BMJ Open

Implementing Dementia Care Management into routine care – study protocol of a cohort study in the region Siegen-Wittgenstein in Germany (RoutineDeCM)

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-085852
Article Type:	Protocol
Date Submitted by the Author:	27-Feb-2024
Complete List of Authors:	Thyrian, Jochen René; German Centre for Neurodegenerative Diseases, site Rostock/ Greifswald; University Medicine Greifswald, Institute for Community Medicine Boekholt, Melanie; Deutsches Zentrum für Neurodegenerative Erkrankungen (DZNE) Boes, Charlotte; Caritasverband Siegen-Wittgenstein e.V. Grond, Martin; Klinik für Neurologie und Neurogeriatrie, Klinikum Kremer, Stefanie; Alzheimer Gesellschaft Siegen-Wittgenstein Herder-Peyrounette, Anja; Gesundheitsregion Siegerland Seidel, Katja; German Centre for Neurodegenerative Diseases Theile-Schürholz, Anna; University of Siegen Haberstroh, Julia; University of Siegen
Keywords:	Primary Care < Primary Health Care, Dementia, Health Services, Patient-Centered Care

Title

Implementing Dementia Care Management into routine care – study protocol of a cohort study in the region Siegen-Wittgenstein in Germany (RoutineDeCM)

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Abstract

Background: Dementia Care Management is an evidence-based model of care. It has proven its efficacy and cost-effectiveness and has been applied to different settings and different target groups. However, it is not available in routine care in Germany. The scientific evidence has influenced the National Dementia Strategy, in which one measure is to examine the possibility and requirements to implement it into routine care. The aim of this trial is to implement dementia care management into routine care in a selected region in Germany and evaluate the effect on participants.

Methods: For the duration of 12 months, n=90 patients and their informal caregivers with cognitive impairment are recruited in different routine settings in primary care (general hospital, physicians network, ambulatory nursing service, counseling service) by partners in primary care. They receive an adapted Dementia Care Management (DeCM) to the specific setting using participatory methods. DeCM is delivered by specifically qualified dementia care managers and consists of a comprehensive assessment of health care needs followed by algorithm-/ and person-based support in health care planning, implementing and monitoring. The duration of the intervention is 6 months and data assessments are conducted prior to (Baseline), at the end of (FU1) and 6 months after the end of the intervention (FU2). Primary outcomes are unmet needs at FU1 and FU2. Secondary outcomes are anti dementia drug treatment, neuropsychiatric symptoms and caregiver burden at fu1 and fu2. Further outcomes are: cognition, frailty and health related quality of life. A separate process evaluation accompanies the implementation.

Discussion: The study provides empirical evidence whether and how dementia care management is implemented effectively in a region. It shows whether it is effective in decreasing unmet needs and what other factors are associated with that. Furthermore, it allows comparisons of outcomes between DCM in scientific settings and in routine settings. Thus, it supports the national roll-out of DCM like proposed in the national dementia strategy.

Ethics and dissemination: The Ethics Committee of the university medicine Greifswald, Germany has reviewed and approved the study (registration number BB110/22). Dissemination plans are in place.

Trial registration: ClinicalTrials.gov Identifier: NCT05529277; submitted 26th of august 2022, first posted, 7th of September 2022

Funding: This trial is funded by the Federal Ministry of Health (BMG); grant# ZMI1-2521FSB907. The funding body does not have any influence on the design of the study, the collection, analysis, and interpretation of data and in writing the manuscript.

Trial status

Protocol version 1.0; 27th of February 2024; Recruitment start: 1. September 2022, end of recruitment: 30th of september 2023, approximate end of study:30th of September 2024

The study protocol was submitted before the end of data assessment. An earlier submission could not be accomplished due to an unexpectedly increased workforce during the study period with less human resources than anticipated. However, the trial was registered before recruitment started and the study protocol submitted for publication was in principle not altered in comparison to the registration.

Conflicts of interest

The authors declare that there is no conflict of interest.

Article Summary:

- Test the hypothesis that the intervention decreases the unmet needs in people with cognitive impairments and/-or their caregivers.
- A prospective cohort trial of a pre-specified and standardized complex intervention for people with cognitive impairment and/or their informal caregivers
- Stakeholders from different health providers jointly recruit participants and deliver the intervention in routine care
- The intervention is adapted from the evidence-based model of collaborative care "Dementia Care Management

Strengths and Limitations of this study

There are strengths and limitations of the study. Strengths include (a) the intervention having proven its efficacy and efficiency in a cluster-randomised controlled trial, (b) the participatory development of the intervention to be implemented, (c) the early involvement of stakeholders to implement the study, (d) the close cooperation between various stakeholders from different settings, (e) implementation in real life, making the results easily transferable to routine care..

