

# Supporting elderly people with cognitive impairment during and after hospital stays with Intersectoral Care Management [intersec-CM]: study protocol for a randomised controlled trial

**Angela Nikelski**

Evangelisches Klinikum Bethel

**Armin Keller**

German Center for Neurodegenerative Diseases (DZNE)

**Fanny Schumacher-Schönert**

German Center for Neurodegenerative Diseases (DZNE)

**Terese Dehl**

Universitätsmedizin Greifswald

**Jessica Laufer**

German Center for Neurodegenerative Diseases (DZNE)

**Ulf Sauerbrey**

University Hospital Jena

**Diana Wucherer**

German Center for Neurodegenerative Diseases (DZNE)

**Adina Dreier-Wolfgramm**

Universitätsmedizin Greifswald

**Bernhard Michalowsky**

German Center for Neurodegenerative Diseases (DZNE)

**Ina Zwingmann**

German Center for Neurodegenerative Diseases (DZNE)

**Horst Christian Vollmar**

Ruhr-Universität Bochum

**Wolfgang Hoffmann**

Universitätsmedizin Greifswald

**Stefan H. Kreisel**

Evangelisches Klinikum Bethel

**Jochen René Thyrian** (✉ [rene.thyrian@dzne.de](mailto:rene.thyrian@dzne.de))



German Center for Neurodegenerative Diseases (DZNE) <https://orcid.org/0000-0001-6889-693X>

## Study protocol

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# Abstract

**Background** Sectorization of health care systems causes inefficient treatment, especially for elderly people with cognitive impairments. The transition from hospital care to primary care is insufficiently coordinated, and communication between health care providers is often lacking. Consequences include a further deterioration of health, higher rates of hospital readmission, and institutionalization. Models of collaborative care have shown their efficacy in primary care by improving patient-related outcomes. The main goal of this trial is to test the effectiveness of a collaborative care model for people with cognitive impairment (PCI) and current hospital treatment due to a somatic illness to improve the continuity of treatment and care across the transition between the in-hospital and adjoining primary care sectors.

**Methods** The trial is a longitudinal multisite randomized controlled trial with two arms (“care as usual” and “intersectoral care management”). Inclusion criteria at the time of hospital admission due to a somatic illness: age 70+, cognitive impairment (Mini Mental State Examination, MMSE  $\leq$  26), live at home, provide written informed consent. Each participant will have a baseline assessment at the hospital and two follow-up assessments at home (three and twelve months after discharge). The estimated sample size is n=398 participants together with (where available) their respective informal caregivers. In the intersectoral care management group, specialized care managers will develop, implement and monitor individualized treatment and care based on comprehensive assessments of the patients and informal caregivers for unmet needs at the hospital and in their homes. Primary outcomes are (1) activities of daily living, (2) readmission to the hospital, and (3) institutionalization. Secondary outcomes include (a) frailty, (b) delirium, (c) quality of life, (d) cognitive status, (e) behavioral and psychological symptoms of dementia, (f) utilization of services, and (g) informal caregiver burden.

**Discussion** In the event of proving efficacy, this trial delivers proof of concept for implementation into routine care. Cost-effectiveness analyses as well as an independent process evaluation increase the likelihood of meeting this goal. The trial allows in-depth analysis of mediating and moderating effects for different health outcomes at the interface between hospital care and primary care. Highlighting treatment and care, the study will provide insights into unmet needs at the time of hospital admission, the opportunities and barriers to meeting those needs during the hospital stay and after discharge.

## Background

The German health care system is strongly sectorized with health service providers offering a) outpatient treatment and care predominantly provided by GPs and specialists in private practice, b) inpatient treatment and care provided in hospitals, or c) rehabilitation. While treatment and care within each of these sectors can generally be of high quality, there is often a challenge to deliver continuous treatment and care across these sectors. Treatment pathways for people with chronic diseases or the needs of elderly people suffering from multimorbidity and cognitive impairments often include frequent transitions between these sectors. However, in Germany, the boundaries between sectors are often rigid, rendering transitions between sectors a threat to treatment continuity and care coordination, which often results in unfavorable outcomes for the patient. After this problem had already been identified and described in

detail by the “Advisory Council on the Assessment of Developments in the Health Care System” in 2012 (1), a number of different remedies were proposed. Their impact, however, has been limited to date. This study addresses the lack of integrated cross-sectoral approaches to overcome the challenges caused by the sectorized German health care system.

In particular, there is a lack of sustainable management at the interface between in- and outpatient treatment. Treatment and care need to be oriented more toward the patients’ needs rather than the hospitals’ processes or the needs of specific diseases (2, 3). There is evidence that patient involvement is positively associated with health behavior and treatment outcomes (4, 5). In Germany, some discharge management is mandatory by law and has to be available in each hospital (6). It is financed by statutory health insurance and has just recently been specified and extended (7, 8). However, the discharge management in routine care differs greatly from the expert standard proposed by, for example, the “German Network for Quality Development in Nursing” (9). There should be more emphasis on individualized needs assessment, continued care after discharge and, most importantly, the inclusion of informal caregivers and/or relatives in the process of discharge. Especially in elderly people with cognitive impairment, it is well known that the need for professional and informal care at home increases. However, caregiving is burdensome (10, 11), and as such, the informal caregiver requires attention and support by health services providers. Preventing caregivers’ burden is not only beneficial to the caregiver but also to the patient and—from a societal perspective - to the health care system.

