Study protocol

Project title:

Preventing and approaching crises for frail community-dwelling patients through innovative care (PRACTIC) - an effectiveness study

Participatory action research in a cluster randomised controlled trial

This protocol represents **Work Package 2 (WP2)** in the PRACTIC-study (**Pr**eventing and **a**pproaching **c**rises for frail community-dwelling patients **t**hrough **i**nnovative **c**are). The PRACTIC-study consist of four work packages:

WP1	Characteristics of crises in frail patients receiving home-care services
WP2	**Evaluation of the effect of an adapted version of the TIME model in the prevention and treatment of crises in frail community-dwelling people**
WP3	Pre-specified process-evaluation of the intervention in the RCT
WP4	Administration and project coordination

Abstract

Background:

Demographic changes, with an increasing number and proportion of older people with multimorbidity and frailty, will put more pressure on home care services in municipalities as well as on specialist health care. Frail multimorbid people receiving home care services are at risk of developing crisis often resulting in adverse events, coercive measures, and acute institutionalisation. Crises also pose increased demands and stress on the next of kin. There is a lack of evidence based interventions to prevent and resolve crises in community settings. Our hypothesis is that through interventions targeting the patients, the next of kin, the patients' social context, and healthcare service, crises may be prevented and resolved. This project aims to test the effectiveness of an adapted version of a bio-psychosocial person centred model the Targeted Interdisciplinary Model for Evaluation and Treatment of Neuropsychiatric Symptoms, (TIME) to prevent and resolve crises for frail community-dwelling people receiving home care services. In addition, we will analyse factors associated with the effect of TIME, and we will explore the experiences the users have with the introduction of TIME in the services.

Design/Methods: This is a participatory action research design (PAR) in a six-month cluster randomized controlled trial (RCT). The trial will be conducted in 30 municipalities including 150 frail community-dwelling participants receiving homecare services judged by the services to have imminent crises. Each municipality will be defined as a cluster and will be randomized to receive either the locally adapted TIME intervention (the intervention group) or care as usual (the control group). TIME is a manual-based, multicomponent programme that will include a rigorous assessment of the crises, one or more interdisciplinary case conferences and the testing and evaluation of customised treatment measures. Primary outcome: Difference in change between intervention and control group in individual goal achievement to resolve or reduce the challenges of the crises, between baseline and 3 months using the PRACTIC Goal Setting Interview (PGSI), which is inspired by the Bangor Goal Setting Interview (BGSI scale of 1–10). Secondary outcomes: Difference in change in the PGSI scale at 6 months, and in neuropsychiatric symptoms (NPS), quality of life, distress

perceived by professional careers and next of kin, and institutionalization at 3 and 6 months. For the exploration of the factors associated with the effect of the intervention we will use multiple level regression analysis of the data from the RCT. To explore the experiences of the users of home care services with the intervention we will use qualitative in-depth interviews of dyads with 15 patients and next of kin who participated in the RCT.
Trial registration: ClinicalTrials.gov identifier, ID: NCT05651659. Registered 15.12.22.

Keywords: frailty, crises, home care services, community-dwelling people, behavioural and psychological symptoms of dementia (BPSD), psychosocial interventions, case conferences, participatory action research (PAR), randomized controlled trial (RCT), PRACTIC Goal Setting Interview (PGSI)

Protocol

Background

Worldwide, the proportion and absolute number of older individuals are increasing dramatically. The population aged 60 and older is expected to double by 2050 worldwide, and the proportion of people receiving care at home has increased over the past ten years (1, 2). In Norway, approximately 200,000 people are currently receiving home care services, while there are approximately 40,000 beds in nursing homes (3). The majority of people would rather reside and receive care at their homes than in an institution (4). One of the main health and societal challenges for municipalities, now and in the future, is to offer high-quality health care services for a growing population of older people with complex needs due to frailty and multimorbidity (5). Patients may experience distress because they are unable to manage the situation at home, even though they may prefer to avoid institutionalization. The considerable distress experienced by informal caregivers revolves around the lack of sufficient support from home care services and the limited availability of nursing home places (6). Home care services can be described as a complex organization with various service components ranging from practical assistance in the home to the delivery of advanced medical treatment. To enable people to live safely at home, home care services are interdependent on other sectors, such as general practitioners (GPs), the hospital sector, primary health care workers, and social care (4, 7).

There is a significant variation among patients receiving home care services in terms of functional abilities, age, living conditions, and chronic diseases (8). A considerable number of these patients have multiple chronic conditions, commonly referred to as multimorbidity (4). Estimates suggest that within the next twenty years, the population of elderly individuals with multimorbidity will double (9). The prevalence of frailty is estimated to be 11% among adults aged ≥65 years, increasing to 50% among those >80 years of age (10). Most frail individuals are multimorbid, but not all multimorbid individuals are frail (11). Frailty has been described as a state of physiological vulnerability with a reduced capacity to adapt and manage internal and external stressors (12). Studies have emphasized the relevance and utility of a biopsychosocial definition of frailty, including the terms physical frailty, psychological frailty, and social frailty. Social frailty is an important dimension of the frailty concept and makes people with low incomes, low educational levels, and low housing standards vulnerable to various adverse health outcomes. Combining these three dimensions into a multidimensional concept of frailty promotes the use of targeted multidomain interventions tailored to older adults' frailty status (13, 14).

Definition of crisis

People who are at an increased risk of developing crises are often frail. Crises are major stressors for patients, their next of kin, and the care staff and often lead to adverse events, acute institutionalisation and the use of coercion (15, 16). Crises can be described as '*a process in which the stressors cause an imbalance requiring an immediate decision which leads to a desired outcome and therefore crisis resolution*' (15). In the Preventing and approaching crises for frail community-dwelling patients through innovative care (PRACTIC) study, we will operationalize this definition to describe crises in practice as "critical challenges and symptoms that demand immediate and new actions". The challenges and symptoms that trigger and maintain crises are heterogeneous and vary between patients and may include depression, poor nutrition status, rejection of care, incontinence, neuropsychiatric symptoms (NPSs), and social isolation (12). The 'Mind the Gap report' from the Advisory Board of the Global Forum for Health Care Innovators states that 1–5% of community-dwelling patients are high-risk patients and 15–35% are patients with an increasing risk. The literature on crises among patients receiving home care services has mainly explored the phenomenon in relation to people with dementia living at home (15, 16).

The need for new multicomponent interventions possible to adapt to the local context

One of the most demanding challenges for health care authorities and home care services is to develop and implement high-quality health care models for the growing population of frail community-dwelling patients (17). In addition to early recognition and response to clinical signs and symptoms, as recommended by the Norwegian Health Directorate, providing health care for this group of frail patients represents a change from a merely task-oriented service to a service that aims to assess the complex biopsychosocial character of frailty (18). There are large variations in the content and organization of Norwegian home care services, and research pertaining to these services has largely been descriptive, with a preponderance of qualitative studies (19, 20). There is a paucity of studies investigating the effectiveness of interventions (20). A study testing a structured follow-up program using a checklist for frail community-dwelling adults found no common perception among nurses or their leaders that the approach was useful to ensure high-quality health care (21). This finding supports the conclusion of a Cochrane Review in 2016 summarizing primary care interventions for patients with multimorbidity (22). The review revealed no clear positive improvements in clinical outcomes, health service use, medication adherence, patient-related health behaviours, health professional behaviours or costs. The authors concluded that to improve outcomes for people with multiple conditions, there is a need for new multicomponent interventions, targeting both the heterogeneity of patients and their multimorbidity. To our knowledge, no effectiveness study of interventions targeting heterogeneous groups of home-dwelling patients with multimorbidity has been conducted in Norway. The proposed project will develop knowledge beyond the current state by also including the experimental testing of an intervention (20).