Limitations are: (a) the budgetary constraints not allowing to roll out the intervention systematically, thus the risk to recruit a somewhat selective sample. (b) The restriction to one region with certain specifics that might limit the generalization of the results to other regions and the whole country, (c) the assessment of very few variables, limited by time available with the patient and focus on use of the variable for care rather than for scientific purposes.

Keywords

Dementia, cognitive impairment, implementation, routine care, primary care, care management, unmet needs, intervention

Word count (manuscript): 2.838

Introduction

Background and rationale

The demographic change is an increasing challenge to industrialized and aging societies like Germany. Among others, there is an increase in number of people with age-associated illnesses like dementia. Current estimates indicate 1.8 million people living with dementia (PwD) in Germany in 2021 and anticipate a considerable increase in the number during the next 10 years [1]. A broad alliance for PwD and their families was established by stakeholders of associations and institutions covering politics, health care, non-governmental organizations, patient representatives and similar. Presided by the Federal Ministry of Health (BMG) and the Federal Ministry of Family, Senior citizens, Women and Youth (BMFSFJ) a National Dementia Strategy (NDS) was put into place in July 2020 [2]. This strategy describes the current challenges for society, social and health care in detail and proposes distinct measures for the next years. One of the four action fields targets measures for the support of PwD and their informal caregivers, the improvement of counselling and care for those are a strategic aim. A distinct measure is the evaluation of dementia care management (DCM) for implementation in routine care as one measure of social law XI.

DCM is an evidence-based model of collaborative care. Especially in Germany its effectiveness and cost-effectiveness has been scientifically proven. In Germany, DCM was evaluated in a cluster-randomized controlled trial [3,4,5]. Based on this, it was adapted and evaluated for example for the management of people with cognitive impairment at the interface of hospital care and ambulatory care [6,8] or for the improvement of health care specifically for informal caregivers [7]. Based on the current state of evidence, DCM in Germany can be described and defined as follows:

(i) A specifically qualified nursing expert assesses unmet needs (medical, nursing, psychosocial) of people with cognitive impairment and their (informal) caregiver.

(ii) Based on the data and computer supported, the expert develops an individual, personalized care plan (if possible in cooperation with relevant care providers, the patient and informal caregivers).

A qualification curriculum was defined and an education program for DCM was established which is available now [9]. In spite of the intervention having been operationalized in great detail [10,11], the positive scientific results [5], and the acceptance of the concept by health care experts [3,12], DCM has not been transferred and implemented in current routine health care.

To achieve this, implementation studies are necessary, which consider the requirements of the current health care system and can deliver evidence-based recommendations for successful implementation. These include recommendations regarding setting, financing, inclusion of stakeholders/-health care providers, the process of implementation and information about effects and efficacy under routine conditions. The process of adapting DCM for implementation into a region was the aim of the Pilot DelpHi-SW-Study [13]. In this study, processes and procedures of the intervention were discussed and an adapted dementia care management was established (DeCM) to the regional setting using participatory research methods. In cooperation with stakeholders, health care providers, PwD and caregivers from the county of Siegen-Wittgenstein an DeCM intervention for implementation is available. However, implementation has not been conducted yet and knowledge is missing what the effect of the implemented intervention is on care of people with dementia and/-or their caregivers.

Objectives

The overall objective of the trial is to test the effect of an adapted dementia care management intervention (DeCM) in routine care of the region Siegen-Wittgenstein on PwD and their caregivers.

The specific hypotheses are:

Primary:

DeCM decreases the unmet needs in people with cognitive impairments and/-or their caregivers.

Secondary:

- DeCM improves the frequency of medical treatment with antidementive medication.
- DeCM decreases the frequency and severity of neuropsychiatric symptoms.
- DeCM decreases caregiver burden.

Other:

There is an association between the effect of DeCM and cognition, frailty and/-or health related quality of life.

Methods

Study design

RoutineDeCM is a prospective cohort trial of a pre-specified and standardised complex intervention for people with cognitive impairment and/or their informal caregivers with three time points in routine care.

Ethics approval and consent to participate

Written, informed consent to participate will be obtained from all participants. The Ethics Committee of the university medicine Greifswald, Germany has reviewed and approved the study with letter on 9th of august 2022. (registration number BB110/22).

Study setting

The study is organized in the health care system of the German county of Siegen-Wittgenstein, North-Rhine-Westphalia. Stakeholders from different health providers (Alzheimer Gesellschaft, clinic, ambulatory physicians, nursing services) jointly recruit participants and deliver the intervention. The list of participating sites is illustrated in the clinical trial registry.

Participants

All patients and users with cognitive impairment and/-or their informal caregivers are eligible to participate if the stakeholders of the study provide services to them initially. Written informed consent is obtained by specifically trained dementia care manager (study staff) during routine care.

