

# Effects and Costs of a Day Care Centre Program Designed for People with Dementia-A 24 Month Controlled Study

Anne Marie Mork Rokstad<sup>1\*</sup>, Ingeborg Halse<sup>1</sup>, Signe Tretteteig<sup>1</sup>, Maria Lage Barca<sup>1</sup>, Øyvind Kirkevold<sup>1</sup>, Louise McCabe<sup>2</sup>, Geir Selbæk<sup>1</sup>, Liv Taranrød<sup>1</sup>, Ingelin Testad<sup>1</sup>, Solfrid Vatne<sup>3</sup>, Corinna Vossius<sup>4</sup>, Anders Wimo<sup>5</sup> and Knut Engedal<sup>1</sup>

<sup>1</sup>Ageing and Health, Norwegian Centre for Research, Education and Service Development, Vestfold Hospital Trust, 3103 Tønsberg, Norway

<sup>2</sup>School of Applied Social Science, University of Stirling, Scotland

<sup>3</sup>Molde University College, Norway

<sup>4</sup>Centre for Age-related Medicine, Stavanger University Hospital, Norway

<sup>5</sup>Division of Neurogeriatrics, Department of Neurobiology, Care sciences and Society, Karolinska Institutet, Stockholm, Sweden

## Abstract

**Background:** Attending day care centres with programs specifically designed for patients with dementia is believed to postpone admittance to nursing home as well as increase quality of life and well-being for both patients and their family carers. Therefore, the Norwegian Ministry of Health and Care Services is presently offering funding to all municipalities that wish to establish day care centre programs for this group of patients. There is only limited knowledge on the effectiveness of day care centre programs designed for patients with dementia. Our research group aims to investigate to what degree attendance in day care centres with programs designed for people with dementia is effective to postpone admittance to nursing home care, to enhance quality of life for the patients and to relieve burden of care for the family carers.

**Methods/Design:** The study is a quasi-experimental trial with a comparison group and a qualitative inquiry. Four hundred patients with dementia and their family caregivers will be included in the trial. Assessments will be made at baseline, after one and two years. Data collection will be made at three levels; at patient level with measures of cognition, depression, coping, quality of life, functioning in activities of daily living, neuropsychiatric symptoms and time of death; at family carer level with measures of depression, coping and burden; and at societal level with measures of nursing home admittance, hospital stays and use of other health and social care resources. For the qualitative analysis, 20 dyads of patients receiving a day care program and their family carers will be asked to participate. The main focus will be to explore how the day care centre programs affect both the patients and the family carers' daily life. Five of these dyads will be followed closely throughout two years.

**Trial registration:** Clinical Trial number NCT01943071.

**Keywords:** Dementia; Day care centre programs; Patients, family carers; Cost-consequence analysis.

## Background

The prevalence of dementia worldwide will reach 115.4 million in 2050 [1]. In Norway about 70,000 people have dementia and 60-65 % of them live in their own homes, either alone or together with a family member [2]. The remaining patients with dementia live in nursing homes and other long term care facilities [3]. The need for assistance from family carers and social and health care services, in the activities of daily living, for patients with dementia increases as the disease progresses. In the severe stages of the disease, the patients need constant assistance. At this level of deficiency most patients with dementia are admitted to nursing home care in Norway. Since the number of patients with dementia will double in 30 years due to increased number of older persons in the population, it is reasonable to assume that the need for care in nursing homes will increase and so will the costs associated with care. Thus, we need to know if a day care centre program could increase the quality of life for patients with dementia, relieve the burden of care for the family members and above all, postpone nursing home admittance.

In Norway day care centre programs as well as domiciliary nursing, and nursing-home care are within the jurisdiction of the local authorities. They have the responsibility both for the capacity and the quality of these services. Late in the 2007, the Norwegian Ministry of Health and Care Services launched the national dementia plan "Norwegian Dementia Plan 2015-making the most of the good days" [4]. One of the priorities in this plan is that patients with a dementia diagnosis should have access to a day care centre program close to

their own home. From 2012, the Ministry has given funding to all municipalities that establish a day care centre designed for patients with dementia. The goal of the Ministry is to provide a day care program for 5,000 new patients within 2015. One of the reasons why the Ministry is prioritizing this is that a day care program is expected to be less expensive than care in nursing homes or other living accommodation [5]. Thus, it is crucial to collect valid knowledge about whether day care centre programs for patients with dementia can postpone admittance to and shorten the stay in nursing homes. Furthermore, evaluations of the impact of day care programs on quality of life for the patients with dementia and the family carers, and costs associated to care, are urgently needed.