Current figures indicate that elderly people visit the emergency unit in hospitals more often than younger people do. In addition to their somatic illness, many of these patients also face mental health problems. Approximately 50% of the patients have cognitive impairments, 27% suffer from delirium, 8–32% suffer from depressive symptoms, 21% suffer from apathy, and 9% suffer from agitation/ aggression and others (12). In general, approximately half of the patients in hospitals belong to the age group of people older than 65 years (13). However, until today, cognitive impairments in the hospital are severely underdiagnosed. According to the German Federal Health Reporting Database ([www.gbe-bund.de](http://www.gbe-bund.de)), there was a total of 19,632,764 patients treated in hospitals in Germany in 2014. Only 0.002% had a diagnosis of dementia (14). However, an international review of prevalence rates of dementia suggests ranges from 3.4% to 43.3% depending on the age composition and study design, the setting and the identification/screening criteria (15). A nationwide survey of 1,844 head nurses yielded an average point prevalence of 23% of persons with cognitive impairment (PCI), independent of the specialty of the ward (16). Accordingly, official data from the German Federal Health Reporting Database ([www.gbe-bund.de](http://www.gbe-bund.de)) seem to underestimate the number of PCI and, consequently, the associated challenges for PCI, their informal caregivers and the primary healthcare providers. Current German primary data indicate point prevalences of PCI close to 20% based on a screening test (17). The point prevalence of dementing illnesses in German hospitals has been reported to be 18.4%. Delirium, most often on the basis of dementia, was present in 5.1%. Only 60.0% had no cognitive impairment (18). It is well established that cognitive impairments and resulting behavioral and psychiatric symptoms pose a challenge for (a) the patient, relatives, and informal caregivers, (b) the treatment of the patient, (c) the hospital team caring for the patient and (d) the hospital setting in general. Behavioral and psychological symptoms of dementia

(BPSD) are common in older hospital patients with cognitive impairment in hospitals and are associated with considerable distress in the nursing staff (19). Admission to the hospital is associated with the presence of cognitive problems or worsening of pre-existing cognitive problems, which increase the risk for readmission, institutionalization or mortality (20–22). These risks are aggravated by factors such as comorbidities, malnutrition, activities of daily living, depression and other mental disorders.

Upon discharge from the hospital, these risks complicate the transition to primary care and increase the need for postdischarge support for patients living in their homes. However, the specific needs of these patients are not adequately addressed in Germany today: a) postoperative treatments (by out-patient practitioners and therapists) and care arrangements are not sufficiently coordinated, b) medical reports and patient data necessary for the continuation of treatment and care are communicated incompletely or delayed between hospitals and GPs, and c) guidelines for intersectoral clinical pathways do not exist. These structural deficits, in summary, lead to insufficient treatment and care for many elderly patients with cognitive impairment, cost-intensive unscheduled rehospitalizations and premature institutionalization. Ultimately, both patients and healthcare providers are often dissatisfied.

One approach to overcome those interface problems from a patient-centered perspective is collaborative case/care management. In Germany, in the field of cognitive impairment/dementia, the DelpHi-MV study (Dementia: life- and person-centred help in Mecklenburg-Western Pomerania) (23, 24) tested the efficacy of a model of collaborative care in patients with dementia living in their own homes. The DelpHi-MV study is a general practitioner (GP)-based cluster-randomized controlled intervention trial in the primary care setting that evaluated the efficacy of Dementia Care Management (23). The results of DelpHi-MV have shown improvements in relevant patient- and informal caregiver-related outcomes (24). Compared with care, the usual behavioral and psychiatric symptoms of dementia and informal caregiver burden were decreased significantly. Moreover, in the subgroup of patients who did not live alone, quality of life for patients increased. Patients with dementia receiving DelpHi care management had an increased chance of antidementia drug treatment.

In a separate acceptance study, approximately 80% of the GPs participating in the study indicated that care management as provided in the DelpHi-MV study should become a basic service in routine care (25). Its further development for application in an intersectoral setting seems promising since the intervention modules are well defined, the necessary qualification for the dementia care managers has been developed (26, 27) and a computerized intervention management tool has been programmed (28). It is based on the principles of (i) individualized needs assessment, (ii) computer-supported development of a modular treatment and care plan, and (iii) implementation of this plan and the monitoring of its practicability and acceptance.

Based on the DelpHi experience, the objective of the Intersec-CM interventional trial is to test the efficacy of intersectoral care management for people with cognitive impairment (PCI) around the time of discharge from the hospital back into primary care. The main hypotheses are as follows:

- PCI receiving intersectoral care management during the transition from the hospital to their homes and into primary care show better patient-oriented health outcomes than PCI receiving care as usual at time points 3 and 12 months after discharge.
- PCI receiving intersectoral care management during the transition from the hospital to home have a lower frequency of unscheduled readmissions to the hospital than PCI receiving care as usual.
- PCI receiving intersectoral care management during the transition from the hospital to home are less likely to be institutionalized 12 months after discharge from the hospital than PCI receiving care as usual.