Intervention description

The intervention is adapted from the evidence-based model of collaborative care “Dementia Care Management” [11]. Dementia Care Managers have been qualified according to a publicly available curriculum in DCM [9]. These experts visit participants at home and conduct a systematic comprehensive assessment of the participant´s health, care and psychosocial needs. The assessment is conducted face-to-face as an interview with data provided by the participant being simultaneously entered into a specific software (Intervention Management System, IMS) on a tablet. The IMS provides all items that need to be assessed. It covers sociodemographic data, health data, needs of the participant and other data that is needed to be able to do care planning. The IMS processes the data and uses pre-defined algorithms to identify unmet needs. These unmet needs are assembled in a report and discussed with the participant. Utilizing shared decision making a care plan for the following 6 months is developed. Based on the individual needs and plan, the Dementia Care Manager will support the participant in implementing interventions and measures to meet the needs, monitor their implementation and adjust the plan, if necessary. Those contacts are at the participant´s home or by telephone, depending on the needs and preferences of the participant. The aim is that after 6 months the participant is well integrated into routine care and needs no or only little help from the Dementia Care Manager. Therefore, a first follow-up data assessment to measure the progress of unmet needs is scheduled 6 months post baseline for all participants at their homes. A second follow-up data assessment is conducted 12 months post baseline to measure long-term outcomes with all participants at their homes.

Criteria for discontinuing or modifying interventions

The intervention will be discontinued if the participant decides to withdraw informed consent. The intervention will also be discontinued if the participant moves out of the study region or is institutionalized. A modification of the intervention is not planned as the intervention itself is already highly individualized and dynamic.

Strategies to improve adherence to interventions

There are regular meetings and supervisions with the study staff to discuss challenges in conducting the study and delivering the intervention. This will increase adherence to the intervention. Furthermore, the delivery and monitoring of the intervention is computer-supported. All measures are documented and study staff is urged by the IMS to document measures and monitor their implementation regularly. The IMS is monitored by study staff to identify missing data and missing documentation as early as possible and discuss this with Dementia Care Managers at regular meetings.

Patient and Public Involvement

Patients and stakeholders were involved as co-researchers in the design of the intervention. Adapting the intervention was an iterative process before the study was finalized. The results will be discussed with an advisory board of experts by experience (provided by the Alzheimer Society) and presented to participants, patients and the public at the end of the study.

Variables and Outcomes

The primary outcome indicates the effect of the intervention in this trial and is defined as the change of unmet needs 6 and 12 months after inclusion in the study. Unmet needs are assessed using a generic standardized assessment implemented as computer-assisted IMS. It addresses caregiver burden, medical needs, home care needs, psychosocial needs (depression, sleep quality, pain, hearing, seeing, teeth problems, dementia related problems, medical aids). Adding the needs indicated provides a number of unmet needs.

The secondary outcomes are outcomes that have illustrated the efficacy of DCM in randomized-controlled trials before. They serve as variables that can be compared across studies and thus indicate whether efficacy in this trial is comparable to others. Secondary measures are:

(i) Antidementia drug treatment: The collection of primary data on medication in the context of the HMR includes both prescription drugs and over-the-counter drugs. . following antidementia drugs will be considered: donepezil (N06AD02), rivastigmine (N06AD03), galantamine (N06AD04) and memantine (N06AX01).

(ii) Neuropsychiatric Symptoms: The Neuropsychiatric Inventory (NPI; [14,15]) 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. The presence (0= no, 1= yes) is asked. If present, the severity (rated 1 through 3; mild to severe) and frequency (1 to 4, rarely to very often) of each neuropsychiatric symptom are rated on. Thus the score for each dimension ranges from 0 = not present, 1= mildly and rarely to 12 = severe and often. A total NPI score is calculated as the sum of

the frequency by severity scores of each domain range: 0 to 144, the higher the more neuropsychiatric symptomatic).

(iii) Caregiver Burden: The short form of the Zarit-Burden Inventory (ZBI-7; [16,17]) will be used. The revised version ZBI is a caregiver self-report measure to examine burden, which is associated with functional/ behavioral impairments and home care situation. It contains 7 items using a 5-point scale. Response options range from 0 (Never) to 4 (Nearly Always).Total scores range from 0 indicating low burden to 28 indicating high burden.

(iv) Other outcomes used to examine moderating or modifying factors include cognition (DemTect [18]), frailty (Edmonton Frail Scale, [19]) and health-related quality of life (EQ-5D-5L, [20].

