1. Continuity of care for patients with dementia in Norwegian home care service

2. Introduction

In Norway, the estimated need for beds in nursing homes by 2030 is approximately 40,000 and will by 2060 increase to approximately 70,000 (1). Many municipalities will struggle to meet these expectations, and without the requested number of beds, the number of people with dementia who need home care services will increase in the years to come (2).

One aim of the healthcare policies in many countries is to enable people with dementia to live at home for as long as possible, and indeed, more than half of the people with dementia today live at home (2, 3). Moreover, 90% of people with dementia in Norway receive care from family members. In the last months before admission to a nursing home, patients with dementia receive 160 hours of care from their family members (1), in contrast to 16 hours home care services from the municipality. Due to the use of resources and costs of nursing homes, postponing nursing home admission for people with dementia is an important socioeconomic goal to achieve.

Dementia is currently one of the greatest global health issues. By 2030, the number of people diagnosed with dementia is estimated to reach 65.7 million (4), with prevalence increasing exponentially with age. Dementia leads to decreased function in cognitive function and ADL function, and behaviour changes (5). Neuropsychiatric symptoms (NPS) in people with dementia are often a primary cause of nursing home admission (6, 7). In Norway, the prevalence of dementia among older people receiving home care is 41.5%, and 30% of the people receiving home care have mild cognitive impairment (MCI). The most prevalent NPS in people with dementia receiving home care are depression (47.5%), apathy (33.7%), anxiety (33.0%), and irritability (31.1%) (8). The causes of NPS and affective symptoms in people with dementia are often multifactorial, caused by biological, psychological, and social factors, and any intervention in response needs to address all those aspects (9).

In Norway, home care services are an around-the-clock, universal, publicly funded responsibility of each municipality. Users of the services comprise a variety of patients who differ in terms of age, disease, and condition. Consequently, home care services encompass a range of service organizations and resources used, compared to the more uniform institutional care services. Patients with dementia who receive home care services often receive frequent visits, sometimes once a day or more, on a long-term basis. Since staff provide three daily shifts, several different members of the staff will often visit the patient over a one-week period. To provide good healthcare services for people with dementia, it is necessary that the staff, general practitioners (GP), family and next-of-kin adopt a systematic approach to the patients’ needs, and to make use of his or her information. However, in a small survey conducted by the research centre for old age psychiatry, SI, in 29 municipalities in Norway (61.1% response rate, unpublished results), we found that the organization of home care services in different municipalities varied in terms of the scope of services, the information shared among home care services, family and next-of-kin, and GP, and the diagnosis and follow-up of patients with dementia and impaired cognitive function. Although most municipalities studied offered primary nursing, barriers such as staff shortage interfered with those efforts.

The Norwegian National Quality Regulations for Healthcare Services has identified continuity of care (COC) as essential to provide good quality of the home care services (3). A review of 16 studies on the effect on COC found an association between COC and increased patient satisfaction, decreased hospitalization, and improved preventive healthcare (10). To establish the value of COC in home care services for patients with dementia, it is necessary
to define the concept of COC and identify ways to assess it. In healthcare, COC is often described in terms of three core elements: informational, management, and relational COC. Informational COC refers to using information about past events and personal circumstances to make current care appropriate for everyone, whereas management COC refers to a consistent, coherent approach to disease management that responds to the patients changing needs. Lastly, relational COC refers to an ongoing therapeutic relationship between the patient and one or more providers (11-13).

Early measurement of COC has been pursued largely from a service-oriented, clinician-centred perspective, from which simple indices have been favoured and provider continuity (e.g. seeing the same doctor, visits from the same nurse) has been a persistent theme in assessment (14, 15). Although that view of COC remains important, consensus among practitioners and researchers holds that COC is a multidimensional construct that needs to be considered both in the process of care and from the perspective of patients (11, 16). Data on the organization of home care services in Norway are unstructured and have not been analysed in relation to data on patients’ symptoms, diseases or personal experiences with COC and individually adapted services. However, continuity of home care services is necessary to facilitate the assessment and treatment of people with dementia and cognitive failure (2, 8, 17, 18). A survey of patients in need of complex care in 11 countries revealed that care was often poorly coordinated and that models to improve the evaluation and treatment of care are required (19).