Participatory action research (PAR) in combination with an RCT has been suggested as a design to enhance local adaptations of an intervention to the local context and needs (23, 24). There are multiple variations in the content and organization of Norwegian home care services, with various service components ranging from practical assistance in the home to the delivery of advanced medical treatment (19). The possibility of success for innovative interventions is probably higher if the interventions are not too complex, with no aim of changing the organization of health care

services (23, 25). A flexible complex intervention has been emphasized as an important factor for interventions to be effective and increasing their applicability (24, 26-28). According to Hawe et al. (24), it is the function and processes of the intervention that should be standardized, not the components in the intervention. Adaptation of the components should be performed both at the research project level and at the implementation level in municipalities (24). Using a PAR design will help to adapt the components of the intervention to these variations, thereby enhancing implementation in each municipality. As a part of the main PRACTIC study, a process evaluation study will be conducted in parallel with the RCT (29). This will ensure that these variations in the organization mentioned earlier and the necessary adaptations are accounted for.

The TIME intervention

TIME (Targeted Interdisciplinary Model for Evaluation and Treatment of Neuropsychiatric Symptoms) is a Norwegian evidence-based model for problem-solving regarding neuropsychiatric symptoms (NPSs) in dementia and other mental diseases. The model is based on the theoretical frameworks of cognitive behavioral therapy (CBT) and person-centered care (PCC) (28). TIME has also been used in clinical practice for other complex issues, such as nutritional failure, multimorbidity, and general functional loss (30). It is a multicomponent interdisciplinary model consisting of three overlapping phases, which are the core components of the model. First is the assessment phase where the care staff and the physician collaborate in a comprehensive biopsychosocial assessment. The second phase is the reflection phase with interdisciplinary case conferences based on principles from cognitive behavioural therapy (the ABC method), where a customized treatment plan is developed. The ABC method from cognitive behavioral therapy is used as an analytic tool for the analyses of complex challenges in case conferences (31). The third phase is the action and evaluation phase, and each treatment measure in the plan is implemented and systematically evaluated. The TIME model is effective for treating NPSs in dementia and has been proven feasible in nursing homes (NHs) (28, 32). Our research centre has pilot tested the model in home care services (33). One of the assets of TIME is interdisciplinary case conferences, and interdisciplinarity is essential in the approach to a crisis. Based on the results from the pilot test, the inclusion criteria for the patients were broadened, and the content of the training for all employees was further developed (33). In addition, the schedule for the training and implementation was adapted to everyday routines for home care services. Further adaptation of the TIME model to home care services will be performed continuously at local project group meetings during the RCT in the intervention municipalities.

A goal-oriented primary outcome

To evaluate the effects of a biopsychosocial intervention to prevent and resolve crises in a heterogeneous population, there is a need for a goal-oriented outcome comprising this variability. The goal of the intervention and the outcome will necessarily vary from patient to patient (26). We have therefore translated and modified a validated individual goal-oriented interview (The Bangor Goal-Setting Interview, BGSI) (34) to establish a common primary outcome to be used in the RCT. The PRACTIC Goal Setting Interview (PGSI) is a Norwegian adapted version of the BGSI. In the PGSI, the individual goals set for each patient represent treatment and actions targeting the challenges and symptoms that trigger and maintain the patient's crisis. The difference in goal achievement between the intervention and control groups, as further explained in the Methods section, defines our primary outcome.

Theoretical framework

The study is based on a theoretical framework of complexity science and a biopsychosocial understanding of crises (35, 36). In this framework, frailty means that the frail patient is prone to instability caused by complex interactions among biological, psychological and social stressors (14, 36). If this instability rises, it eventually culminates in the development of a crisis that, according to our description of crises, demands immediate and new actions. Describing frailty and crises as complex phenomena sets the stage for why interventions should be constructed and implemented as flexible complex interventions to be able to assess, prevent, and resolve crises (24). This also includes the choice of design and methods for testing the effectiveness of an intervention.

Aims and research questions

The primary purpose of this study is to test the effectiveness of an adapted version of a biopsychosocial person centred model (TIME) to prevent and resolve crises for frail community-dwelling people receiving home care services. We have formulated the following research questions:

RQ1**:** Can the TIME model adapted for home care service, prevent, and resolve crises in frail people receiving home care services?
RQ2: Which participant characteristics or organizational factors are associated with the effect of the TIME model?
RQ3: What are the experiences of the users of home care services on how crises were approached during the trial?

Design and methods

Study design

For RQ1 we will use a participatory action research (PAR) design in a cluster randomized controlled trial (RCT) with two parallel groups: intervention municipalities (IMs) and control municipalities (CMs) (23, 37). Figure 1 shows a flow chart of the clusters and individuals through the phases of the trial based on the power calculation.

PAR aims to ensure adaptation of the components of the intervention to the local context (23, 37). This will be done by establishing a local project team in each municipality consisting of two representatives from the research group and local participants (representatives of local managers, staff, and GPs). These groups will adapt the implementation process and the TIME model according to the cyclic Deming process: plan, do, check, act, and adjust (38). The implementation process will be adapted to the local context to fit with the organizational structure already established in home care services. For example, the content and time used for educational and training purposes can vary depending on the educational level and established educational arenas. These variations will be registered during the process. For the TIME model, the core components (functional) of the intervention (TIME) must be fixed, and other components can be adapted to the local context and the patients included. An assessment phase must be performed, but *what* to assess and the *types* of clinical scales to be used can vary (processes). Case conferences using the inductive cognitive ABC model for the analyses of crises must be conducted, but the timeframe and participants of these conferences will vary. The action and evaluation phase must be conducted, but the timeframe and types of actions and evaluations can vary. These adaptations of the model will be accurately mapped in each setting during the study, and this mapping will be a part of the process evaluation study in the PRACTIC study (29). In this trial, we will follow the recommendations from the CONSORT

statement for randomized trials of nonpharmacologic treatments (39).

For RQ2 we will utilise an explorative design with multilevel regression analysis based on the participants' characteristics from the RCT and organizational data including staff characteristics from the process evaluation study in WP3.

For RQ3 we will use an explorative design with qualitative in-depth interviews of dyads with 15 patients and next of kin who participated in the RCT. Qualitative methods provide contextual based knowledge about people's experiences and how they interpret, understand and link meaning to events (40). The aim is to get a deeper understanding of how crises were approached during the trial as experienced by the users of the home care services in the intervention municipalities. Because the questions and topics of the interviews concern personal critical situations, individual interviews are perceived as the most appropriate method of collecting data.