## Methods/design

### Study design and sites

This study is a multisite, longitudinal, randomized controlled intervention trial (RCT) with two arms (intervention and “care as usual”) and four time points of data assessment (screening, baseline, follow-up 1, follow-up 2). The aim is to compare the effectiveness of an intervention (intersectoral care management designed to improve health and social outcomes of PCI in inpatient and ambulatory care) between a group receiving the intervention and a group receiving “care as usual”. There are two sites participating in this trial, the Evangelisches Klinikum Bethel in Bielefeld/ North Rhine-Westphalia and the University of Medicine in Greifswald, Mecklenburg-Western-Pomerania, with its sites in Wolgast and Greifswald. The first patient was enrolled on the 1<sup>st</sup> of November 2018. Recruitment is planned for 12 months; thus, the last patient enrollment is on the 31<sup>st</sup> of October 2019. We expect the last follow-up assessment 13 months later on the 30<sup>th</sup> of November 2020. The design of the study is summarized in Figure 1: Ethical approval for this trial has been obtained from the Ethical Committee of the University Medicine Greifswald (Registry number: BB 159/17) and the Ethical Committee of the Chamber of Physicians Westphalia-Lippe (Registry number: 2017–688-b-S). The trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT03359408) (NCT03359408).

—Please insert Figure 1 about here—

### Study population and selection criteria

Elderly PCI admitted to a general hospital with somatic illnesses are eligible for the study. The inclusion criteria for these index participants were as follows: age 70+ with cognitive impairment detected with a standardized screening instrument (Mini Mental State Examination, MMSE  $\leq$  26) (29), having lived at home prior to the index admission, living in the catchment area of the hospital, and providing written informed consent (personally or by the legal guardian when necessary). The exclusion criteria were acute stroke as the primary reason for admission, terminal disease, and nonsufficient language skills.

Since the treatment and care of elderly people with cognitive impairment may be dependent on informal caregivers, index participants are asked to name their informal caregivers (e.g., spouse, child, friend). The informal caregiver is then invited as an independent study participant upon provision of written informed consent. While we put effort into recruiting this group, the participation of an informal caregiver is not a necessary requirement for the inclusion of an index participant.

## Intervention

The framework for the intervention is the evidence-based Dementia Care Management as conducted in the DelpHi-MV study (23, 24). In principle, it consists of (i) a comprehensive assessment of the health and social status of the patient at the time of admission to the hospital; (ii) a comprehensive needs assessment at the time of admittance to the hospital or shortly after; (iii) if applicable and available, an assessment of informal caregiver health and burden; (iv) a systematic, written feedback to the treating hospital physician and nursing staff with recommendations for treatment and care for the patient after discharge (hospital information letter; these recommendations are based on predefined algorithms using the results of the assessment); (v) the assessment of the patient's health situation at the time of discharge; (vi) a comprehensive needs assessment at the patient's home immediately after discharge; (vii) if applicable and available, an assessment of the informal caregivers' health and burden; and (viii) support in meeting patients' needs identified by the needs assessment.

The entire intervention delivery by specifically trained study nurses (case manager, social worker and/or Dementia Care Manager) (30) will be supported by a computerized tablet-based Intervention-Management-System (IMS) for intersectoral care management. The system is a rule-based expert decision support system that matches individual patient characteristics to recommendations for treatment and care. The system supports the identification of a patient's unmet needs, selects corresponding patient-specific interventions, and integrates these into an individualized intervention plan. The IMS has been proven to support the systematic identification of unmet needs, to improve the selection of specific intervention modules and to systematically address them (25, 28).

The intervention of this study does not, however, replace any provisions offered by other providers in the hospital or in the ambulatory settings.

## Outcomes

The primary objective of the study is to evaluate the efficacy of intersectoral care management for elderly people with cognitive impairment admitted to the hospital. Primary outcomes are activities of daily living representing functionality after discharge, unscheduled readmissions and premature institutionalization.

They are measured as follows:

- Activities of daily living will be assessed using the Bayer Activities of Daily Living Scale; B-ADL (31), which consists of 25 items indicating everyday problems/challenges. The questionnaire targets community-dwelling patients who suffer mild cognitive impairment or mild-to-moderate dementia. It assesses the patient's general ADL competencies and specific tasks of everyday life in the following domains: medication, hygiene, reading, conversation, telephoning, shopping, food preparation, handling money and financial affairs, household appliances, transportation, leisure activities, everyday tasks that require unimpaired short- or long-term memory, and orientation in familiar and unfamiliar surroundings. The B-ADL also assesses nonspecific tasks requiring cognitive functions for the management of everyday life. These include remembering where to continue with an ongoing task after an interruption, doing two things at the same time, coping with unfamiliar or new situations that require the processing of new information, as well as the safety aspects of ADLs and difficulties performing a task when under pressure.
- To assess readmission to the hospital, the participant will be asked how many times he/she has been hospitalized (unplanned and planned) within the last 12 months. This is one item in the Questionnaire for the Use of Medical and Non-Medical Services in Old Age; FIMA (32), which is administered to assess utilization of health services. The FIMA examines socioeconomic variables and other medical factors by determining health-related costs.
- Institutionalization will be assessed in the course of the study, as the living situation will be checked at each time point of assessment.