There is only limited knowledge on the effectiveness of day care centre programs designed for patients with dementia. In a review from 2011, the Norwegian Knowledge Centre for the Health Service

**\*Corresponding author:** Anne Marie Mork Rokstad, RN and PhD, Researcher and Post doc at Ageing and Health, Norwegian Centre for Research, Education and Service Development, Vestfold Hospital Trust, 3103 Tønsberg, Norway, Telephone: +47 99509819; E-mail: [anne.marie.rokstad@aldringoghelse.no](mailto:anne.marie.rokstad@aldringoghelse.no)

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(NOKC) could only find eight published studies of moderate to poor quality [6], and only two of these were randomized controlled trials. At societal level, two studies reported lower costs for the day care centre group, due to reduced admittance to acute hospitals [5] or nursing homes [7] but cost effectiveness could not be confirmed [8]. At patient level, two studies reported a significant reduction of Neuropsychiatric Symptoms (NPS) in favour of the patients in the day care centres [9,10]. Two studies reported that patients in the day care centre group were sleeping better [10,11]; one study reported increased well-being [10] and one study reported less use of psychotropic drugs by the patients in the day care centre group [12], compared to patients with dementia that did not attend a day care centre. None of the studies reported effect on the patients' cognitive functions. At family carer level, two studies reported less burden and stress [12,13], whereas one study reported less depression among the family carers in the day centre group, compared to the family carers of those not attending a day care centre [13].

The report of the NOKC concludes that the results of the different studies vary and that the quality of the studies is low or very low for all relevant outcomes. Importantly, based on the available literature it is not at all possible to evaluate the questions about the costs and cost effectiveness associated with day care centre. The Swedish Council on Technology Assessment in Health Care came to the same conclusion about the evaluation of the costs effectiveness [14]. Consequently, it is not possible to determine with certainty to what extent day care programs for patients with dementia are effective from a clinical viewpoint.

An observational study carried out between 2007 and 2010, including 219 patients from 28 local authorities with dementia in day care centres in Norway, showed that most of the patients attending the centres had a variety of NPS and were to a large degree dependent in the activities of daily living (ADL). About 75% received domiciliary care services from district nurses [15]. One in three patients left the day care centre within a mean observation time of 20 months, mainly due to nursing home placements or death. Those who dropped out had more severe dementia, more NPS, were more dependent in ADL and their family carers had higher levels of burden. This study shows that the patients were probably offered a day care centre program too late [15] and that the day care centres were possibly used as a respite care service for patients waiting for nursing home placement. This was also one of the findings in the study by Engedal published fourteen years ago [5], where 15 out of 38 patients with dementia left the day care program within 12 months due to nursing home placements.

The main objective of this study is to explore the effects of a day care centre program for patients with dementia on postponing nursing home placement and reducing associated costs. The proportion of patients permanently admitted to nursing home during a period of 24 months will be the primary outcome for the effect and the cost-consequence analysis. Secondary outcomes will be measured after 12 and 24 months at three levels; 1) on patient level (quality of life, functioning in ADL, cognition, depression, NPS and death), 2) on family carer level (level of burden, depression and quality of life) and 3) on societal level (days spent in nursing home within the two years of participation, the use of health and social care resources and the costs associated with care).

Additional objectives are to describe the organization of various day centre care programs and the activities offered to the patients, the co-operation between the professional caregivers in the day care centres and the family carers, and lastly to examine the patients' and

family carers' experiences of the impact of the day care centre programs on their everyday life.

## Design and Methods

### Study design and setting

A quasi experimental trial with a comparison group will be performed to evaluate the effect of the day care centre programs by comparing results (proportion of patients permanently admitted to nursing-home care and outcomes on patient-, family carer- and societal level) from patients attending (intervention group) and patients not attending (comparison group) a day care centre program designed for people with dementia using standardized assessment tools. Furthermore, a survey will be used to explore the communication and co-operation between the professional staff at the day care centre and the family carers by administering questionnaires developed for this purpose. Finally, qualitative interviews will be made with 20 dyads of patients and family carers to collect their in depth experience with the day care centre program. Five of these patients and their family carers will be followed closely as case examples for two years.