Settings and target population

This study is part of the larger PRACTIC (Preventing and approaching crises for frail community-dwelling patients through innovative care) study. The trial will include approximately 30 randomly selected municipalities and their home care services from all health care regions in Norway. From each region, a sample of small, medium, and large municipalities will be invited to participate. From those 30 included municipalities, 150 users of home care services and their next of kin will be invited to participate in the trial. The local project team will collaborate with the research team in the adaption of TIME to the local context during the trial. Specially trained nurses (see below, section: Control and intervention phases of the study) will support the research team in the recruitment of participants and the data collection. However, the care providers for the intervention will be the regular staff in the home care services.

Inclusion criteria for patients are: (1) in need of home care services, (2) a score ≥5 on the Clinical Frailty Scale (indicating mild to severe frailty) (41), and (3) perceived by the home care service as being in an unstable situation with a high risk for acute institutionalisation or showing resistance to care. The only exclusion criterion is an expected short life expectancy (i.e., <4 weeks).
Inclusion criteria for next of kin (for RQ3) are (1) being next of kin of a user of home care services who meets the above mentioned inclusion criteria (2) regular contact with the patient (i.e., at least once a week).

Fig.1. The PRACTIC trial: Flowchart of the clusters and individuals throughout the phases of the trial

RQ1 and RQ2 Sample size calculation based on the primary outcome

The proposed sample of 150 participants is based on a power calculation with clusters of approximately five participants from each of the 30 municipalities. Based on a previous trial, a minimal clinical important average difference on the PGSI scale is set to 2 points between intervention and control group with a standard deviation (SD) for change of 2.83 in each group (40). To observe a statistically significant difference with a power of 80%, an intra-cluster (municipality) correlation coefficient (ICC) of 10% and an estimated attrition rate of 25% for the primary outcome at three months, we will need approximately 150 participants. We assume a high attrition rate since the participants are at high risk for acute institutionalisation (see inclusion criteria).

This trial must perform cluster randomisation, with the municipality as the cluster, for two main reasons. The intervention is a biopsychosocial intervention that involves the entire interdisciplinary team and staff in the home care services of the participating municipalities to optimize the approach towards a group of patients in the municipalities. In addition, without cluster randomisation, the study runs the risk of transmitting all or parts of the intervention model to the individual control patients in the same municipalities (42). The patients in the control group will receive care and treatment as usual, but they will probably also profit from the extra attention given by the home care services because of their participation in the RCT and because of the use of the measure for the primary outcome, the PGSI. In this way, we can isolate any effects on goal achievements to prevent or resolve crises to the main difference between IMs and CMs, i.e., the TIME intervention.

RQ3 Selection of participants for the individual in-depth interviews
For the interviews in RQ3, we will use a purposeful sample of approximately 15 dyads with 15 patients and next of kin from the intervention municipalities in the RCT (43). To minimize selection bias in selecting the municipalities that will be represented in the interviews, we will select five of them randomly from the pool of the 15 municipalities which had received the intervention with TIME and recruit 3 participants from each of these municipalities (44). Local project nurses (see below in section Control and intervention phases of the study) in each municipality will inform eligible participants and their next of kin about the interviews and hand out written information, consent forms, and a franked envelope to be returned to the research team, if they consent to participate. Precautions will be taken to ensure that the members of the local project group that inform the users and their next of kin, do not have any care-relation to the participants. The researcher will send a short letter to the eligible participants after one week and invite them to contact the researchers or the local project group by phone if they have any questions. The aim is to ensure that the participants have received all necessary information needed to take a well-informed consent. Many potential participants will have difficulty understanding only written information due to mild cognitive impairment or impaired vision, and the researcher can provide additional oral information. The researcher will not require a replay regarding participation in the study at the time of this contact.

Randomisation
Municipalities will be randomly assigned to either the intervention group or the control group. A statistician will perform the randomisation procedure independently of the project management team and the municipalities. The project management team will provide the home care services in the municipalities with the randomisation and allocation results immediately following this procedure. The intervention will start with the educational sessions (described below) within one to two weeks after randomisation.

Control and intervention phases of the study
Education and training for the staff in intervention municipalities (IMs) and control municipalities (CMs)

Depending on the size and organization of the home care services, approximately four project nurses from each organizational unit of the home care services in each IM and CM will be given special

responsibility in the trial. Before randomisation, these nurses will complete a one-day educational course on the procedures for the trial. Their main task will be to recruit participants according to the inclusion criteria, obtain written consent for participation, and facilitate the interviews for the assessments of the participants at baseline, three months, and six months. The manager of the home care services will select these nurses in the municipality based on the following criteria: health care professionals who work on a nearly full-time basis, have shown interest in professional development and have gained legitimacy with the rest of the staff. Thus, these health care professionals can be selected among registered nurses, auxiliary nurses, or members of other professional groups (e.g., social workers or occupational therapists) in home care services.

After this coeducational session for both the IMs and CMs, the CMs will continue care and treatment as usual (CTAU). Care and treatment as usual will usually involve medication follow-up and medical procedures, personal care, dressing, and bathroom assistance.

Specific education and training of staff in the IMs

The staff in the IMs will complete four hours of lectures, training and role-play related to TIME. The educational program is aimed at as many employees as possible in the organization and provides basic knowledge about the TIME model. The education and training team will consist of eight specialist registered health care professionals in geriatrics or geriatric psychiatry and one physician with special competence in nursing home medicine. All members of the education and training team are familiar with TIME and have used the model for some years in real-world clinical settings. The lectures will be standardized according to the steps listed in the TIME manual.

The leaders of the home care service in the IM will attend these lectures to ensure that these leaders provide support to the staff during the trial. We will also encourage the GPs in the municipalities to participate. Each staff member in the IM will be provided with the TIME manual, which describes the intervention step by step. They will also be given access to an educational film about TIME and to a website to support the intervention. The project nurses who participated in the coeducation for the inclusion criteria in each municipality in the IM will now hold a special responsibility for putting the model into practice based on the manual. These nurses will therefore receive three additional hours of education, training and role play about the different components of TIME and the implementation of the intervention. In the trial, they will be referred to as TIME administrators. Immediately after randomisation and allocation, the project management team will contact these TIME administrators via telephone and instruct them to begin to implement the intervention according to the TIME manual for the patients included in the trial. This telephone call is made from a few days up to one week before the education and training sessions are given. The TIME manual is available online.

One specialist registered nurse from the education and training team will attend and supervise the TIME administrators' first case conference on their first patient in their municipality. For the remainder of the intervention, and for the other patients included in the trial, the TIME administrators and the staff will carry out the intervention independently.

Table 1. The assessment phase
Table 2. Agenda and timeframe for the case conferences

Procedures for data collection

Specially trained nurses (data assessors) from the project's research centre who are not affiliated with the municipalities will, together with staff members in the home care services, assess patients' baseline characteristics before randomisation. These data assessors will after randomisation be blinded to the randomisation result. They will assess the effect of the intervention via telephone by interviewing the participants, the next of kin and the staff members who know the patient best, at three months and six months after baseline assessments. All assessors are nurses with substantial experience and formal training on the use of the assessment scales. They will attend a one-day course on the use of the assessments scales before start of the trial. A description of the questionnaires, including data assessors, respondents and the time point(s) at which they are administered, is provided in Table 1.