Study procedure

Study staff will approach eligible participants during routine visits in their respective institution. After providing written informed consent, the baseline assessment will be conducted at the participant's home. Upon finishing baseline, the intervention will be conducted during an approximate period of 6 months. Based on the number of needs and their priorities for the participant, the number and duration of home visits differs and additional telephone contacts can be scheduled. The follow-up assessments will be conducted in person at the participant´s homes. The time taken for the assessments differs based on the cognitive capacity of the participant and the number of care needs. It is up to the judgement of the trained interviewer to postpone assessments to a later date if it is too burdensome in one date. (see figure 1: SPIRIT: Schedule of enrolment, interventions, and assessments)

Figure 1: SPIRIT: Schedule of enrolment, interventions, and assessments

	Study Period				
	Enrolment	**Allocation**	***Post allocation***		***Close-out***
TIMEPOINT**	$-t_1$	**0**	t_0	t_1	t_2
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTION:					
Dementia Care Management			⟷	⟷	
ASSESSMENTS:					
Eligibility criteria	X				

Sociodemography, health status			X	X	X
Primary outcome: care needs			X	X	X
Secondary outcome: antidementia drug treatment			X	X	X
Secondary outcome: neuropsychiatric symptoms			X	X	X
Secondary outcome: caregiver burden			X	X	X
cognition			X	X	X
frailty			X	X	X
health related quality of life			X	X	X

Sample size

The estimation of number of participants was based on previous literature about the efficacy of DCM and number of participants that can be served given the human resources available for the intervention per year. One full time staff conducting DeCM is expected to manage n=60 persons with cognitive impairment. This number is sufficient to show a statistically significant reduction of unmet needs by two unmet needs.

Based on an empirical number of unmet needs and their standard deviation in a study of community dwelling people in Germany [Thyrian et al. 2016] a sample size of 56 achieves 90% power to detect a difference of -2,0 between the actual mean of 6,8 and the null hypothesized mean of 8,8 with an estimated standard deviation of 5,0 and with a significance level (alpha) of 0,050 using a one-sided one-sample t-test. A total of 4 people were assigned to deliver the intervention with a total working time of 1.5 full time equivalents, thus we expected to have n=90 participants in the study

Recruitment

Participating partners in this study deliver the regular health care to people with cognitive impairments and their informal caregiver. As such, they are aware of the number of people served per year and the estimated n=60 per year and full-time person was rated to be doable before applying for the grant. The grant itself provided sufficient funding for 1.5 full time equivalents delivering the intervention and the additional work resulting in a total sample expected of n=90). A legal contract was put into place, where recruitment and provision of service is written down, too

Data collection and management

Plans for assessment and collection of outcomes

Data is assessed and documented by professionally trained study staff using the study specific software IMS. Base data (e.g. contact information, family doctor, health insurance) is initially recorded for each

participant at baseline assessment and optionally updated at FU1 and/-or FU2. Each assessment includes several modules, such as questionnaires or diagnostic tools, for either PwD or caregivers. For each module technical data such as the duration, interviewer information, IMS version and change log is stored. In case of diagnostic tools, scores are calculated and displayed in real time by IMS and scores of previous test are displayed in FU1 and/ or FU2. As quality control, mandatory fields are used in IMS whenever applicable. Individual modules need to be completed before synchronization is possible and an incomplete status is highlighted by IMS. Monthly meetings between Dementia Care Managers and the scientific study team are conducted to discuss recruitment and progress, intervention and data collection issues.

Plans to promote participant retention and complete follow-up

In case of a discontinuation of participation, the reason for dropping out of the study is noted. The deletion of previously assessed data is possible but has to be requested specifically by the participant in question.

Data management

Data will be pseudonymized after completion of the study, but no later than one year after the end of data collection, and will be retained in this form for at least 10 years in accordance with guidelines for Good Research Practice [DFG, 2019]. During the study the data can be accessed by selected personnel only: the Dementia Care Managers conducting interviews and intervention, IT-staff and study coordination personnel to ensure data quality and to create data monitoring reports. The monitoring reports, which only include pseudonymized data, are discussed between coordination staff and Dementia Care Managers regularly. Any corrections on missing/ implausible values are incorporated either directly into the IMS or coded in the data procession software [R core Team, 2022].

Confidentiality

The collected data is assessed using a password secured tablet or computer in an additionally password secured software. The data is then transferred using a password protected personal VPN connection to a local server run by the German Center for Neurodegenerative Diseases. Data sharing with research institutions outside of the consortium is not envisioned at this time, but may be made possible upon reasonable request. In this case, only anonymized data would be shared.

Adverse event reporting and harms

No adverse events related to the participation in this study are expected or likely. The intervention has proven to be safe. However, adverse events and harms can happen unrelated to but while being in the study. The study staff with contact to participants is specifically trained and experienced in the working environment of the health care system and know how to react in medical emergencies. They do have access to the relevant health institutions as part of the study team.

Statistical methods

Statistical methods for primary and secondary outcomes

Pre-post analyses will be performed using descriptive methods and appropriate regression models. A more detailed analysis plan will be written. Additional analyses are planned for subgroups based on demographic and clinical data. Data imputation is not planned at this point.