### Study sample

#### Inclusion criteria:

- Age of 65 years or more and living at home
- Patients in the day care centre group must have attended the centre for at least four weeks and have been there no longer than 12 months
- Dementia of either Alzheimer's type, vascular dementia, dementia with Lewy bodies/Parkinson's disease or a mixture of these types of dementias
- Capacity to give informed consent as judged by the professional caregivers
- A Mini Mental Status Examination (MMSE) score of  $\geq 15$
- Having a family carer willing to participate, who see the patients personally at least once a week
- Attending the day care centre program at least twice a week (intervention group)

#### Exclusion criteria:

- Having applied for nursing home placement
- Suffering from a serious co-morbid physical disorder with life expectancy less than six months

**Power calculation and recruitment:** The primary outcome will be admittance to nursing home care at the 24 month follow-up. In accordance with the results of Engedal [5] and Taranrød [15] we expect that 45% of the patients receiving day centre care will be admitted to nursing home care within 24 months, whereas that will be the case for 62% of the patients of the comparison group. Consequently, we will need 172 patients in each group to demonstrate a difference between the groups with 80% power and p-level of 0.05. We will include 200 patients/family carer dyads in each group, allowing for a 15% drop out rate. Thus the study sample will consist of 400 patients with dementia living at home and in addition one of their primary family carers. Two-hundred dyads of participants (patient and family carer) will constitute the intervention group presumed that the patients attend day care centre programs at least twice weekly. Two-hundred dyads of patients

with dementia without such service living at home and their family carer will act as the control group. Participants in the intervention group will be recruited from day care centres designed for patients with dementia and patients in the control group will be recruited from local authority dementia teams and in-home care service offices. The participants will be recruited from municipalities spread across Norway.

In the qualitative study 20 dyads of patients receiving a day care centre program and their family carers will be invited to participate. They will be recruited from different kinds of day care centre programs making it possible to explore the subjective experience of attending a variety of day care centre programs.

**Method**

**Intervention:** The intervention consists of a stay in a day care centre specially designed for patients with dementia for at least two days a week. Any type of day care centre with a specialized program designed for people with dementia is eligible for inclusion in the study.

**Control condition:** The control condition is “care as usual”.

**Data collection**

Trained psychiatric or geriatric nurses will be recruited as assessors, and before start of the study they will receive information about the study and be trained in the use of the various assessment scales.

**Baseline information:** At baseline, as the patients are included in the study, demographic data of patients and family carers such as gender, age, marital status, living condition and educational level, will be collected. Additionally, a list of previous and present disorders and the use of drugs will be collected. Two experienced psychiatrists will independently diagnose dementia according to the ICD-10 criteria [16] using all the available information from the data collection and the day care centre or dementia teams’ records. Divergences in diagnoses will be settled in a consensus meeting. The following measures on the patient level will be tapped (see table 1): The Mini Mental State Examination (MMSE) [17], the Clock Drawing test (CDT) [18], the Trail Making Test A (TMT-A) [19], the 10 word test of the Consortium to Establish a Registry in Alzheimer’s Disease (CERAD) [20] and the Clinical dementia Rating Scale (CDR) [21], the Montgomery Asberg Depression Rating Scale (MADRS) [22] and the Cornell Scale for Depression in Dementia (CSDD) [23] by interview with a family carer. The Neuropsychiatric Inventory questionnaire (NPI-Q) [24,25] will be used to evaluate NPS. Function in every day life activities will be measured with Lawton and Brody’s Physical Self-Maintenance Scale and Instrumental Activities of Daily Living Scale (PADL and IADL) [26]. Quality of life (QoL) will be measured with the Quality of Life-Alzheimer’s Disease (QoL-AD) [27] scale by interviewing both the patients and a family carer, and coping with the Locus of Control of Behaviour (LCB) [28]. The Anosognosia Rating Scale (REED) [29] will be used to measure the patients’ level of insight of their deficiencies. To diagnose dementia a structured assessment of symptoms, debut, type and course will be used.

At family carer level we will perform measurements with the QoL-AD, the MADRS, the LCB and burden of care with the Relatives’ Stress Scale (RSS) [30] (see table 1).

Resource use at societal level will be analysed using the Resource Utilization in Dementia (RUD) instrument [31,32], which collects data of the use of formal and informal care the last month. Costs connected to the use of services will be calculated based on the RUD data. Additionally, cost of drug use will be calculated based on the

medication lists. A generic measure, the EQ-5D [33], will be used to calculate quality adjusted life years (QALY’s) (see table 1).

**Follow-up information at 12 and 24 months:** All tests and evaluation scales that were used at baseline will be repeated at 12 and 24 months (Table 1). In addition, all admittance to nursing homes (short and long term care), hospitals, and increased services given by the domiciliary care offices will be collected by telephone interviews with the family carers and/or professional caregivers in alternate months. Dates of nursing home placement and/or death will be recorded, both short-term care and long-term care when appropriate.