Baseline data and primary and secondary outcome measures

The primary outcome of the trial is the difference in the change between the intervention and control groups in individual goal achievement to resolve or alleviate the challenges regarding crises between baseline and three months using the PGSI (scale of 1–10) (34). We chose this primary outcome because there is a need for a targeted outcome that comprises the variability in a heterogeneous population. It is very unlikely that a participant would be harmed due to participation in the RCT; therefore, it is not deemed necessary to have a harm outcome in the study. In the RCT, no new experimental treatments for the patients will be introduced, and care and all treatment actions will rely on recommended national care and treatment guidelines.

The secondary outcomes are the differences in the change between the intervention and control groups in the PGSI scale at 6 months, in neuropsychiatric symptoms (NPSs) measured by the Neuropsychiatric Inventory (NPI-NH) (45), quality of life measured by the Quality of Life in Late-Stage Dementia scale (QUALID) (46, 47), distress perceived by the next of kin measured by the Relative Stress Scale (48), rejection of care measured by the Minimum Data Set (49), activities of daily living assessed with the Physical Self-Maintenance Scale (PSMS) (50), prescribed medications collected from the medical records (51), frailty measured with the Clinical Frailty Scale (CFS) (52), institutionalization at three and six months, and pain and discomfort assessed by the EQ-5D questionnaire (53) at six months. All these questionnaires have been proven to have acceptable validity and reliability. The trial will also collect data to be used as covariates in the RCT and to describe the sample of participants. These data will be collected with questionnaires answered by the staff in home care services:

a) Age (covariate in the RCT), sex, level of education and employment status, marital status, living conditions (living alone or with someone)
b) Hours a week and type of home care service
c) Relation to next of kin (e.g., next of kin and how often they meet)
d) Physical health measured with the General Medical Health Rating Scale (GMHR) (54)
e) Cognitive function assessed by the Clinical Dementia Rating Scale (CDR) (55) (covariate in the RCT).

Table 3 Overview of the data collection in WP2 with primary and secondary outcome measures

Data collected	Interviewers	Respondents	Baseline	3 months	6 months
Characteristics of the participants					
Age[a], gender, level of education and employment status, marital status and living conditions	Data assessors from AFS[b]	Staff members in the home care services	X		
Hours a week and type of service from the home care service	Data assessors from AFS	Staff members in the home care services	X		
Number of visits per day from the home care service	Data assessors from AFS	Staff members in the home care services	X		
Relation to next of kin (e.g., next of kin and how often they meet)	Data assessors from AFS	Staff members in the home care services	X		
Diseases (known diagnosis)	Data assessors from AFS	Staff members in the home care services	X		
Frailty, measured with the Clinical Frailty Scale (CFS)[c]	Data assessors from AFS	Staff members in the home care services	X		X
Physical health, measured with the General Medical Health Rating Scale (GMHR)[d]	Data assessors from AFS	Staff members in the home care services	X		
Cognitive Function - the Clinical Dementia Rating Scale (CDR)[e]	Data assessors from AFS	Staff members in the home care services	X		
Primary outcome					
PRACTIC Goal Setting Interview (PGSI)[f]	Data assessors from AFS	Patient, next of kin and staff members in the home care services	X	X	X
Secondary outcomes					
Medication from medical records	Data assessors from AFS	Staff members in the home care services	X	X	X
Rejection of care - Minimal Data Set (MDS)[g]	Data assessors from AFS	Staff members in the home care services	X	X	X
Neuropsychiatric Inventory Nursing home version (NPI-NH)[h]	Data assessors from AFS	Staff members in the home care services	X	X	X
Activities of Daily Living - assessed with the Physical Self-Maintenance Scale (PSMS)[i]	Data assessors from AFS	Staff members in the home care services	X	X	X
The EQ-5D questionnaire[j], to evaluate pain and discomfort	Data assessors from AFS	Patient	x		X
Quality of Life in Late Stage Dementia scale (QUALID)[k]	Data assessors from AFS	Staff members in the home care services	X	X	X
RSS (Relative Stress Scale)[l] Next of kin	Data assessors from AFS	next of kin	X	X	X

Notes: [a]Age is to be used as covariates in the RCT; [b]AFS = Research centre for Age-related Functional decline and disease; AFS, Innlandet Hospital Trust); [c]Clinical Frailty Scale (CFS) (41); [d]General Medical Health Rating Scale (GMHR) (54); [e]Clinical Dementia Rating Scale (CDR) is to be used as covariates in the RCT (55); [f]PRACTIC Goal Setting Interview (PGSI) (56); [g]Minimal Data Set (MDS) (57); [h]Neuropsychiatric Inventory (NPI-NH) (45); [i]Physical Self-Maintenance Scale (PSMS) (50); [j]EQ-5D questionnaire (53); [k]Quality of Life in Late Stage Dementia scale (QUALID) (46, 47); [l]Relative Stress Scale (48).

Data describing the municipalities and the organization of the home care services will be assessed in the process-evaluation study part (WP3) of the PRACTIC project. To capture the care providers' adherence and fidelity to the adapted TIME model during the trial, members of the research team will contact one of the TIME administrators in each IM two times with two months interval during the trial to fill in a fidelity checklist with the four main components of TIME (i.e., the assessment phase, the performance of the case conferences, the actions taken and a systematic evaluations of these actions). This check-list will also capture any adaptions of the intervention and the TIME model done by the local project group. The checklist will be developed as a part of the PRACTIC process evaluation study in WP3.

Data collection for the qualitative data (RQ3)

The interviews will based on a semi-structured interview guide where the participants will be asked to reflect on two main themes (58): 1) their experiences on how their health and care challenges were approached and eventually resolved during the trial and 2) their experiences in participating in shared decision-making about their care with the home care services and their GP. These main themes will be developed upon during the interview with open-ended and exploratory questions. When other key themes emerge spontaneously during the interviews, time will be allotted to elaborate these themes.

Data processing and statistical analysis of quantitative data for RQ1 and RQ2

The data will be presented as frequencies and percentages for categorical and means (standard deviations) for the continuous variables. The normality of continuous variables will be assessed graphically. If necessary, skewed data will be transformed. Differences in the changes in outcomes between the intervention group and the control group will be assessed by a linear mixed model with fixed effects for time component and group and the interaction between the two. The analysis will be performed as an intention-to-treat analysis. A significant interaction will imply the differences in change between the groups. Random effects for patients nested within municipalities and slopes (if significant) will be included into the model. Individual time point contrasts will be derived within each group at each time point with the corresponding 95% confidence intervals and p-values. Linear mixed model correctly adjusts estimates for intra-cluster correlations as well as for intra-individual correlations due to repeated measurements in time. The model also handles unbalanced data by allowing inclusion of all available information, also from dropouts. The analyses for primary and secondary outcomes will be adjusted for baseline PGSI-scores, baseline severity of dementia (Clinical Dementia Rating), and age of the participants.

