation: caregivers will be provided with information on techniques of reminiscence (e.g. use of life history book, music, objects that represent important events) and environmental reality orientation (e.g. signs and clocks especially designed for PwD).

6. Communication: in this session information will be given about aphasia that a PwD may experience and how this affects communication. Strategies that can be used to deal with this will be discussed. Also, attention will be paid to possible problems with swallowing.

7. Assertion: information will be given about assertive, non-assertive and aggressive behaviors and strategies to cope with criticism. Important is that the rights of the caregiver are observed and needs are heard and met.

8. Therapeutic use of activities: the purpose of this session is to identify activities that are meaningful and enjoyable for the PwD but are increasingly difficult to perform. The caregivers will be provided with knowledge of activity analysis that enables them to break down these activities into component steps and to modify or eliminate steps that prevent the PwD from performing them.

9. Organization of work and safety in the home: this session is about simplifying, prioritizing and using outside assistance of work to achieve a better balance between work and leisure. Also, attention will be paid to safety at home.

10. Nursing skills: issues associated with dementia like incontinence, personal care, medication and mobility will be discussed. Caregivers will be provided with information on how to give personal care like washing, assistance with dressing, to rise from a chair or bed and manage incontinence.

11. Fitness: benefits of exercise for both the caregiver and the PwD will be emphasized. If possible, exercises or walks will be included in the program. In case of disability, alternatives for walking will be discussed.

12. Nutrition: in this session attention will be paid to the changes in diet, food intake, food preferences and nutritional needs of the PwD. Caregivers will be given advice how to deal with this and also to improve the eating experience.
13. Caring for yourself: in this session caregivers will be given the opportunity to identify their need for support. Also, attention will be paid to stress management and relaxation techniques.
14. Using community services: information will be given about the large variety of relevant support services (e.g. day care, support at home) and how to get access to these services. Special emphasis will be given to the financial aspects of these services.

**Program for the PwD**

The program for the PwD is divided into general pleasant activities and sessions focused on the handicaps that come with dementia. General activities include relaxation, physical activity, social interaction and creativity; sessions focused on handicaps that coincide with dementia include information on changes in e.g. cognition caused by dementia and coping with loss of memory and reminiscence. The program will be adjusted according to the possibilities and the wishes of the group.

**Outcome measures**

**Description of outcome instruments**

*Primary outcome caregivers*
- Care Related Quality of Life - 7 dimensions (CarerQol-7D): scores seven items on care related satisfaction, relational problems concerning the PwD, mental health, time management, financial problems, social support and physical health of the caregiver. All items are scored on a scale running from no problems, some problems to a lot of problems. These scores will be transformed to represent a utility score or tariff between 0 and 100 by adding up the relative weights of the items (part of The Older Persons and Informal Caregivers Survey Minimum Data Set: TOPICS-MDS)

*Secondary outcomes caregivers*
- CarerQol - visual analog scale (VAS), whereby 0 means completely unhappy and 10 completely happy (part of TOPICS-MDS).
- Self-Rated Burden Scale - VAS is a self-report measure of burden experienced in the caregiver role. Rating takes place on a scale from 0 to 10, higher scores indicate higher burden \(^{30}\) (part of TOPICS-MDS).
- Objective burden caregiver: number of hours per week spent on caregiving (part of TOPICS-MDS).
- RAND-36/short form (SF)-36 is used to measure experienced health or health related quality of life. The survey includes scales concerning physical functioning, role limitations due to physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and general mental health. Higher scores indicate better health \(^{31}\) (part of TOPICS-MDS).
- EuroQol-5 Dimensions + Cognition (EQ-5D+C): health instrument assessing quality of life on five dimensions: mobility, self-care, activities, pain and discomfort, anxiety and depressed mood with an additional question concerning cognitive problems. All items are scored with no problems- some problems – extreme problems which can be transposed in 1-2-3 \(^{32,33}\) (part of TOPICS-MDS).
- Psychotropic drugs use: this will be categorized in antipsychotics, anxiolytic drugs, antidepressants and hypnotics.
- Center of Epidemiologic Studies Depression (CES-D) screens for depressive symptoms on 20 items. Each item can be scored as rarely, some or a little of the time, occasionally or a moderate amount of the time and most or all of the time. This score is categorized as transposed in 0-1-2-3 and the maximum score is 60; 16 is an indication for depression \(^{34}\).
- Hospital Anxiety and Depression Scale, anxiety subscale (HADS-A) is a fourteen-item scale that generates ordinal data, developed to determine levels of anxiety or depression. Seven of the items relate to anxiety and seven relate to depression, each item on the questionnaire is scored from 0-3 implying that a person can score between 0 and 21 for either anxiety or depression. Higher scores indicate more symptoms \(^{35}\).
- Perseverance Time: the period that the caregiver indicates that he or she is capable of maintaining the current level of care if the situation remains stable. Perseverance time was categorized in less than a week, more than a week but less than a month, more than a month but less than six months, more than six months but less than a year, more than a year but less than two years or more than two years \(^{36,37}\).
Secondary outcomes PwD