Secondary outcomes of this trial are not explicitly targeted by the intervention but were chosen as important moderating or mediating factors for this trial. Among those, we consider the following: a) frailty, b) delirium, c) quality of life, d) cognitive status, e) neuropsychiatric symptoms, f) utilization of health services, and g) informal caregiver burden. We assume a), b), f) to be moderating factors and c), d), e), g) to be mediating factors.

- Frailty will be measured using the Edmonton Frail Scale (EFS) (33). The EFS is a reliable tool in geriatric medicine to assess the frailty of older patients on the domains of cognition, general health status, functional independence, social support, medication use, nutrition, mood, continence and functional performance. Scores can range from 0 (not frail) to 17 (severe frailty).
- Delirium will be assessed using the Family Confusion Assessment Method (FAM-CAM) (34). It consists of up to 7 items inquiring about the presence (yes/ no) of different delirium-specific symptoms and 1 item about general mental health since the last visit (better, worse, about the same). More information regarding the occurrence, stability, duration, frequency and recency are asked when a symptom has been reported as present in the items section of the questionnaire. A score can be calculated according to an algorithm published by the authors that delivers a score for suggested delirium to be present (1) or not (0). The FAM-CAM is a screening instrument and is not intended to provide a clinical diagnosis. Due to economic and time constraints in this intervention study, a detailed, guideline-oriented diagnosis of delirium is not available.



- Quality of life of the PCI will be assessed by using the EQ–5D for both the PCI and the caregiver (35). The EQ–5D is a standardized instrument developed by the EuroQol Group to provide a simple, generic measure of health for clinical and economic appraisal. Scores range from 0 (Death) to 1 (best possible health).
- Cognitive status will be assessed using the Mini Mental State Examination; MMSE (29). The MMSE is a 30-point questionnaire designed to measure cognitive impairment. The questions are grouped into seven categories, each representing a different cognitive domain or function: orientation to time (5 points); orientation to place (5 points); registration of three words (3 points); attention and calculation (5 points); recall of three words (3 points); language (8 points) and visual construction (1 point). Scores range from 0 (lowest cognitive status) to 30 (cognitive status not impaired).
- Neuropsychiatric symptoms will be assessed using the Neuropsychiatric Inventory; NPI (36). The NPI represents an interview by proxy on twelve dimensions of neuropsychiatric behaviors, i.e., delusions, hallucinations, agitation, dysphoria, anxiety, apathy, irritability, euphoria, disinhibition, aberrant motor behavior, night-time behavior disturbances, and appetite and eating abnormalities. Scores range from 0 (no neuropsychiatric symptom) to 144 (severe symptoms very often in all 12 dimensions).
- The utilization of health services will be assessed using the Resource Utilisation in Dementia Questionnaire; RUD (37) and the FIMA (32). The RUD will be used to assess the provision of informal care as well as informal caregivers' productivity losses. The FIMA assesses the frequencies of the utilization of medical and formal care services. Scores indicate whether a service is used (score 1) or not (score 0).
- Informal caregiver burden will be assessed using the 7-item (short) version of the Zarit-Burden Inventory; ZBI–7 (38). The short version ZBI is a caregiver self-report measure to examine burden that is associated with functional/behavioral impairments in the social, psychological and physiological context and home care situation. Scores range from 0(no burden) to 28 (highest possible burden)

Data assessment tools for these dimensions will be chosen based on either their recommendation by the JPND expert group or common use in larger German trials such as IDEMUCK (39), DelpHi-MV (23, 40, 41), DemNet-D (42–45) or IDA (46). These instruments are validated, and this will guarantee valid results and comparability in German and international studies. An overview of the assessment points of the outcome measures is provided in Figure 2.

## Sample size

The estimated enrollment for the study is  $n = 398$  index participants and (where available) their respective informal caregivers. This sample size is necessary in the context of a complex intervention, which could not be proven to be efficacious in smaller cohorts. A sample size of  $n = 199$  persons per arm is needed to detect effects on activities on daily living with a Cohen's  $d = 0.25$  (47). We expect a Cohen's  $d = 0.25$  based on the DelpHi-MV study (24), which was approximately the size of the effect of the intervention on

patients' activities on daily living (preliminary analyses since activities of daily living were not the primary outcome in this trial, but considered as secondary outcome). As the Intersec-CM intervention is adapted from Dementia Care Management, this should give a good estimate of what effect to obtain. In comparison between the intervention and control conditions at a significance level of  $p = 0.05$  and a statistical power of 80%, the sample size needed to obtain the same effect size as in the DelpHi-MV study ( $d = 0.25$ ) requires  $n = 199$  patients per arm. This planning includes that outcomes expected to deliver stronger effects are sufficiently powered.