The targeted interdisciplinary model for the evaluation and treatment of neuropsychiatric symptoms (TIME).

The targeted interdisciplinary model for the evaluation and treatment of neuropsychiatric symptoms (TIME) is a multicomponent intervention with a biopsychosocial approach, based on the theoretical framework of cognitive behavioural therapy and person-centred care (20). The model is especially suitable for the assessment and the treatment of patients with dementia and other complex psychiatric diseases. TIME consist of three overlapping phases. The first is a registration and assessment phase, including an examination of the patient that also involves obtaining her or his medical record and personal background information and an assessment of symptoms with clinical instruments such as the NPI-NH. The second is a guided reflection phase, in which one or more case conferences are conducted for the entire group of staff and the GP. A thorough systematic reflection based on cognitive therapeutic principles is performed, and measures are customized for the patient. Her or his situation is discussed using the cognitive problem-solving method. One problem at a time is analysed (20, 21) systematically, with the help of the five-column sheet technique in order to analyse assessed facts, performing interpretations, exploring staff members emotions (i.e., reactions), planning actions to take, and deciding on the evaluation of the actions (20, 21). The third phase is an action and evaluation phase where the treatment plan is put into action and the actions are evaluated systematically. Our research centre recently tested the effectiveness of TIME for the reduction of agitation among patients with dementia in nursing homes in a randomized controlled trial and found favourable results (22). Implementing TIME in home care services can be an important quality-enhancing measure to reduce NPS and improve COC for patients with complex multifactorial problems in dementia, from both an individual and service-based point of view.

2.1 Needs descriptions

Home care services in Norway will expand in the coming years due to an increased number of elderly in the society. COC is a cornerstone in primary care today, and methods of increasing COC for home care patients with complex and comorbid diseases need to be developed. The anticipated results of our research will thus benefit patients in home care services and their relatives, chiefly by giving patients in home care services better qualitative assessments and treatment. Moreover, providing appropriate treatment to patients in home
care services could delay nursing home admission, which would benefit society and possibly be more cost effective.

3. Hypotheses, aim, and objectives.
The chief objective of our study is to explore how patients with dementia, family members and staff experience the home care system in Norway and COC. Is their experience of home care service changing when introducing the TIME as a strategy to treat and provide quality care for patients with dementia and NPS in home care services? We hypothesize that the home care services can implement TIME and thereby improve responses to affective symptoms for patients with dementia, especially those with complex multifactorial problems in dementia.

We will perform three sub studies. 1) An exploratory study of the staffs´ experience of home care service with mixed-methods. 2) An exploratory study of the patients´ experience with and needs for home care services with individual interviews. 3) A feasibility pilot study of the intervention with TIME using a cluster randomized controlled design with a parallel qualitative part exploring staffs´ and family members experience of the intervention.

Our research question (RQ) are:

RQ1  What are the staff´s perspectives on the organization of home care services?

RQ2  How does the organization of home care services influence the patients´ experience of COC?

RQ3  What are the staff’s and families’ experience of COC in providing home care services to patients with dementia, and will the experience change after implementing TIME in the home care service?

RQ4  Is an intervention with the TIME-model feasible in the home care service, and what are the main challenges for the implementation?

4. Project methodology.
4.1. Project arrangements, method selection and analyse
We will use both quantitative and qualitative methods to examine the patients’, family members’ and staff’s experience with COC in the home care service. The Medical Research Council (MRC) framework of Complex interventions is a recommended framework when both the process and the effect of the intervention should be evaluated (23, 24).

The first phase in the framework of complex interventions is the exploratory phase, including our sub study 1 and 2. The second phase contains a feasibility study and includes our sub study 3. The evaluation phase is the third phase, in which we in a later project will perform a full-scale RCT testing the effect of the TIME model in home care service. The last phase is the implementation phase.

Sub study 1. Survey and qualitative focus group interviews of leaders in home care services (RQ1)
Data collection in sub study 1 is now completed (Norwegian Centre for Research Data [NSD] no. 55316). A questionnaire with 73 questions investigating the organization of home care services, was sent to leaders of home care services in two counties in the middle of Norway and one municipality in the north of Norway. The leaders have been asked questions about the organization of the home care service, how the patients’ services are assigned, and how the cooperation with other health care services are. Totally 49 questionnaires were returned.