Main outcome PwD:
- Neuropsychiatric Inventory 12-item (NPI) is an informant-rated measure of the frequency and severity of neuropsychiatric symptoms such as agitation, psychosis, depression and apathy in people with dementia (NPS), collected through an interview with the caregiver. Higher scores indicate more and more-severe NPS 38.

Other outcomes PwD:
- Functional status will be assessed with an adapted version of the Katz index of independence basic activities of daily living (ADL), instrumental activities of daily living (IADL) supplemented with a question concerning mobility: Katz-15 (part of TOPICS-MDS). Caregivers are asked if assistance is needed for six basic functions like bathing and dressing and eight instrumental functions like telephoning and food preparation. Scores are binary: 0 is independent, 1 is dependent, resulting in a sum score between 0-15, with a higher score indicating higher level of dependency 39.
- Resource utilization: use of medical facilities as well as admission to the care of a nursing home starting from a week before baseline during the entire follow-up period (part of TOPIC-MDS). Use of services, such as home care, day care and visits of case managers in the week before assessment will be recorded at baseline and at three and six months.
- Dementia Quality of Life Instrument DQI: will be used to assess quality of life of the person with dementia and covers five health domains (memory, orientation, dependency, social activities and mood). The DQI is derived from EQ-5D to measure quality of life in mild to moderate severe dementia 40.
- Cohen-Mansfield Agitation Inventory- Community (CMAI-C) is an informant-rated measure of the frequency of agitated behavior in people with dementia, collected through an interview with the care-giver. The range is from 29 to 203, higher scores indicate more frequent agitation 41.
- Geriatric Deterioration Scale (GDS) will be used to classify people with dementia based on the relative severity of their cognitive impairment and functional status: range is from one to seven, higher scores indicate more severe dementia 42.
Focus group
At meetings after three and six months caregivers are asked which sessions of the intervention were most helpful and whether the information they received actually applied to practice. Also, caregivers are asked what information or subjects they missed in the intervention and if some sessions were not useful and could just as well have been omitted. In preparation to its implementation in regular care participants were asked how much they would have been prepared to pay for the training if it had not been a subsidized study.

Statistical analysis
Sample size calculation
Sample size calculation is based on the effects found in the first Australian study. In this study 96 couples were included, 65 in the immediate and waiting group and 31 in the control group. With 144 couples, equally divided over intervention and control groups, there should be enough power to demonstrate a medium effect size (average 0.5): significance of 0.05, power of 0.8 and anticipated attrition rate of about 10%.

Outcome analysis
For the primary outcome, CarerQol 7D at 3 months, a linear regression model will be developed to test the response variable for differences between intervention and control (care-as-usual) groups adjusted for the baseline outcome scores.

For the primary equation, a primary intention-to-treat (ITT) analysis will be performed. Also, a secondary per-protocol (PP) analyses will be conducted. The ITT population includes all information from participants randomized to each treatment arm, whereas the PP population only includes information of those who completed the program in the treatment arm to which they were allocated.

Secondary outcome variables are Neuropsychiatric symptoms (NPI), quality of life, Rand-36, EQ-5D, CarerQol -VAS, Self-Rated Burden Scale, psychotropic drugs (yes/no), CES-D, HADS-A, perseverance time, KATZ 15, DQI, care consumption (yes/no), CMAI, and GDS were all measured at baseline and after 3 and 6 months and compared between intervention and control (care-as-usual) and adjusted for baseline values.
For the secondary outcome variables multilevel analyses will be used to account for the dependency of repeated measurements. The restricted iterative generalized least squares algorithm will be used to estimate the regression coefficients, while the Wald test will be used to obtain a p-value for each regression coefficient. Linear or binary multilevel analysis will be conducted depending on outcome measure. Subgroup analyses will be performed to assess the heterogeneity of treatments effects.