Expected results and discussion

The trial will deliver empirical evidence for the implementation of dementia care management into routine care for a geographical region in Germany. The results are expected to be transferable to other regions as well and thus serve as a blue print to implement dementia care management nationwide. While changing health care is a joint endeavor of various stakeholders and not solely up to a research consortium, the results will show (a) whether the heath care related outcomes of an adapted dementia care management are comparable to clinical trials. (b) Inform about differences between a clinical trial and the implementation study, that influence implementation. (c) Generate evidence and knowledge for further refinement and improvement of efficacy of dementia care management, and (d) will generate expertise about dementia care and dementia care management in a region that will be sustainable even after the funding for the study ends and thus improve the regional health care system.

Results of the study will be shared with the general public, the funder, the participating stakeholders, the participants and the scientific community using various methods. Among others a homepage is set up, (scientific) reports will be published, talks will be given. There a no publication restrictions.

Conflicts of interest

The authors declare that there is no conflict of interest.

Abbreviations

BMFSFJ	Federal Ministry of Family, Senior citizens, Women and Youth
BMG	Federal Ministry of Health
DCM	Dementia Care Management
DeCM	adapted Dementia Care Management for regional implementation
FU1	Follow-up 1, 6 months post baseline
FU2	Follow-Up 2, 12 months post baseline
PwD	People/person with dementia
HMR	home medication review
IMS	computer-assisted intervention management system
NDS	National Dementia Strategy
NPI	Neuropsychiatric Inventory
ZBI	Zarit Burden Interview

Declarations

Acknowledgements

Not applicable.

Author contributions

RT is the Principal Investigator; he conceived the study and designed the study together with JH.

MB and KS contributed to the study design, adapted the intervention and are responsible for the acquisition of data.

MB, KS and ATS coordinate the training and discussion meetings of study staff.

ATS is responsible for data monitoring, monitoring reports and analyses.

CB, AHP, SK and MG contributed to the acquisition, the concept adaptation and provided the infield study staff.

RT Wrote the manuscript, MB and ATS contributed significantly to the manuscript text.

All authors have reviewed the work critically, have approved of the final version to be published and have agreed to be accountable for all aspects of the work.

Availability of data and materials

The study team has access to the final trial dataset, which is regulated in a cooperation agreement. Upon reasonable request, the data set will be made available to other scientists.

The authors declare that they have no competing interests.

References

1. Blotenberg I, Hoffmann W, Thyrian JR. Dementia in Germany: Epidemiology and Prevention Potential. Dtsch Arztebl Int. 2023(Forthcoming).

2. BMFSFJ, BMG. National Dementia Strategy [Nationale Demenzstrategie]. In: Bundesministerium für Familie S, Frauen und Jugend (BMBF) &, (BMG) BfG, editors. Berlin2020.

3. Thyrian JR, Hoffmann W. Dementia care and general physicians--a survey on prevalence, means, attitudes and recommendations. Cent Eur J Public Health. 2012;20(4):270-5.

4. Thyrian JR, Fiss T, Dreier A, Bowing G, Angelow A, Lueke S, et al. Life- and person-centred help in Mecklenburg-Western Pomerania, Germany (DelpHi): study protocol for a randomised controlled trial. Trials. 2012;13:56.

5. Thyrian JR, Hertel J, Wucherer D, Eichler T, Michalowsky B, Dreier-Wolfgramm A, et al. Effectiveness and Safety of Dementia Care Management in Primary Care: A Randomized Clinical Trial. JAMA Psychiatry. 2017;74(10):996-1004.

6. Nikelski A, Keller A, Schumacher-Schonert F, Dehl T, Laufer J, Sauerbrey U, et al. Supporting elderly people with cognitive impairment during and after hospital stays with intersectoral care management: study protocol for a randomized controlled trial. Trials. 2019;20(1):543.

7. Klein OA, Boekholt M, Afrin D, Dornquast C, Dreier-Wolfgramm A, Keller A, et al. Effectiveness of a digitally supported care management programme to reduce unmet needs of family caregivers of people with dementia: study protocol for a cluster randomised controlled trial (GAIN). Trials. 2021;22(1):401.

8. Boekholt M, Nikelski A, Schumacher-Schoenert F, Kracht F, Vollmar HC, Hoffmann W, et al. Supporting elderly people with cognitive impairment during and after hospital stays with Intersectoral Care Management [intersec-CM] – results of a randomized clinical trial. submitted.

9. Dreier A, Thyrian JR, Eichler T, Hoffmann W. Qualifications for nurses for the care of patients with dementia and support to their caregivers: A pilot evaluation of the dementia care management curriculum. Nurse Educ Today. 2016;36:310-7.

10. Eichler T, Thyrian JR, Fredrich D, Kohler L, Wucherer D, Michalowsky B, et al. The benefits of implementing a computerized intervention-management-system (IMS) on delivering integrated dementia care in the primary care setting. Int Psychogeriatr. 2014;26(8):1377-85.