In the longitudinal design, the sample size will decrease over time for various reasons. Loss to follow-up due to death, migration, declined informed consent and nonparticipation for logistic and organizational reasons will occur. Migration is unlikely to have a large effect because the 70+-year-old group tends to be geographically stable. Where a participant is lost to follow-up, efforts will be made to locate and recontact the participant. The data will be included in the main analysis. Withdrawal of initial consent will be documented wherever possible together with the reasons provided. We consider "loss to follow-up" to be approximately 30%, so that at least  $n = 279$  participants will provide completed data assessment at Follow-Up 2.

In summary, the sample size is sufficient to detect even moderate effects on the outcomes. Since this trial is the first RCT addressing these research questions in Germany (48), we cannot precisely calculate our sample size based on previous studies and do rely to some extent on assumptions. International studies are not readily comparable to the specificities of the German health care system. The trial will aim to reach the sample size calculated and will be prolonged if recruitment takes longer than expected.

## Study procedure

Target patients will be screened for cognitive impairment by study staff at the time of hospital admission or shortly after when their clinical status allows for this. The screening procedure consists of assessments to estimate cognitive impairment (including delirium) and its severity, including the 4AT (49), the Richmond Agitation-Sedation Scale (RASS) (50) and the Mini Mental State Examination (MMSE) (29).

People meeting all inclusion criteria will be informed personally and in writing about the intersec-CM trial. They will be invited to participate in the trial, and upon written informed consent, a baseline assessment will be conducted. The baseline assessment is based on the patients' hospital records (sociodemographic data, ICD-10 diagnoses, medication history) and a personal, structured interview. The interview uses established and valid instruments to assess activities of daily living (Barthel Index, (51)), frailty (Edmonton Frailty Scale; EFS) (33), nutrition (screening items of the Mini Nutritional Assessment; MNA; (52)), mobility (The Hierarchical Assessment of Balance and Mobility; HABAM) (53), pain (screening items), and sleep quality (screening items from the Pittsburgh Sleep Quality Index; PSQI) (54), depression (screening items). The interview includes a comprehensive needs assessment based on the

Camberwell Assessment of Need for the Elderly (CANE) (55) questionnaire and an adapted version of the Delphi-MV-needs assessment (26, 40).

After baseline assessment, each individual will be randomized into either the intervention or “care as a usual” group. The randomization method used is a computerized permuted block randomization. This method ensures that the ratio of intervention and “care as usual” CAU-participants is distributed evenly 1:1. Allocation to either intervention or CAU is conducted at the study center after baseline assessment so that the study staff is blind to the allocation during the initial assessment and cannot influence allocation. Full blinding will not be possible once the intervention has started due to the type of intervention.

Immediately following randomization, standardized and systematic feedback based on clinically relevant parameters ascertained in the baseline assessment will be issued to the treating hospital staff (hospital information letter) in both groups. The letter includes assessment data, but in the intervention group, it additionally includes recommendations for treatment and care to plan the discharge and to prepare activities regarding utilization of ambulatory services, medication, social integration and medical treatment after discharge. In both groups, medical status at the time of discharge will be documented using patient records. Patients in the intervention group will be contacted immediately after discharge, if possible, in person, to continue to deliver the intervention as outlined above. Otherwise, telephone contact is initiated with the intention to plan a timely in-person visit or visits by the specifically trained study nurses.

Follow-up assessments of all outcome measures and in both groups will be conducted 3 months and 12 months after discharge in structured personal interviews conducted preferably at the participant’s home. The place and time of the follow-up assessments are chosen for the highest possible convenience of the participants.

## **Data Collection**

Specially trained study staff will collect the data needed for the trial. Data will be collected in computer-assisted face-to-face interviews and by extraction from patients’ records. All interviews will be standardized using validated and reliable questionnaires. To reduce interviewer bias, study staff will be retrained and supervised weekly to ensure the optimum degree of comparability. The source of information in the interviews will predominantly be the participant with cognitive impairment. However, due to cognitive impairment, the validity of the information obtained may be compromised. The informal caregiver –if available– will serve as a proxy to validate facts (such as sociodemographic, ADL) and to fill in gaps in the patient’s answers. The source of each information will be documented and controlled for.

Data will be stored on a tablet-based computer at the time of assessment. This allows for plausibility checks at the time of assessment, reducing errors that would otherwise result from transferring data from

written paper notes to the computer. Data collection will take place in the hospital (screening, baseline) and at the participants' home (follow-up 1, follow-up 2).

## Data Analysis

### Statistical Analysis

Statistical analysis will be calculated as *intention-to-treat analyses* (ITT), including all individuals providing baseline values of the outcome variables. Missing follow-up values will be imputed. We will perform ITT analyses to reduce the impact of drop-out during the follow-up. To check whether systematic drop-out during the baseline assessment may influence the results, we will run multivariable logistic regressions with drop-out (yes/no) as the dichotomous outcome. The study group, sociodemographic variables and clinical parameters based on the screening (such as MMSE, 4A test) will be included as predictors. These analyses will be performed three times for 1) drop-out overall, 2) drop-out due to death, and 3) drop-out due to withdrawal of informed consent.

To describe the study sample, appropriate summary statistics such as the mean, median, minimum and maximum for continuous variables and frequencies and percentages for categorical data will be used.