The assumptions of normality and homogeneity of the variance in the linear regression models will be assessed by inspecting normal probability plots and plots of standardized residual vs. predicted values. If assumptions are not met variables will be transformed in order to comply with the assumptions. If this does not yield acceptable distributions, dichotomization of variables or non-parametric statistics will be considered. All statistical tests will be performed two-sided at a 5% significance level.

**Missing data**

We will conduct a missing value analysis to identify patterns in missing values of variables. Subsequently, we will analyze whether baseline characteristics differ between participants with missing data and those without missing data for the response variables at the final measurement (6 months). Based on these analyses we will infer whether missing values are likely to be missing (completely) at random (MCAR, MAR) or missing not at random (MNAR). In the event of MCAR or MAR we will use multiple imputation techniques and present the outcome of analyses from both unimputed and unimputed and imputed data. In the event of MNAR we will not replace missing values and conduct an available case analysis.

**Ethics**

The study has been submitted for approval to the Human Research Ethics Committee University of Groningen, The Netherlands. It was concluded that no assessment was needed based on the Law considering Scientific Research in Humans. Written consent will be obtained from all participating caregivers and if possible from their partners with dementia.
DISCUSSION

More at Home with Dementia (Beter Thuis met Dementie) is a caregiver training program that is adapted from a successful residential care setting in Australia to an intervention at a holiday location in the Netherlands. The presented study aims to determine the effectiveness of this intervention after adapting it to the Dutch health care and society and performed outside a nursing home or hospital. Primary and secondary outcomes for caregivers and individuals with dementia will be assessed with standardized measures. Additionally, qualitative outcomes for caregivers will be collected in focus groups. The outcomes of the study will be used to determine effectiveness of the intervention and if confirmed we will advocate to implement the training in usual care. Also, with the quantitative and qualitative results based on the experiences and recommendations of the participants at hand we will also explore the more generic aspects of this intervention, as many of the content items of the sessions are not very dementia specific. It is, therefore, conceivable that the content of the training, possibly also applies to other target groups with other chronic diseases such as M. Parkinson and Multiple Sclerosis and for caregivers who don’t live with the patient with dementia like children or other close relatives and friends.

We believe that, considering the demographic changes and experienced burden, approaching care problems in dementia should be targeted at both patient and informal caregiver, and therefore studies like this one are of both scientific and societal importance.

ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>PWD</td>
<td>Person With Dementia</td>
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<tr>
<td>GDS</td>
<td>Geriatric Deterioration Scale</td>
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<tr>
<td>NPS</td>
<td>Neuropsychiatric Symptoms</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<td>DSM</td>
<td>Diagnostic and Statistical Manual of Mental Disorders</td>
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<td>CarerQol-7D</td>
<td>Care Related Quality of Life 7 dimensions</td>
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<td>TOPICS-MDS</td>
<td>The Older Persons and Informal Caregivers Survey Minimum DataSet</td>
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<tr>
<td>VAS</td>
<td>visual analog scale</td>
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<tr>
<td>RAND-36/SF-36</td>
<td>RAND-36/short form 36</td>
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<tr>
<td>Acronym</td>
<td>Full Form</td>
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<td>EQ-5D+C</td>
<td>EuroQol-5 Dimensions + Cognition</td>
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<tr>
<td>CES-D</td>
<td>Center of Epidemiologic Studies Depression</td>
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<td>HADS-A</td>
<td>Hospital Anxiety and Depression Scale, anxiety subscale</td>
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<tr>
<td>ADL</td>
<td>Activities of Daily Living</td>
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<tr>
<td>IADL</td>
<td>Instrumental Activities of Daily Living</td>
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<tr>
<td>DQI</td>
<td>Dementia Quality of Life Instrument</td>
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<tr>
<td>CMAI-C</td>
<td>Cohen-Mansfield Agitation Inventory- Community</td>
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<td>ITT</td>
<td>intention-to-treat</td>
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<tr>
<td>PP</td>
<td>per-protocol</td>
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<tr>
<td>M(C)AR</td>
<td>missing (completely) at random</td>
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<tr>
<td>MNAR</td>
<td>missing not at random</td>
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REFERENCES

17. Parker D, Mills S, Abbey J. Effectiveness of interventions that assist caregivers to support people with dementia living in the community: a systematic review. *Int J Evid Based Healthc.* 2008;6(2):137-172.