For RQ2 the dependent variables will be the changes from baseline in primary or secondary outcomes that are statistically significant after the implementation of TIME. Independent variables will be participants characteristics from the RCT, and organizational data (staff characteristics and organizational data) assessed in the process evaluation study in WP3.

Data analysis of qualitative data for RQ3

For the analysis, thematic content analysis will be used. Thematic content analysis is a method with the purpose to identify, analyse, and report patterns and themes in qualitative data (59, 60). The aim is to provide a systematic description of both the manifest and latent content of the data, and in the

end to evolve new concepts and understanding of phenomena. Accordingly, our analysis will consist of four steps: (1) an overall impression obtained from repeated reading of the transcribed text; (2) identification of meaning units using coding and condensation of these meaning units. Coding will be effected by labelling related text elements, excised from the original text, and reassembled as meaning units in a new document; (3) abstraction of these units by grouping them into subthemes and then the subthemes into main themes; and (4) a summation of these subthemes and themes seen in the context of our research questions, existing theory or new theoretical formulations, if necessary (59).

Ethical considerations

The Data Protection Official, Innlandet Hospital Trust, has approved applications. The collected data from the sampled patients will be de-identified and stored on a secured research server at Innlandet Hospital Trust. Participants with the capacity to provide consent will be asked to give their written consent; assessment of such capacity will be performed by the local project nurses (RN) who have experience of doing such assessment. In addition, these RN will be given extra training by the research team, who has long clinical experience in preforming capacity assessment. For patients considered to lack the capacity to consent, the next of kin will be informed about the research and asked to provide consent on the patient's behalf. The consent implies an understanding of what it means to participate in the RCT and the interviews and the ability to express an informed choice. Separate consents for participating in the RCT and the interviews will be obtained. It is very unlikely that a participant would be harmed because of participating in either the RCT or the interviews. In the RCT, no new experimental treatments for the patients will be introduced, and care and treatment actions will rely on recommended national care and treatment guidelines. The patients in the control group will receive care and treatment as usual but will probably also profit of the extra attention given by the services because of participating in an RCT. It is not possible to achieve blinding of the local home cares services for the recruitment process since it is the local home care services with the aforementioned local project nurses who will be responsible for the recruitment process based on the inclusion criteria (e.g., perceived by the home care service as being in an unstable situation). This will also be the case for the results of the allocation process (i.e., to the intervention or control group).

For RQ3, both patients and their next of kin who are invited to participate in interviews will be asked to give their written consent. During the interview, the participants will be well taken care of by interviewers who have long clinical experience in working with people with cognitive impairment. If during the interview the patient indicates or signals that he/she wants to stop, the researcher will immediately end the interview. A patient who lacks understanding of what it means to participate in research but consents to participate in an interview will be given the opportunity to bring their next of kin to the interview. Even if some of the participants have cognitive impairment and lack of capacity to understand the concept of research, they may still have the capacity to understand and express relevant views on the services they receive. Hearing their experiences with crises and how it was handled by the service is therefore important. This is a patient group that is prone to crises, but also to neglect and probably poorer treatment from the service since they often have difficulty promoting their needs, preferences, and desires. This is an important reason why this group of patients should be included in both the RCT and the interview study with the common final aim to improve approaches towards crises.

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Since the local project groups can consist of staff members from home care services, precautions will be taken to ensure that the members of the local project group that inform the users and their next of kin, don't have any care-relation to the participants invited to participate in the interview study (RQ3). In this way the users of home care services and their next of kin should do not feel obliged to participate upon being informed about the project. Members of the local project groups will only share information about the project with users and hand out written information and consent forms. In this way, the members of the local project group will not know whether the users of home care services and their next of kin have consented to participate or not.

Potential impact of the proposed research

Due to the patients' multimorbidity, changes in home care services can hardly be introduced as standardized solutions based on single diagnoses but should be made through holistic approaches based on multimorbidity and functional impairments. The PRACTIC study will enhance innovation where health professionals, management, and users actively participate in the development of new knowledge and a new approach towards each patient and where this process is adapted to local structural conditions. The project is likely to enforce a systematic cooperation with the GPs, where diagnostic work-up and follow-up become one of the most important tasks. For the home care services, this means a cultural change from a mainly task-oriented service based on failure in activities of daily life, to an interdisciplinary assessment and follow-up service of functional impairment in the user group. If successful, the intervention can, based on the process evaluation study in WP3, easily be implemented in the healthcare services with minimal extra resources. Improving the approaches to crisis may reduce the use of specialist healthcare services.

Project organization and collaboration

This study is a part of the PRACTIC study: Preventing and approaching crises for frail community-dwelling patients through innovative care. The project is owned by the Research Centre for Age-Related Functional Decline and Disease (AFS), Innlandet Hospital Trust, Ottestad, Norway. The project manager of the PRACTIC study is PhD MD Sverre Bergh, research leader at AFS, who will, together with professor Øyvind Kirkevold (AFS), PhD MD Bjørn Lichtwarck (AFS) and PhD RN Janne Myhre (AFS) also be part of the research team in this project. The research group has extensive research experience in health care services for patients with complex care needs.

The project has organized two reference groups, one with end-users (patients and next of kin) and one with staff from the home care services including GPs. The reference groups will meet with the central project group regularly during the project period. A steering group will be organized, consisting among others of stakeholders from municipalities and the county governor of Innlandet. The design of the project will enable close cooperation with end-users and stakeholders in the municipalities, through the establishment of local project groups in each municipality.

Collaborators in the project

Collaborating municipalities will recruit participants to the different sub-studies, **organize local project groups**, be active in the local adaptation and development of the TIME model, and participate in the reference groups. So far, **four municipalities have signed an intentional agreement**. The municipalities will contribute to the teaching of staff and data collection.

Hochschule fùr Gesundheit (hsg) Bochum, University of Applied Sciences (Germany, Prof. Daniela Holle), has developed the case conference model WELCOME-IdA, similar to the TIME model, and published papers on a step-wedged **cRCT and the process evaluation** (61-63). They will contribute to the plan for the analyses, interpretation of the results, and writing of papers in WP2 and WP3.
The Norwegian National Advisory Unit on Ageing and Health (Norway, Prof. Geir Selbæk), has extensive experience in performing research in municipality healthcare in Norway, including recruitment of participants from home care service. They will participate in all WPs, in the design of the study, recruitment of municipalities and participants, analysis and writing of papers.
The Centre for Development of Institutional and Home care Services (USHT) Innlandet (PhD Irene Røen and Målfrid Schiager) has a **network of collaborating municipalities** in Innlandet county, and a network of USHTs in Norway. They will contribute to the design of the study, will **recruit 30 municipalities** for the study, and will contribute to the organisation of the study and collaboration with the municipalities.
Collaborating partners in the study will not have access to any of the data.

Plan for activities
Three papers will be published in international peer reviews open journals.
In addition, results from this study will be presented by oral presentation at national and international congress.