The *primary analyses* will be conducted by using separate generalized linear models to test intervention efficacy. The main outcome variables at follow-up 1 (3 months after discharge) and follow-up 2 (12 months after discharge) will be the dependent variables. Model specification will correspond to the scale level of the outcome variable under investigation: activity of daily living (Bayer ADL) will be calculated by linear mixed regression, while for readmission into the hospital and institutionalization, logistic models will be used. The models will be adjusted for age, sex and living situation of the patients. The study group is the predictor of interest (care as usual vs. intervention). To account for the stochastic dependency patients treated in one of the two different study centers (Bielefeld and Greifswald), the study center will be included as a random effect variable. The baseline value of the outcome variable will be included as a covariate to reduce residual variance and to account for inter-individual variance at baseline. A positive intervention effect is defined as a significant regression coefficient (one-sided test) of the study group variable. Missing data will be imputed by multiple imputations via chained equations, stratified by study group. The overall alpha of the different primary outcome analyses will be adjusted.

For secondary analysis, sociodemographic variables (age under 80/above 80 years), sex (men/women), living situation (alone/not alone) and clinical parameters such as cognitive status, delirium and frailty will be included. These variables either showed an impact in the DelpHi-MV study (24, 56) or are expected to moderate the health trajectory of elderly people in general. The inclusion of sociodemographic and clinical parameters should result in decreased residual variance and enhanced statistical power. To improve the quality of the regression models, possible interaction effects will be analyzed for study group, age group, living situation and clinical parameters.

Economic evaluations will be conducted using methods that are consistent with those of published methodological guidelines for economic evaluations (57). Healthcare costs per patient will be calculated for a retrospective period of three months (Follow-up 1) and one year (Follow-up 2) from a public payers and societal perspective using published unit costs (58). To analyze differences in QALYs and costs, a linear mixed regression model will be used. The incremental cost-effectiveness ratio will be calculated using the incremental cost per QALY gained by the intervention compared with usual care. We will calculate the probability of the intervention being cost-effective at a wide range of willingness-to-pay margins using nonparametric bootstrapping to handle the sample uncertainty (59–61).

## Quality assurance and safety

To ensure high quality over all dimensions of this trial, several measures are put into place. A *scientific advisory board* will be installed, comprising experts in the field. This board will meet twice during the trial. A first meeting was held in January 2018 to critically discuss and fine-tune the design of the trial. A second meeting will be held in 2020 to advise on the scientific analysis and to discuss the first results.

A *trial steering committee* is installed, comprising all research partners. This committee meets at least every 6 months to monitor the trial. This committee evaluates whether the study sticks to the timeline, the work packages are sufficiently addressed and all milestones are met. If difficulties in meeting the requirements are encountered, this committee proposes solutions on the management level. Alterations of the study design will be discussed with the funding agency.

To ensure the quality of intervention delivery, there is regular supervision provided to the study staff to monitor intervention delivery and to fine-tune methods, skills and knowledge. To guarantee a high degree of standardization of the intervention, a computer-assisted IMS will be used.

Assessing and storing data needs to comply with legal standards of data privacy protection and data safety. Data management is conducted in compliance with the Data Protection Concept of the Institute for Community Medicine, Greifswald in its current version. This concept has been approved by the states data safety and freedom of information officer of Mecklenburg - Western Pomerania. This concept contains specific regulations regarding cooperation with the German Center for Neurodegenerative Diseases (DZNEs) at Rostock/ Greifswald and other partners. The Data Protection Concept of the Institute for Community Medicine, Greifswald, includes data security as well as data protection measures. For example, aspects such as informed consent management, restricted access to patient identifying data and medical data, pseudonymization for data analysis and dissemination, disposal of patient identifying data and IT security measures are addressed.

## Limitations

There are several limitations to be considered in this trial, which might be a threat to the reliability, validity and generalizability of the results. A) all subjects in the study are staying in the hospital due to an acute

illness or planned treatment not necessarily associated or connected with cognitive impairment. This causes heterogeneity of index illnesses that might decrease comparability between subjects. However, there is an objective, reliable and valid inclusion criteria for each participant, so that conclusions can be drawn for this sample. Also, the study is a close to routine care trial and since the complex intervention aims at the whole health care situation with consideration of comorbidity, this will not decrease the meaning of our results. B) Adherence to the study protocol might be difficult because the trial is conducted in routine care rather than in an experimental setting. This is a trade-off between evaluating the effect purely due to the intervention and the effect under close to routine conditions. We chose the second aim since it raises the chances of and gives more guidelines to the implementation (if the intervention is successful). C) Cognitive impairment might decrease the validity of information given by the participants. However, some measures (like i.e. quality of life) have to be provided by the participant him or herself, since they are subjective. Other information can and will be checked by the study assistants dependent on the cognitive status of the participant (like demographic data). We do include caregivers into the study and ask for patient records to achieve the best possible valid information. Furthermore we will include cognitive status as mediating factor in our analyses.

## Discussion

The relevance of this study for old and very old people is high. Intersec-CM addresses a) relevant problems in the health care system (sectorization of the in-hospital and primary care sector) and b) inadequate treatment and care for acutely ill patients with cognitive impairment in the transition between the hospital and primary care as a highly prevalent target group. It makes use of evidence-based methods with relevant outcomes for elderly patients (quality of life, activities of daily living) and relevant outcomes to the overall health of the target group.