In addition, 14 in depth interviews with leading head nurses have been completed, to gain insights into the organization of the services and their perspectives on the services. The qualitative interviews will present information about the services given to patients with
dementia and factors that can promote or prevent implementing TIME. For this data material we will use Malterud’s systematic text condensation to develop theoretical categories. Systematic text condensation is a descriptive and explorative method for thematic cross-case analysis of qualitative data, including four steps of analysis (25).

We will use data from both the questionnaire and the qualitative interviews to answer RQ1. This study will give us the staff’s perspectives on the organization of home care services.

Sub study 2. Qualitative individual interviews with patients receiving home-based care (RQ2)
In sub study 2 we will perform qualitative individual interview with patients receiving home care services, living in various municipalities in Hedmark and Oppland counties. Patients in different stages of dementia will participate to the study. The qualitative interviews will give us information on how the organization of home care services influence the patients’ experience of COC (RQ2). Focus will be on how the participants experience COC with the number of staff visiting their home, and how routines is taken care of when several staff members perform the services to the patients. All interviews will be taped and transcribed. About 10 patients will participate, but the numbers of participants will depend on the information richness of the collected data material. Like the analyse in sub study 1, we will use Malterud’s systematic text condensation analyses to develop theoretical categories of how people with dementia experience COC in home care services.

The results from sub study 1 and sub study 2 will give us the opportunity to optimize the TIME-model for use in home care services settings. Customizing the TIME-model to patients in home care services is important for the implementation of the TIME-model in sub study 3.

Sub study 3. Pilot study to test the intervention TIME (RQ3 and RQ4)
Sub study 3 is a pilot study, where we will test the TIME intervention in home care service in municipalities chosen by convenience-based sampling. The pilot study will have a Cluster Randomized Control Trial (RCT) design. This design is recommended in studies where interventions, like the TIME model, will be tested for feasibility before a definitive Cluster RCT. After the pilot study, we will perform qualitative, individual interviews with family members of the patients, and focus group interviews with home care staff.

**Cluster Randomized Controlled trial (RCT) (RQ3)**
A cluster RCT will give us important and necessary information about how to use TIME for COC in home care service. The cluster RCT will contain two parallel groups, where randomization is performed based on clusters. One municipality is a cluster, and all patients from the same municipality will thus be randomized to the group of municipalities receiving the TIME intervention or to the group receiving care as usual as the control group. Totally 50 patients (10 municipalities) will be included, 25 (5) patients in the intervention group, and the same number in the control group. Randomization will be done by a statistician, based on random allocation software.

The primary outcome in the 6 months cluster RCT pilot study will be the reduction from baseline to follow up at 6 months of affective symptoms, the sum of the scores on the single items anxiety and depression as measured with the Neuropsychiatric Inventory, Nursing Home Version (NPI-NH; (26, 27).

Patient data collected
- Age, gender, and marital status
- Type of home care services and hours per week
- Diagnoses (chronic diseases)
- Clinical Dementia Rating Scale, CDR (28)
- Neuropsychiatric Inventory, NPI-NH (26)
- Cornell scale for depression score, CSDD (29, 30)
- Quality of Life in Late-Stage Dementia scale score, QUALID (31, 32)
- Dementia diagnosis by ICD-10 available from the medical record
- General Medical Health Rating scale (GMHR) (33)
- Algorithm for the diagnosis of dementia
- Resource Use in Dementia (RUD) (34, 35)

Relatives or next-to-kin data collected
- Age, gender and relation to the patient
- Hours spent caring for the patient
- Relatives Stress scale score (RSS) (36, 37)

Home care services data collected
- Size of home care services (i.e., number of patients)
- Number of different nurses per patient per month.
- Number of staff per administrative leader (i.e., department manager)
- Number of regular face to face meetings with the GP
- Individual-based statistics for care services in the municipality IPLOS (38)

Primary outcome data
- NPI-NH affective subsyndrome score (NPI-depression + NPI-anxiety)

Secondary outcomes data
- NPI-NH score for all 12 items
- NPI-NH caregiver distress score
- CSDD (29, 30)
- QUALID (31, 32)
- RSS (36, 37)
- Transferring to nursing home

Data will be collected at baseline and at the end of the implementing phase. Data collection will be performed by project nurses recruited outside the home care services. They will interview the staff or family members who knows the patient best. All data collectors will be nurses with extensive experience and formal training in administrating assessment scales. The assessors will be blinded to the randomization of the home care services. Interviews will be done by telephone or face to face, depending on what is best for the person interviewed.