Time schedule
PhD 75% position for four years
01.06.22: Application to the Regional Committees for Medical and Health Research Ethics. Application to the The Data Protection Commissioner, Innlandet Hospital Trust.
01.04.22 – 31.08.22: : Detailed planning of the project, recruitment of municipalities, signing agreements with municipalities and establishing local project groups in each municipalities.
01.09.22 – 31.12.22: Educational sessions for the local project nurses in the home-care services designated to assist with the inclusion of patients and their next of kin.
01.01.23 – 31.12.23: The RCT: Inclusion of participants, baseline measurements, randomisation and allocation procedures, start of intervention with educational sessions in IM, and follow-up data collection of outcomes after 3 and 6 months after baseline in IM and CM.
01.01.24 – 30.06.24: In-depth interviews for RQ3.
01.01.24 – 31.01.25: Analyses of data from the RCT (RQ1) and for RQ2, writing and submission of two papers.
01.02.25 – 30.11.25: Analysis of interviews for RQ3, writing and submission of paper.
01.08.25 – 31.03.26: Writing of thesis, dissertation, and dissemination.

Abbreviations

Declarations section

Consent to publish
Not applicable

Competing interests

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The authors declare that they have no competing interests.

Authors' contributions

Availability of data and materials

The datasets supporting the conclusions of this article are available on the website for the PRACTIC study.

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References

1. World Health Organization. The World report on ageing and health. Report No.: ISBN: 9789241565042. Geneva: World Health Organization; 2015. 267 p.
2. OECD. Health at a Glance 2015: OECD indicators. Paris: OECD Publishing; 2015.
3. Statistisk Sentralbyrå. Sjukeheimar, heimetjenester og andre omsorgstjenester ['home care services and other forms og helalth care serviceses']: Statistisk sentralbyrå, Statistic Norway; 2019 [Available from: https://www.ssb.no/helse/statistikker/pleie.
4. Genet N, Boerma W, Kroneman M, Hutchinson A, Saltman R, B. Home care across Europe: current structure and future challenges: World Health Organization. Regional Office for Europe; 2012 [Available from: https://apps.who.int/iris/bitstream/handle/10665/327948/9789289002882-eng.pdf.
5. Hopkinson JB, King A, Mullins J, Young L, Kumar S, Hydon K, et al. What happens before, during and after crisis for someone with dementia living at home: a systematic review. Dementia. 2020;20(2):570-612.
6. Teng C, Loy CT, Sellars M, Pond D, Latt MD, Waite LM, et al. Making decisions about long-term institutional care placement among people with dementia and their caregivers: systematic review of qualitative studies. Gerontologist. 2020;60(4):e329-46.
7. Tarricone R, Tsouros AD. Home care in Europe: the solid facts: WHO Regional Office Europe; 2008.
8. Nylenna M. Helsetjenesten i Norge. Et overblikk [Healthcare services in Norway. An overview]. Norwegian, Oslo: Gyldendal Akademisk; 2014.
9. Kingston A, Robinson L, Booth H, Knapp M, Jagger C, project M. Projections of multi-morbidity in the older population in England to 2035: estimates from the Population Ageing and Care Simulation (PACSim) model. Age Ageing. 2018;47(3):374-80.
10. Collard RM, Boter H, Schoevers RA, Oude Voshaar RC. Prevalence of frailty in community-dwelling older persons: a systematic review. J Am Geriatr Soc. 2012;60(8):1487-92.
11. Vetrano DL, Palmer K, Marengoni A, Marzetti E, Lattanzio F, Roller-Wirnsberger R, et al. Frailty and Multimorbidity: A Systematic Review and Meta-analysis. The journals of gerontology Series A, Biological sciences and medical sciences. 2019;74(5):659-66.
12. Travers J, Romero-Ortuno R, Bailey J, Cooney M-T. Delaying and reversing frailty: a systematic review of primary care interventions. Br J Gen Pract. 2019;69(678):e61-9.
13. Teo N, Gao Q, Nyunt MSZ, Wee SL, Ng TP. Social frailty and functional disability: findings from the Singapore longitudinal ageing studies. J Am Med Dir Assoc. 2017;18(7):637.e13-.e19.

14. Teo N, Yeo PS, Gao Q, Nyunt MSZ, Foo JJ, Wee SL, et al. A bio-psycho-social approach for frailty amongst Singaporean Chinese community-dwelling older adults–evidence from the Singapore Longitudinal Aging Study. BMC Geriatr. 2019;19(1):350.
15. Vroomen JM, Bosmans JE, van Hout HP, de Rooij SE. Reviewing the definition of crisis in dementia care. BMC Geriatr. 2013;13(1):10.
16. Ledgerd R, Hoe J, Hoare Z, Devine M, Toot S, Challis D, et al. Identifying the causes, prevention and management of crises in dementia. An online survey of stakeholders. Int J Geriatr Psychiatry. 2016;31(6):638-47.
17. Di Pollina L, Guessous I, Petoud V, Combescure C, Buchs B, Schaller P, et al. Integrated care at home reduces unnecessary hospitalizations of community-dwelling frail older adults: a prospective controlled trial. BMC Geriatr. 2017;17(1):53.
18. Helsedirektoratet. Tidlig oppdagelse og rask respons ved forverret somatisk tilstand. Nasjonale faglige råd 2020 [Available from: https://www.helsedirektoratet.no/faglige-rad/tidlig-oppdagelse-og-rask-respons-ved-forverret-somatisk-tilstand.
19. Hoel KA, Rokstad AMM, Feiring IH, Lichtwarck B, Selbæk G, Bergh S. Staff's perspectives on the organization of homecare services to people with dementia—a qualitative study. Nurs Open. 2021;8(4):1797-804.
20. Forskningsrådet. Omsorgstjenesteforskningen i Norge - kunnskapsnotat. Oslo: Forskningsrådet; 2019.
21. Naess G, Wyller TB, Kirkevold M. Structured follow-up of frail home-dwelling older people in primary health care: is there a special need, and could a checklist be of any benefit? A qualitative study of experiences from registered nurses and their leaders. J Multidiscip Healthc. 2019;12:675-90.
22. Smith SM, Wallace E, O'Dowd T, Fortin M. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. The Cochrane database of systematic reviews. 2016;3:CD006560.
23. Leykum LK, Pugh JA, Lanham HJ, Harmon J, McDaniel RR, Jr. Implementation research design: integrating participatory action research into randomized controlled trials. Implement Sci. 2009;4:69.
24. Hawe P, Shiell A, Riley T. Complex interventions: how "out of control" can a randomised controlled trial be? BMJ. 2004;328(7455):1561-3.
25. Lichtwarck B, Myhre J, Selbaek G, Kirkevold O, Rokstad AMM, Benth JS, et al. TIME to reduce agitation in persons with dementia in nursing homes. A process evaluation of a complex intervention. BMC Health Serv Res. 2019;19(1):349.
26. Vernooij-Dassen M, Moniz-Cook E, Verhey F, Chattat R, Woods B, Meiland F, et al. Bridging the divide between biomedical and psychosocial approaches in dementia research: the 2019 INTERDEM manifesto. Aging Ment Health. 2019;25(2):206-12.
27. Clare L, Kudlicka A, Oyebode JR, Jones RW, Bayer A, Leroi I, et al. Goal-oriented cognitive rehabilitation for early-stage Alzheimer's and related dementias: the GREAT RCT. Health Technol Assess. 2019;23(10):1-242.
28. Lichtwarck B, Selbaek G, Kirkevold Ø, Rokstad AM, Benth JS, Lindstrøm JC, et al. Targeted interdisciplinary model for evaluation and treatment of neuropsychiatric symptoms: a cluster randomized controlled trial. The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry. 2018;26(1):25-38.
29. Dalbak ETG, Væringstad A, Lichtwarck B, Myhre J, Holle D, Bergh S, et al. Preventing and approaching crises for frail community-dwelling patients through innovative care (PRACTIC). Study protocol for a process evaluation of a complex intervention in home care service (submitted). 2023.
30. Lichtwarck B, Væringstad A, Hoel K-A. TID Tverrfaglig Intervensjonsmodell ved utfordrende atferd ved Demens - Manual 3.utgave Ottestad: Sykehuset Innlandet,