We expect that the trial will add scientific evidence to improve the treatment and care of people with cognitive impairments at the interface between hospital and primary care. We assume that the adapted concept of Dementia Care Management improves patient-oriented outcomes as well as system-relevant outcomes. In the event of proving efficacy, this trial will deliver a proof of concept for implementation into routine care and—ideally—will change the current health care system to the better. The expected results from this trial could facilitate the implementation of intersectoral care management systematically on a larger scale. Cost-effectiveness analyses as well as an independent mixed methods process evaluation (which will be described in more detail elsewhere) increase the likelihood of meeting these goals.

Scientifically, the trial allows in-depth analysis of mediating and moderating effects for different health outcomes at the interface of hospital and primary care. We expect frailty to be a risk factor for worse health outcomes over time. Additionally, we will add knowledge about the trajectory of cognitive status and/or delirium from hospital stays to primary care. Identifying risk factors will help to improve treatment and care by targeting them in future interventions or by making changes to the system.

Highlighting treatment and care, our study will provide insights into unmet needs at the time of hospital admission, the opportunities and barriers to meeting those needs during the hospital stay or shortly after. There will be descriptive analyses of common needs emerging immediately after discharge and an estimate of which of these needs can be met immediately after discharge. Recommendations regarding how such a functionality of intersectoral care management can be implemented in the current systems will be derived and promoted.

Informal caregivers will be actively involved in all phases of the study. It is now common knowledge that informal caregivers play an important role in dementia care. Our trial will provide descriptive details about informal caregivers who can be involved, at what times, to what extent, and how they are involved. We will add descriptive knowledge about the informal caregivers, their social situation, their own (unmet) needs and whether or not they might benefit from the intervention and, if yes, how exactly. This knowledge might influence concepts on how to systematically involve (and support) informal caregivers in treatment and care at the interface of hospital and primary care and sustainably thereafter.

Ultimately, the results will not be limited to PCI but will extend to elderly people transitioning between the in-hospital and the primary care sector in general.

## **Trials status**

The trial is at the stage of patient recruitment; Recruitment/ first patient enrolled: 1<sup>st</sup> of November 2018. Expected end of recruitment: 31<sup>st</sup> of October 2019; Protocol version 1.0, 20. Feb 2019

## **List Of Abbreviations**

*B-ADL*: Bayer Activities of Daily Living Scale

*CAU*: care as usual

*Delphi-MV*: Dementia: life- and person-centred help in Mecklenburg-Western Pomerania

*EFS*: Edmonton Frail Scale

*EQ-5D*: EuroQol- 5 Dimension

*FIMA*: Questionnaire for the Use of Medical and Non-Medical Services in Old Age

*GDS*: Geriatric Depression Scale

*GP*: General Physician / General Practitioner

*ICER*: Incremental-Cost-Effectiveness-Ratio

*IMS*: Intervention Management System

*MMSE*: Mini Mental State Examination

*NPI*: Neuropsychiatric Inventory

*PCI*: People with Cognitive Impairment

*QALY*: Quality-Adjusted-Life-Years

*RCT*: Randomized Controlled Trial

*RUD*: Resource Utilization in Dementia

*ZBI*: Zarit-Burden Inventory

## **Declarations**

### **Ethics approval and consent to participate**

The study is conducted in accordance with the criteria (valid at present) of the Declaration of Helsinki, the ICH guidelines for Good Clinical Practice, the Memorandum for Safeguarding Good Scientific Practice (German Research Foundation/DFG), the International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS/WHO), and the CONSORT Statement of recommendations for reporting trials. An independent advisory board is established including Patient and Public Involvement (PPI) representatives as well as scientific experts that also review the adherence to the above-mentioned guidelines during the entire course of the study.

Only subjects who provide valid written informed consent will be included. Thus, prior to participation, all participants will receive oral and written information on the study, including information on data protection procedures and potential risks and benefits. Since the inclusion criteria for our study are cognitive impairment, there is an algorithm in place to obtain valid informed consent. In case of incapability of giving informed consent, the legal representative and/or the informal caregiver will be asked in addition to the PCI.

Ethical approval for this trial was obtained from the Ethical Committee of the University Medicine Greifswald (Registry number: BB 159/17) and the Ethical Committee of the Medical Chamber Westphalia-Lippe (Registry number: 2017–688-b-S). The trial is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT03359408).

### **Consent for publication**

Not applicable.

### **Availability of data and material**



There is no plan to provide public access to the data.

## Competing interests

The authors declare that they have no competing interests.

## Funding

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## Authors' contributions

Each author has made substantial contributions to this work, has approved the submitted version and has agreed to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even those in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

In more detail, HCV, WH, SHK, and JRT were leading in the conception of this study. AK, AN, TD, JL, US, FSS, DW, HCV, WH, SHK, JRT developed the design of the study. ADW, BM, DW, IZ, HCV, WH, SHK, and JRT contributed to the acquisition of the study. AN and AK have drafted the work, and JRT, TD, and WH have substantively revised the draft.