As a part of phase 3 and 4 in The Medical Research Council (MRC) framework of Complex interventions (23, 24), information about admission to nursing home for patients included in both the intervention and the control group in sub study 3 is important. Secondary outcomes data of transferring to nursing home will be obtained.

Qualitative individual interviews with family members and qualitative focus group interviews with staff (RQ4)

To clarify how staff and family members experience COC in caring for patients with dementia at home and whether their experiences change by implementing TIME. The qualitative interviews will be conducted after the intervention with TIME. By interviewing the participants after the intervention of TIME, vulnerable information about their experience with the TIME model for patient with dementia in home care service will appear. We will include up to 16 family members, depending on the sample richness, in individual interviews. For ethical reasons, individual interviews are more appropriate for family members than focus group interviews.

For the staff, we will conduct three focus group interviews with five to eight staff members from the intervention group. One group for the leading registered nurses, one group for the TIME administrators and one group for staff. We will use a loose interview structure based on an interview guide in which informants may reflect on main themes, followed by a period for them to respond to open-ended, elaborate questions. The topics will be:
1. Staff and family members’ experience with COC in home care services.
2. The staff and family members experience with the patient’s psychiatric symptoms.
3. Changes in the experience with COC in home care services and the patient’s psychiatric symptoms after implementation of TIME.

If during the interviews other key themes spontaneously emerge, time to address those issues will be provided.

Interviews will be analysed with systematic text condensation, a method for cross-case analysis of different types of qualitative data (25). The method is therefore well suited for analysis of both focus group and individual interviews. Systematic text condensation represents a pragmatic approach, and consists of four steps, an overview of the material, identifying meaning units, condensation, and synthesizing the themes in collected data (25).

The TIME intervention

All municipalities in the intervention group will receive training in TIME. Training will be similar to the training used in the TIME nursing home study (20), given to the whole staff and the GP and consist of 2 hours of lessons about dementia and NPS and 3 hours of lessons about TIME. As in the TIME nursing home study, the leading registered nurse in the ward will be required to participate in training (20). The staff of the home care service will receive the TIME manual and access to the TIME website. From each municipality, three staff members will receive additional training and thereafter have responsibility for performing the intervention.

The municipalities in the control group will receive the two hours lessons about dementia and NPS. After the cluster RCT pilot study is ended, municipalities in the control group will receive the same three-hour lessons in the TIME as the intervention group of municipalities.

4.2. Participants, organization and collaboration

The cohorts in the three sub studies are all based on convenient sampling, based on existing and future collaboration with municipalities in Oppland and Hedmark. Participants are recruited by leaders and nurses in the home care service in the different municipalities.

Sub study 1

In sub study 1, the quantitative part of the study consists of 49 questionnaires. Inclusion criteria for the qualitative part of sub study 1 was being a leading head nurses/leaders of home care services in Hedmark and Oppland county, and consenting to participate.

Sub study 2

In sub study 2, the number of participants will depend on the richness of the data from the patients to address the aim of the study. The study will attempt to include participants of both sex, living in both large and small municipalities, with different severity of dementia. We assume that it will be enough with 10 participants, but the final number of participants will be decided after preliminary analysis of the interviews.

Inclusion criteria will be

- mild, moderate and severe degree of dementia
- consent to participate

Exclusion criteria will be

- Severely reduced communication ability

Sub study 3

The cluster RCT pilot study will, in addition to be a feasibility study also give information to perform a power calculation for the upcoming larger cluster RCT. We assume that 25 patients
in each group is sufficient in this cluster RCT pilot study. In the qualitative interviews, we will include the nurses from the home care service who know the patient best, and family members that consents to participate. Participants from small, medium and large municipalities in Norway will be invited to participate in the study.