Forskningssenter for Aldersrelatert Funksjonssvikt og Sykdom (AFS); 2019 [updated 01.08.2019.
31. Beck JS. Cognitive behavior therapy: Basics and beyond. New York: Guilford Press; 2011.
32. Lichtwarck B, Myhre J, Goyal AR, Rokstad AMM, Selbaek G, Kirkevold O, et al. Experiences of nursing home staff using the targeted interdisciplinary model for evaluation and treatment of neuropsychiatric symptoms (TIME) - a qualitative study. Aging Ment Health. 2019;23(8):966-75.
33. Hoel KA, Lichtwarck B, Væringstad A, Feiring IH, Rokstad AMM, Selbæk G, et al. Targeted interdisciplinary model for evaluation and treatment of neuropsychiatric symptoms (TIME) in home care services: a cluster randomized feasibility trial. BMC Health Serv Res. 2022;22(1):415.
34. Clare L, Kudlicka A, Oyebode JR, Jones RW, Bayer A, Leroi I, et al. Individual goal-oriented cognitive rehabilitation to improve everyday functioning for people with early-stage dementia: a multicentre randomised controlled trial (the GREAT trial). Int J Geriatr Psychiatry. 2019;34(5):709-21.
35. Engel GL. The need for a new medical model: a challenge for biomedicine. Science. 1977;196(4286):129-36.
36. Cilliers P. Complexity and postmodernism: Understanding complex systems. London: Routledge; 2002.
37. Groot Kormelinck CM, van Teunenbroek CF, Kollen BJ, Reitsma M, Gerritsen DL, Smalbrugge M, et al. Reducing inappropriate psychotropic drug use in nursing home residents with dementia: protocol for participatory action research in a stepped-wedge cluster randomized trial. BMC Psychiatry. 2019;19(1):298.
38. Langley GJ, Moen RD, Nolan KM, Nolan TW, Norman CL, Provost LP. The improvement guide: a practical approach to enhancing organizational performance: John Wiley & Sons; 2009.
39. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. Ann Intern Med. 2017;167(1):40-7.
40. Patton MQ. Designing qualitative studies. In M. Patton (Ed.) Qualitative research and evaluation methods. Los Angeles: Sage Publications, Inc; 2015.
41. Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, et al. A global clinical measure of fitness and frailty in elderly people. Canadian Medical Association Journal. 2005;173(5):489-95.
42. Campbell MK, Mollison J, Steen N, Grimshaw JM, Eccles M. Analysis of cluster randomized trials in primary care: a practical approach. Family Practice. 2000;17(2):192-6.
43. Patton M. Designing qualitative studies. In: Patton M, editor. Qualitative research and evaluation methods. United States of America: Sage Publications, Inc.; 2015.
44. Krueger RA, Casey MA. Focus groups: A practical guide for applied research. Los Angeles: Sage publications; 2015.
45. Wood S, Cummings JL, Hsu MA, Barclay T, Wheatley MV, Yarema KT, et al. The use of the neuropsychiatric inventory in nursing home residents. Characterization and measurement. The American journal of geriatric psychiatry : official journal of the American Association for Geriatric Psychiatry. 2000;8(1):75-83.
46. Weiner MF, Martin-Cook K, Svetlik DA, Saine K, Foster B, Fontaine CS. The quality of life in late-stage dementia (QUALID) scale. Journal of the American Medical Directors Association. 2000;1(3):114-6.

47. Roen I, Selbaek G, Kirkevold O, Engedal K, Lerdal A, Bergh S. The Reliability and Validity of the Norwegian Version of the Quality of Life in Late-Stage Dementia Scale. Dementia and geriatric cognitive disorders. 2015;40(3-4):233-42.
48. Ulstein I, Bruun Wyller T, Engedal K. The relative stress scale, a useful instrument to identify various aspects of carer burden in dementia? Int J Geriatr Psychiatry. 2007;22(1):61-7.
49. McCreedy E, Ogarek JA, Thomas KS, Mor V. The minimum data set agitated and reactive behavior scale: measuring behaviors in nursing home residents with dementia. J Am Med Dir Assoc. 2019;20(12):1548-52.
50. Lawton MP. Scales to measure competence in everyday activities. PsychopharmacolBull. 1988;24(4):609-14.
51. Jørgensen LB, Thorleifsson BM, Selbæk G, Šaltytė Benth J, Helvik AS. Physical diagnoses in nursing home residents - is dementia or severity of dementia of importance? BMC Geriatr. 2018;18(1):254.
52. Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, et al. A global clinical measure of fitness and frailty in elderly people. Can Med Assoc J. 2005;173(5):489-95.
53. Toh HJ, Yap P, Wee SL, Koh G, Luo N. Feasibility and validity of EQ-5D-5L proxy by nurses in measuring health-related quality of life of nursing home residents. Qual Life Res. 2021;30(3):713-20.
54. Lyketsos CG, Galik E, Steele C, Steinberg M, Rosenblatt A, Warren A, et al. The General Medical Health Rating: a bedside global rating of medical comorbidity in patients with dementia. J Am Geriatr Soc. 1999;47(4):487-91.
55. Berg L. Clinical Dementia Rating (CDR). Psychopharmacol Bull. 1988;24(4):637-9.
56. Clare L, Kudlicka A, Oyebode JR, Jones RW, Bayer A, Leroi I, et al. Individual goal-oriented cognitive rehabilitation to improve everyday functioning for people with early-stage dementia: A multicentre randomised controlled trial (the GREAT trial). Int J Geriatr Psychiatry. 2019;34(5):709-21.
57. McCreedy E, Ogarek JA, Thomas KS, Mor V. The Minimum Data Set Agitated and Reactive Behavior Scale: Measuring Behaviors in Nursing Home Residents With Dementia. Journal of the American Medical Directors Association. 2019.
58. Kvale S, Brinkmann S. Interviews: Learning the craft of qualitative research. Los Angeles: Sage Publications; 2009.
59. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative research in psychology. 2006;3(2):77-101.
60. Vaismoradi M, Turunen H, Bondas T. Content analysis and thematic analysis: Implications for conducting a qualitative descriptive study. Nursing & health sciences. 2013;15(3):398-405.
61. Halek M, Reuther S, Müller-Widmer R, Trutschel D, Holle D. Dealing with the behaviour of residents with dementia that challenges: A stepped-wedge cluster randomized trial of two types of dementia-specific case conferences in nursing homes (FallDem). International Journal of Nursing Studies. 2020;104:103435.
62. Holle D, Muller-Widmer R, Reuther S, Rosier-Segschneider U, Graf R, Roes M, et al. Process evaluation of the context, reach and recruitment of participants and delivery of dementia-specific case conferences (WELCOME-IdA) in nursing homes (FallDem): a mixed-methods study. Trials. 2019;20(1):45.
63. Holle D, Teupen S, Graf R, Müller-Widmer R, Reuther S, Halek M, et al. Process evaluation of the response of nursing homes to the implementation of the dementia-specific case conference concept WELCOME-IdA: A qualitative study. BMC Nursing. 2020;19(1):14.