**The questionnaire on co-operation:** After attending the day care centre for at least six months we wish by the use of a questionnaire to ask family carers, and the patients with mild degree of dementia about their experiences with the service and the co-operation with the care staff at the day care centre. The questions in this brief survey will be developed based on a literature review, the use of an expert group and tested on a pilot sample as part of the development process.

**The organization and content of various day care programs:** For the analysis of costs associated with the care we need to know how the various day care programs are organized and administered. At baseline, information on such as opening hours, number and occupation of care staff, cost of the users’ transport, meals and the activities taking place on a daily basis will thus be collected. In order to thoroughly evaluate the effects of the day care programs we also need to know their content. A care staff member representative in the day care centres will be asked

Overview of scales, informants and time of measurements at the patient level			
Tests	Baseline	After 12 months	After 24 months
MMSE	PWD	PWD	PWD
CDT	PWD	PWD	PWD
TMT-A	PWD	PWD	PWD
CERAD	PWD	PWD	PWD
CDR	FC, PC	FC, PC	FC, PC
MADRS	PWD, FC	PWD, FC	PWD, FC
CSDD	FC, PC	FC, PC	FC, PC
NPI	PWD, FC	PWD, FC	PWD, FC
PSMS, IADL	PWD, FC	PWD, FC	PWD, FC
OoL-AD	PWD, FC	PWD, FC	PWD, FC
LCB	PWD, FC	PWD, FC	PWD, FC
EQ-5D	PWD, FC	PWD, FC	PWD, FC
RUD	FC	FC	FC
Overview of scales, informants and time of measurements at the family carer level			
MADRS	FC	FC	FC
OoL-AD	FC	FC	FC
LCB	FC	FC	FC
RUD	FC	FC	FC
RSS	FC	FC	FC
Overview of scales, informants and time of measurements at the societal level			
EQ-5D	PWD, FC	PWD, FC	PWD, FC
RUD	FC	FC	FC

PWD: person with dementia; FC: family carer; PC: professional carer  
MMSE: Mini Mental State Examination; CDT: Clock Drawing test; TMT-A: Trail Making Test A; CERAD: 10 word test of the Consortium to Establish a Registry in Alzheimer’s Disease; Montgomery Asberg depression Rating Scale; CSDD: Cornell Scale for Depression in dementia; NPI-Q: Neuropsychiatric Inventory questionnaire; PSMS; IADL: Lawton and Brody’s Physical Self-Maintenance Scale and Instrumental Activities of Daily Living; OoL-AD: Quality of Life- Alzheimer’s Disease; LCB: Locus of Control of Behaviour; RUD: Resource Utilization in Dementia; RSS: Relatives’ Stress Scale

**Table 1:** Measurements to be made in the study from different infomants.



to log all activities that take place during selected weeks at random intervals. For this data collection we have developed an online survey, which is easy to administer and use. This data may be used as covariates in the efficacy analysis on patient and family carer level. To be able to investigate the influence of the day care centre staff's attitude to people with dementia all staff will be asked to complete the Attitudes to Dementia Scale [34].

### In-depth interviews

To get a more thorough understanding of the impact day care centre programs have on the patients' and family carers' daily living patterns, we will carry out in-depth interviews with 20 dyads of patients and their family carers at participating day care centres. These will be recruited from the sample in the controlled trial. In a previous development project in Norway [15], brief statements from users and family carers showed that the majority were very satisfied with the day care program offered. In the present study we would like to go one step further and also ask how the day care program may influence the patients' lives and their relationships to next of kin. In addition, knowledge on how the family carers experience the communication and collaboration with the day care centre staff, what kind of impact the centre has on the patient with dementia and how this influences their daily life is to be collected. The interviews will be based on semi structured interview guides.

### Data management and analysis

The described scales will be designed in Teleform™ and the data will be scanned to data files. For analysis, two-tailed t-tests or Mann-Whitney U tests will be used, as appropriate, to compare continuous caregiver and patient variables. Chi-square tests will be applied to compare dichotomous variables, whereas Pearson or Spearman rank correlation will be used to explore the relationship between continuous variables. Bivariate and multivariate associations between dependent (outcome) and potential explanatory variables will be explored by means of regression models. To evaluate delay in nursing home placement, cox regression analysis will be applied. All participants to be assessed at baseline will be included in the Intention-To-Treat efficacy analysis (ITT). Two-tailed t-tests will be used when comparing outcome variables for normally distributed data and two-tailed Mann-Whitney U tests for skewed data and subgroups with few participants. Chi-square tests will be applied to compare dichotomous variables. Multi level model analyses will be applied in order to adjust for possible differences in effect between groups (cluster effect).