11. Eichler T, Thyrian JR, Dreier A, Wucherer D, Kohler L, Fiss T, et al. Dementia care management: going new ways in ambulant dementia care within a GP-based randomized controlled intervention trial. Int Psychogeriatr. 2014;26(2):247-56.

12. Thyrian JR, Eichler T, Pooch A, Albuerne K, Dreier A, Michalowsky B, et al. Systematic, early identification of dementia and dementia care management are highly appreciated by general physicians in primary care - results within a cluster-randomized-controlled trial (DelpHi). J Multidiscip Healthc. 2016;9:183-90.

13. Seidel K, Quasdorf T, Haberstroh J, Thyrian JR. Adapting a Dementia Care Management Intervention for Regional Implementation: A Theory-Based Participatory Barrier Analysis. Int J Environ Res Public Health. 2022;19(9).

14. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. Neurology. 1994;44(12):2308-14.

15. Cummings JL. The Neuropsychiatric Inventory: assessing psychopathology in dementia patients. Neurology. 1997;48(5 Suppl 6):S10-6.

16. Kühnel M, Ramsenthaler C, Bausewein C, Fegg M, Fodiamont F. Validierung der 7-Item Kurz-Version des Zarit Burden Interviews – Ein Fragebogen zur Erhebung der Belastung von Angehörigen von Palliativpatienten. Zeitschrift für Palliativmedizin. 2018;19(5):256-8.

17. Kuhnel MB, Ramsenthaler C, Bausewein C, Fegg M, Hodiamont F. Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers. Support Care Cancer. 2020;28(11):5185-93.

18. Rolfson DB, Majumdar SR, Tsuyuki RT, Tahir A, Rockwood K. Validity and reliability of the Edmonton Frail Scale. Age Ageing. 2006;35(5):526-9.

19. EuroQol G. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy. 1990;16(3):199-208.

20. DFG. Guidelines for Safeguarding Good Research Practice - Code of Conduct [Leitlinien zur Sicherung guter wissenschaftlicher Praxis - Kodex]. Bonn: Deutsche Forschungsgemeinschaft (DFG); 2019.

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BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2024-085852.R1
Article Type:	Protocol
Date Submitted by the Author:	08-Jun-2024
Complete List of Authors:	Thyrian, Jochen René; German Centre for Neurodegenerative Diseases, site Rostock/ Greifswald; University Medicine Greifswald, Institute for Community Medicine Boekholt, Melanie; Deutsches Zentrum für Neurodegenerative Erkrankungen (DZNE) Boes, Charlotte; Caritasverband Siegen-Wittgenstein e.V. Grond, Martin; Klinik für Neurologie und Neurogeriatrie, Klinikum Kremer, Stefanie; Alzheimer Gesellschaft Siegen-Wittgenstein Herder-Peyrounette, Anja; Gesundheitsregion Siegerland Seidel, Katja; German Centre for Neurodegenerative Diseases Theile-Schürholz, Anna; University of Siegen Haberstroh, Julia; University of Siegen
Primary Subject Heading:	Health services research
Secondary Subject Heading:	Neurology, Nursing, Mental health, Public health
Keywords:	Primary Care < Primary Health Care, Dementia, Health Services, Patient-Centered Care

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Abstract

Introduction: Dementia Care Management is an evidence-based model of care. It has proven its efficacy and cost-effectiveness and has been applied to different settings and different target groups. However, it is not available in routine care in Germany. The scientific evidence has influenced the National Dementia Strategy, in which one measure is to examine the possibility and requirements to implement it into routine care. The aim of this study is to implement Dementia Care Management into routine care in a selected region in Germany and evaluate the effect on participants.

Methods and analysis: For the duration of 12 months, n=90 patients and their informal caregivers with cognitive impairment are recruited in different routine settings in primary care (general hospital, physicians' network, ambulatory nursing service, counselling service) by partners in primary care. They receive an adapted Dementia Care Management (DeCM) to the specific setting using participatory methods. DeCM is delivered by specifically qualified dementia care managers and consists of a comprehensive assessment of health care needs followed by algorithm-/ and person-based support in health care planning, implementing and monitoring. The duration of the intervention is 6 months and data assessments are conducted prior to (baseline), at the end of (FU1) and 6 months after the end of the intervention (FU2). Primary outcomes are unmet needs at FU1 and FU2. Secondary outcomes are anti-dementia drug treatment, neuropsychiatric symptoms and caregiver burden at FU1 and FU2. Further outcomes are cognition, frailty and health related quality of life. A separate process evaluation accompanies the implementation.