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## Harm

The intervention should be conducted without any risk for the participants; it is under the close supervision of the treating physicians. However, assessing data itself can be harmful in the sense of causing anxiety. Study staff will be trained accordingly and have access to specialists in routine care provided by the recruiting centers. There are no invasive procedures planned.

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## Figures

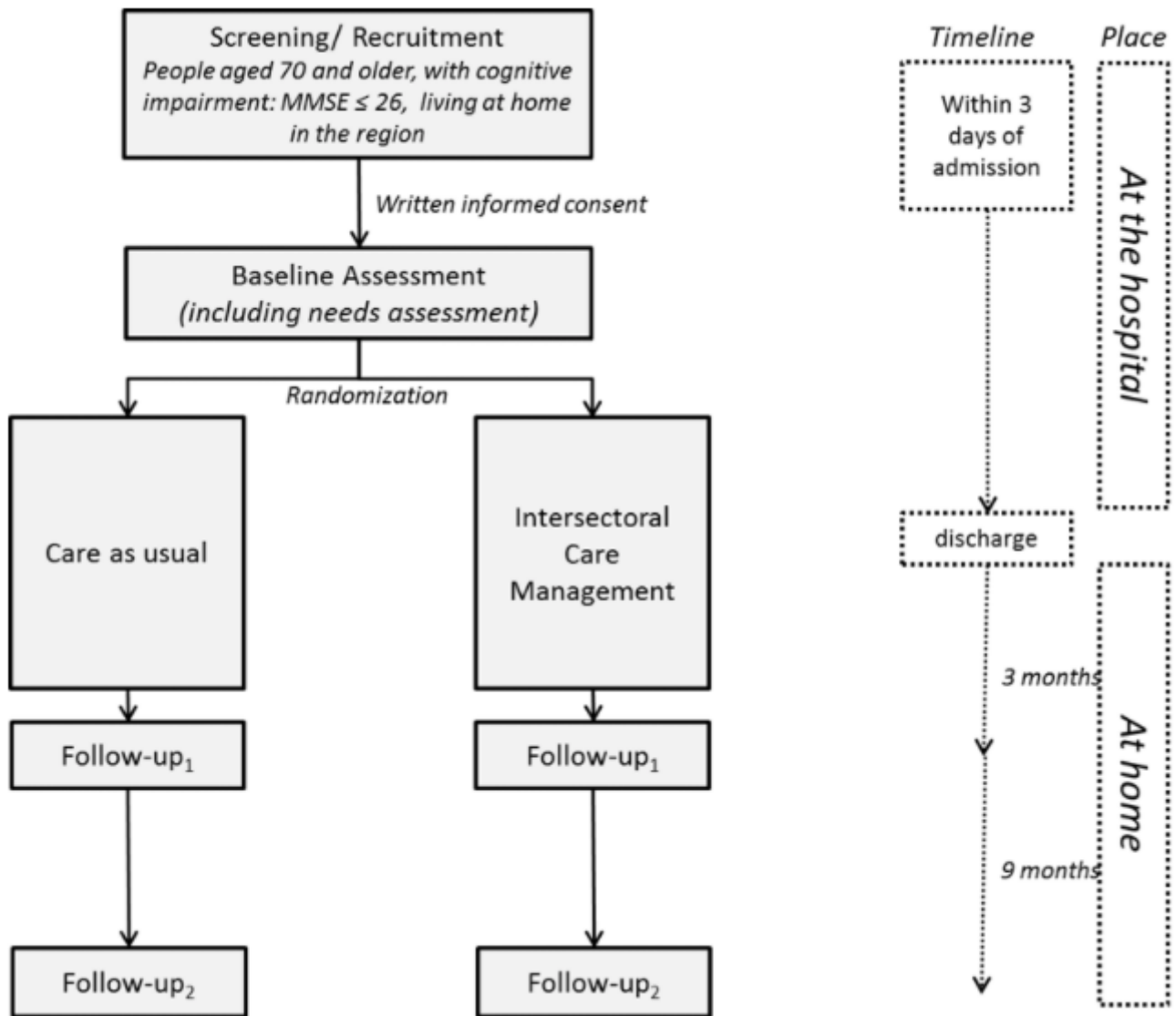


Figure 1

Study design of the intersec-CM trial



	Study Period								
	Screening	Baseline	Randomization	Intervention				Follow-up assessment	
TIMEPOINT**	SCR	BL	after BL	I <sub>1</sub>	I <sub>2</sub>	I <sub>3</sub>	I <sub>4</sub>	FU <sub>1</sub>	FU <sub>2</sub>
<b>ENROLLMENT:</b>									
Eligibility screen	X								
Written informed consent	X								
Allocation to either intervention or care as usual			X						
<b>INTERVENTIONS:</b>									
<i>intersectoral care management</i>				—————					
<i>care as usual</i>				↔					
<b>ASSESSMENTS:</b>									
<i>Baseline assessment</i>		X							
<i>Needs assessment</i>		X			X	X			
<i>Medical records</i>		X			X				
<i>Outcome assessment</i>								X	X

Figure 2

Study design schedule in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist

## Supplementary Files

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