The inclusion criteria for patients will be
- Dementia, defined as a score of 1 or more on the Clinical Dementia Rating Scale (CDR) (28)
- A minimum of 15 minutes of home care services per day for the last 4 weeks
- NPS, defined as a score on the NPI-NH affective subsyndrom (NPI depression + NPI anxiety) of 12 or more (26)
- Informed consent from the participant or family or next-of-kin

Exclusion criteria for patients will be
- Terminal disease

Inclusion criteria for family members will be
- Consent to participate
- Patient receives treatment based on the TIME intervention

Inclusion criteria for staff will be
- Consent to participate
- At least 50% of a full position in the home care service

**Time-line**

Table 1. Time line for the data collection, analyses, papers and ph.d. degree

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The Centre for Old Age Research (AFS) at Innlandet Hospital Trust will be the facilitator of the project. AFS specialises in research on dementia, depression, anxiety, alcohol overconsumption, and drug addiction among the elderly. Kari-Anne Hoel will be the project coordinator and ph.d. candidate in the study. Research leader Sverre Bergh (ph.d.) at the AFS will be the project manager and primary supervisor, and the co-supervisor will be Geir Selbæk, who serves as professor and research director at the Norwegian National Advisory Unit on Aging and Health. Project manager and researcher of the nursing home TIME study, Bjørn Lichtwarck, will be a partner and co-supervisor as well. The dementia team, GP, and other stakeholders in municipal services will be informed before the study design is finalized and included as important partners. Lastly, the Dementia Association, the National Association for Public Health, and the Norwegian Association of Local and Regional Authorities (KS) will also be invited as partners.

4.3 Budget

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4.4 Plan for activities, visibility and dissemination

Starting in August 2018, one ph.d. student holding a 75% position for 4 years will perform the qualitative part of the study and organize the cluster RCT pilot study. We will present the results of the project at both international and national conferences and attempt to present the results to the media. Four papers from the project will be submitted to peer-reviewed journals, the article from sub study 1 in a Norwegian scientific journal. Local and regional authorities will also contribute to the dissemination of the results since they sustain a network of policymakers and stakeholders who should be aware of the results.

Our reports from the randomised controlled trial with TIME in home care settings, will follow the recommendations presented in the CONSORT 2010 (Consolidated Standards of Reporting Trials) statement: extension to cluster randomized trials (39) and extension to randomised pilot and feasibility trials (40).

4.5 Plan for implementation

If the results of the study are favourable, then training in TIME will be offered to municipalities that did not participate in the study. Our research group will also apply for funding of a final larger cluster RCT to test the effectiveness of TIME for reducing NPS in patients with dementia receiving home care services. Via courses throughout Norway and web-based lectures available from the TIME homepage, TIME will be disseminated and implemented in both nursing homes and home care services in Norway. TIME is available in English and can be downloaded from the TIME homepage. As such, an international implementation of TIME is also possible.

5. User involvement

We will organise a steering committee for the project that includes persons representing the patients who are receiving home care services, their family members or next-to-kin, staff members of home care services, GP, and representatives of the municipal administration.

6. Ethical considerations

Applications to the Regional Committees for Medical and Health Research Ethics (REK) and
Norwegian Centre for Research Data (NSD) will be submitted. Inclusion in Sub study 1 is based on informed consent from leaders of home care service, and the study has been approved by the NSD. Participants included in sub study 2 are patients with mild, moderate and severe degree of dementia, but only patients who can consents are able to participate. Each patient will get the opportunity to share their experiences with the home care service. This kind of knowledge can only appear when interviewing patients receiving home care services. An exclusion criterion is severe deficits in communication skills because we consider these patients unable to convey information about COC in home care service. Negative aspects are the time spent on the interview, in addition to the emotions like sadness and aggression that the participants can express because of themes presented in the interviews. Participants will be given the opportunity to bring a family member to the interview.

In sub study 3 the inclusion of patients will require informed consent. If the participant cannot provide an informed consent themselves, we will ask their next-of-kin to provide consent on their behalf. We will instruct the next-of-kin to base their decisions upon what the patients would wanted if they could understand the information given about the project. We will inform all participants that the aim of the project is to evaluate TIME for persons receiving home care services. Since TIME is non-invasive, the intervention is tailored to each patient, and the patients are followed closely by the staff of the home care service throughout the intervention, the risks for adverse effects are low. In sum, the positive effects of the study for patients are projected to exceed the possible negative effects.

For staff and family members, participation in the study will require an informed consent.

7. References