Figure 1. The PRACTIC trial: Flowchart of the clusters and patients throughout the phases of the trial

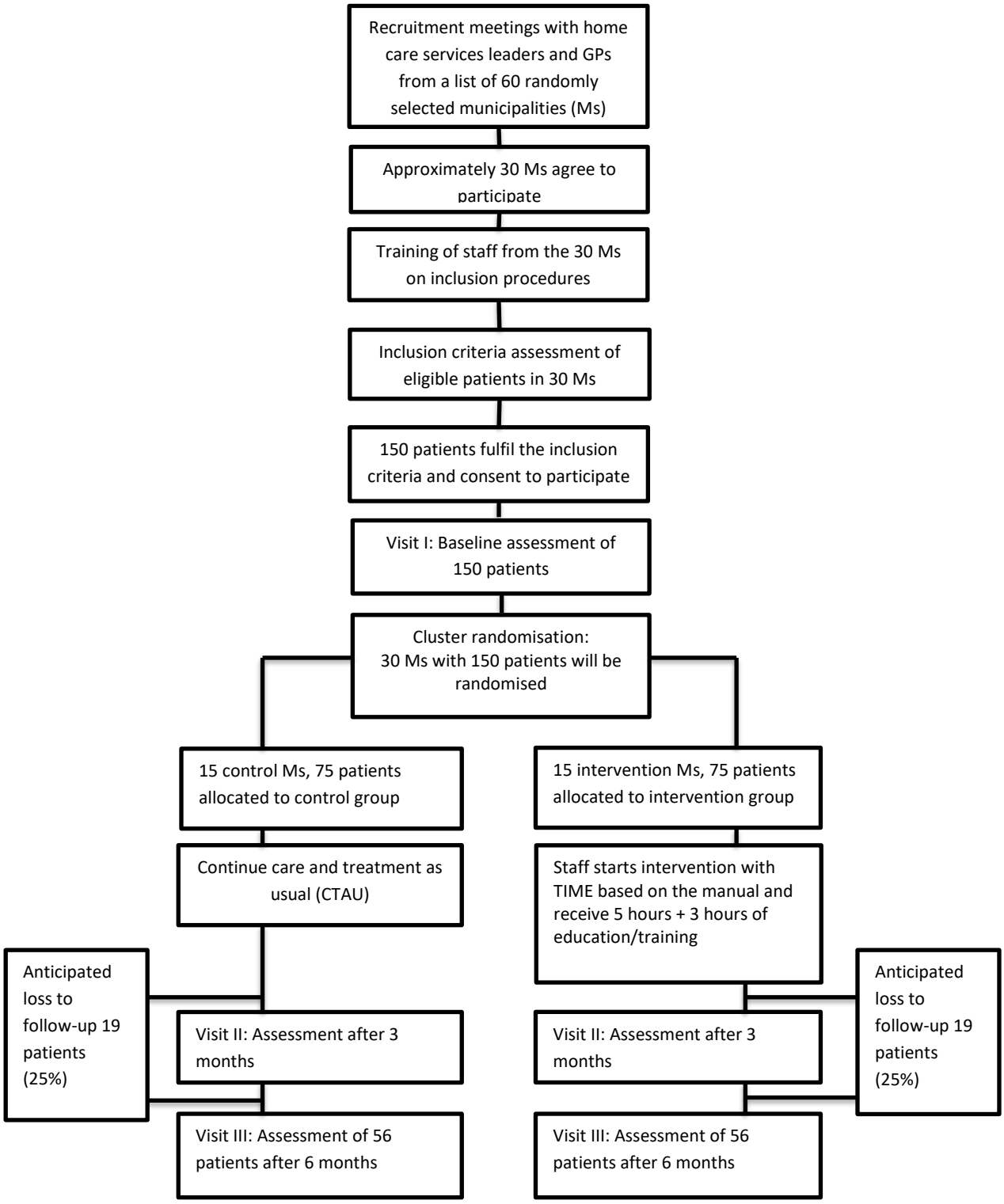

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Table 1. The assessment phase

Checklist for the assessment phase	
The following should be performed:	PRACTIC Goal Setting Interview (PGSI)
	Personal history and conversation with the person: what is the person's perspective? For example, "Who am I?"
	Medical history: A summary
	Somatic and psychological assessment and examination
	ADL assessment: Activities of daily living
	Nutritional screening
Suspected conditions:	☐Yes ☐No If dementia is suspected, start a basic dementia assessment. In the case of known dementia, assess the degree of dementia.
	☐Yes ☐No If pain is suspected, conduct a pain assessment.
	☐Yes ☐No In the case of behavioral and psychological symptoms, map the symptoms.
	☐Yes ☐No In case of nutritional difficulties, perform nutritional mapping.
	☐Yes ☐No In case of acute confusion (delirium), map the synptoms and contact a doctor.
Agree upon a time and place for the case conference: TID administrator/manager	

Table 2. Agenda and timeframe for the case conferences

Agenda for guided reflection meeting (case conference), approximately 1 hour	
Activity	Preparation: Convene a meeting and prepare a meeting room with a blackboard or similar facilities (projector, if available). Check that a flip pad and markers are available. As many as possible from the home care service staff should attend the conference. The leading registered nurse and the GP should attend the conference, if possible.
	1. Status Report: Personal history and main points from the patient's medical record are presented, 10 min. Decide in advance who should prepare and present the patient's personal history and the main points from the medical record.
	2. Create a problem list, approximately 5 min.
	3. Prioritize problems from the list, approximately 5 min.
	4. Draw a five−column table on the whiteboard that includes facts – interpretations (thoughts) - emotions – actions – evaluation.
	5. Describe facts from the registration and assessment phase one problem at a time, approximately 10 min.
	6. Suggest interpretations – guided discovery – discuss and reflect on the interpretations, approximately 10 min.
	7. Describe any emotions experienced by the staff with interpretations by the staff, approximately 10 min.
	8. Suggest SMART (Specific, Measurable, Achievable, Relevant, Time-bound) actions based on the interpretations and decide how and when to perform an evaluation of the actions, approximately 10 min.
	9. Summarize interpretations and actions and close the meeting, approximately 5 min.