Ethics and dissemination: The Ethics Committee of University Medicine Greifswald, Germany, has reviewed and approved the study (registration number BB110/22). All participants provide written informed consent prior to participation. The results will be disseminated in regional workshops, press, online media and talks. They will be submitted to international peer-reviewed scientific journals for publication and presented at scientific meetings and conferences. Furthermore, results will be discussed with the funder and presented to the steering committee of the National Dementia Strategy.

Study registration: ClinicalTrials.gov, NCT05529277 (submitted August 26th, 2022, first posted September 7th, 2022).

Strengths and limitations of this study

- The intervention is close to real life as patients and stakeholders are involved as co-researchers in the design of the study implemented.
- Transferability is high since the study is integrated in routine care, from recruitment to intervention delivery.
- Recruitment by stakeholders in routine care might lead to a selection bias in the sample under examination.
- The restriction to one region with certain specifics might limit the generalization of the results to other regions and the whole country.

Keywords

Dementia, cognitive impairment, implementation, routine care, primary care, care management, unmet needs, intervention

INTRODUCTION

Background and rationale

The demographic change is an increasing challenge to industrialized and aging societies like Germany. Among others, there is an increase in number of people with age-associated illnesses like dementia. Current estimates indicate 1.8 million people living with dementia in Germany in 2021 and anticipate a considerable increase in the number during the next 10 years [1]. A broad alliance for people and their families was established by stakeholders of associations and institutions covering politics, health care, non-governmental organizations, patient representatives and similar. Presided by the Federal Ministry of Health (BMG) and the Federal Ministry of Family, Senior citizens, Women and Youth (BMFSFJ) a National Dementia Strategy (NDS) was put into place in July 2020 [2]. This strategy describes the current challenges for society, social and health care in detail and proposes distinct measures for the next years. One of the four action fields targets measures for the support of People with dementia and their informal caregivers, the improvement of counselling and care for those are a strategic aim. A distinct measure is the evaluation of Dementia Care Management for implementation in routine care as one measure of social law XI.

DCM is an evidence-based model of collaborative care. Especially in Germany its effectiveness and cost-effectiveness has been scientifically proven. In Germany, DCM was evaluated in a cluster-randomized controlled trial [3,4,5]. Based on this, it was adapted and evaluated for example for the management of people with cognitive impairment at the interface of hospital care and ambulatory care [6,8] or for the improvement of health care specifically for informal caregivers [7]. Based on the current state of evidence, DCM in Germany can be described and defined as follows:

(i) A specifically qualified nursing expert assesses unmet needs (medical, nursing, psychosocial) of people with cognitive impairment and their (informal) caregiver.

(ii) Based on the data and computer supported, the expert develops an individual, personalized care plan (if possible, in cooperation with relevant care providers, the patient and informal caregivers).

A qualification curriculum was defined and an education program for DCM was established which is available now [9]. In spite of the intervention having been operationalized in great detail [10,11], the positive scientific results [5], and the acceptance of the concept by health care experts [3,12], DCM has not been transferred and implemented in current routine health care.

To achieve this, implementation studies are necessary, which consider the requirements of the current health care system and can deliver evidence-based recommendations for successful implementation. These include recommendations regarding setting, financing, inclusion of stakeholders/-health care providers, the process of implementation and information about effects and efficacy under routine conditions. The process of adapting DCM for implementation into a region was the aim of the Pilot DelpHi-SW-Study [13]. In this study, processes and procedures of the intervention were discussed and an adapted Dementia Care Management was established (DeCM) to the regional setting using participatory research methods which are described in detail elsewhere [13, 14]. In cooperation with stakeholders, health care providers, People with dementia and caregivers from the county of Siegen-Wittgenstein an DeCM intervention for implementation is available. However, implementation has not been conducted yet and knowledge is missing what the effect of the implemented intervention is on care of people with dementia and/-or their caregivers.

Objectives

The overall objective of the study is to test the effect of an adapted Dementia Care Management intervention (DeCM) in routine care of the region Siegen-Wittgenstein on people with dementia and their caregivers.

The specific hypotheses are:

Primary:

DeCM decreases the unmet needs in people with cognitive impairments and/-or their caregivers.

Secondary:

- DeCM improves the frequency of medical treatment with antidementive medication.
- DeCM decreases the frequency and severity of neuropsychiatric symptoms.
- DeCM decreases caregiver burden.

Other:

There is an association between the effect of DeCM and cognition, frailty and/-or health related quality of life.

METHODS AND ANALYSIS

Study design

RoutineDeCM is a prospective cohort study of a pre-specified and standardised complex intervention for people with cognitive impairment and/or their informal caregivers with three time points in routine care. This study protocol reports the design of a study intended to analyse the effect of the intervention and thus the comparability of efficacy in comparison to other interventions. This study is accompanied by a process evaluation that focusses on implementation [15] and refers to an embedded case study focusing on the stakeholders of the implementation. Both studies are distinct and will together provide qualitative and quantitative evidence for improvement of implementing Dementia Care Management.