The viewpoint for the economic evaluation is societal, and all relevant direct and indirect costs, including informal care, will be included. The basic design is a cost-consequence analysis. If appropriate, bootstrapping methods will be used. QoL-AD will be the denominator at patient level, and MADRS, RSS and QoL-AD at family carer level.

The interviews made in the qualitative study will be recorded, transcribed and analysed using a qualitative content analysis methods based on systematic text condensation [35], a descriptive and explorative method for thematic cross-case analysis of qualitative data. Various steps of structuring, condensation and synthesizing of the raw data material will be made.

### Ethical consideration

The project is funded by unrestricted grants from the Research Council of Norway and has been accepted by the Regional Committee in Ethics in Medical Research in South-East Norway. After written and oral information the patients and the family carers will be asked to

give written informed consent. Only patients with the capacity to give consent will be included. We do not anticipate this project causing any harm to the participants, and feedback from a previous, not published, feasibility pilot study indicates that participating patients, family carers and day care centres appraised taking part in the study.

The study is registered in Clinical Trials (NCT01943071).

### Discussion

The major strengths of this study are the large sample size, the follow-up over two years, and the combination of approaching the aims by the use of both quantitative and qualitative research design. A further strength is the use of standardized test and evaluation instruments that have been widely used in research on this patient group. All the instruments are shown to be reliable and valid. Many of them have also been tested for reliability and validity in Norwegian studies. The assessors will be trained in the use of these tests, many of which will be familiar to them already.

A randomized controlled trial (RCT) design is preferable and considered to be the gold standard when studying effects of interventions. However, the waiting list period for day care centre admittance today is short. We therefore found it unethical to withhold patients from this service during a 24 month observation period. Another possibility would have been to use a stepped wedge RCT design, but this would also imply a longer waiting time for many patients. Therefore, as a substitute for a RCT, we will carry out a quasi-experimental controlled trial and select the study patients from municipalities with a day care centre program designed for people with dementia and from municipalities without such a program. This means that we do not randomize patients to the two groups, but rather select patients randomly from a group who are attending a day care program (intervention group) and match them with patients who are not attending such a service (comparison group). This design may be a weakness of the study, but as we see it inevitable.

Eligible patients in the local authorities, known by dementia teams and in-home care offices, will be asked to participate. However, there may be differences between those who accept the recruitment proposal and those who decline. It could be, for example, that the family carers are overwhelmed already with the responsibility of caring for a patient with dementia, and cannot undertake any additional responsibilities. It could also be that the family carer is ill or depressed. Such reasons for declining participating in the study are understandable, but from a research perspective it may influence our data by including less of those who struggle the most. We consider such circumstances as a weakness of the study, but it would be impossible to avoid that some of the eligible patients or family carers will decline participation. We will collect anonymous information about age and gender on patients that refuse to participate in the study.

The inclusion of participants to the comparison group is expected to be a challenge. The motivation for these patients and their family carers to participate might be modest as there are no obvious benefits for them in participating. Additionally, as we are not able to contact the patients and family carers directly ourselves, we are dependent on the leaders of the dementia teams and in-home care services to assist us in the recruitment. An advantage of the study is our ability to cover the entire Norway, with municipalities of diverse sizes. All types of day care centres will be included, again portraying the diversity of offers for this patient group. Due to the geography of Norway we will need to use several assessors to collect the data. This could confound our results. In

order to minimize this, all assessors will be thoroughly trained at a joint training conference.

This study is considered to be able to contribute to innovation and translation of knowledge.

If the results are positive, they might have a considerable impact on the care of patients with dementia. The policy of the Ministry of Health and Care Services to establish a day care centre in all Norwegian municipalities will be supported.

## Conclusion

In this study, we will use sound quantitative and qualitative methods based on scientific knowledge. We intend to recruit the number participants needed for a sufficient power to examine the effect of a day care centre program specially designed for patients with dementia. The results of the study may have a major impact on international knowledge in this field, and on the policy of the Norwegian Ministry of Health and Care Services. The results will not only be of interest for researchers, but will also have the potential to improve the treatment and care of elderly patients with dementia and their family carers.

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## Competing Interests

There are no competing interests reported.

## Authors' Contribution

AMMR participated in the planning and design of the study and drafted the manuscript, IH participated in the design of the study and the drafting of the manuscript, ST, MLB, ØK, LM, GS, LT, SV, CV, AW all contributed to the design of the study and the scientific content of the manuscript, KE was responsible for the planning and design of the study and contributed to the draft the manuscript.

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