Study setting

The study is organized in the health care system of the German county of Siegen-Wittgenstein, North-Rhine-Westphalia. Stakeholders from different health providers (Alzheimer Gesellschaft, clinic, ambulatory physicians, nursing services) jointly recruit participants and deliver the intervention in their respective setting. The list of participating sites is illustrated in the clinical trial registry.

Participants

All patients and users with cognitive impairment and/-or their informal caregivers are eligible to participate if the stakeholders of the study provide services to them initially. Cognitive impairment was self-reported and/ or the reason for visit in routine care. Written informed consent is obtained by specifically trained dementia care manager (study staff) during routine care.

Intervention description

The intervention is adapted from the evidence-based model of collaborative care "Dementia Care Management" [11]. Dementia Care Managers have been qualified according to a publicly available curriculum in DCM [9]. These experts visit participants at home and conduct a systematic comprehensive assessment of the participant´s health, care and psychosocial needs. The assessment is conducted face-to-face as an interview with data provided by the participant being simultaneously entered into a specific software (Intervention Management System, IMS) on a tablet. The IMS provides all items that need to be assessed. It covers sociodemographic data, health data, needs of the participant and other data that is needed to be able to do care planning. The IMS processes the data and uses pre-defined algorithms to identify unmet needs. These unmet needs are assembled in a report and discussed with the participant. Utilizing shared decision making a care plan for the following 6 months is developed. Based on the individual needs and plan, the Dementia Care Manager will support the participant in implementing interventions and measures to meet the needs, monitor their implementation and adjust the plan, if necessary. Those contacts are at the participant´s home or by telephone, depending on the needs and preferences of the participant. The aim is that after 6 months the participant is well integrated into routine care and needs no or only little help from the Dementia Care Manager. Therefore, a first follow-up data assessment to measure the progress of unmet needs is scheduled 6 months post baseline for all participants at their homes. A second follow-up data assessment is conducted 12 months post baseline to measure long-term outcomes with all participants at their homes.

Criteria for discontinuing or modifying interventions

The intervention will be discontinued if the participant decides to withdraw informed consent. The intervention will also be discontinued if the participant moves out of the study region or is institutionalized. A modification of the intervention is not planned as the intervention itself is already highly individualized and dynamic.

Strategies to improve adherence to interventions

There are regular meetings and supervisions with the study staff to discuss challenges in conducting the study and delivering the intervention. This will increase adherence to the intervention. Furthermore, the delivery and monitoring of the intervention is computer-supported. All measures are documented and study staff is urged by the IMS to document measures and monitor their implementation regularly. The IMS is monitored by study staff to identify missing data and missing documentation as early as possible and discuss this with Dementia Care Managers at regular meetings.

Patient and public involvement

Patients and stakeholders were involved as co-researchers in the design of the intervention. Adapting the intervention was an iterative process before the study was finalized. The results will be discussed with an advisory board of experts by experience (provided by the Alzheimer Society) and presented to participants, patients and the public at the end of the study.

Variables and outcomes

The primary outcome indicates the effect of the intervention in this study and is defined as the change of unmet needs 6 and 12 months after inclusion in the study. Unmet needs are assessed using a generic

standardized assessment implemented as computer-assisted IMS. It addresses caregiver burden, medical needs, home care needs, psychosocial needs (depression, sleep quality, pain, hearing, seeing, teeth problems, dementia related problems, medical aids). Adding the needs indicated provides a number of unmet needs.

The secondary outcomes are outcomes that have illustrated the efficacy of DCM in randomized-controlled trials before. They serve as variables that can be compared across studies and thus indicate whether efficacy in this study is comparable to others. Secondary measures are:

(i) Antidementia drug treatment: The collection of primary data on medication in the context of the HMR includes both prescription drugs and over-the-counter drugs. . following antidementia drugs will be considered: donepezil (N06AD02), rivastigmine (N06AD03), galantamine (N06AD04) and memantine (N06AX01).

(ii) Neuropsychiatric Symptoms: The Neuropsychiatric Inventory (NPI; [16,17]) represents an interview by proxy on twelve dimensions of neuropsychiatric behaviours, i.e. delusions, hallucinations, agitation, dysphoria, anxiety, apathy, irritability, euphoria, disinhibition, aberrant motor behaviour, night-time behaviour disturbances, and appetite and eating abnormalities. The presence (0= no, 1= yes) is asked. If present, the severity (rated 1 through 3; mild to severe) and frequency (1 to 4, rarely to very often) of each neuropsychiatric symptom are rated on. Thus, the score for each dimension ranges from 0 = not present, 1= mildly and rarely to 12 = severe and often. A total NPI score is calculated as the sum of the frequency by severity scores of each domain range: 0 to 144, the higher the more neuropsychiatric symptomatic).

(iii) Caregiver Burden: The short form of the Zarit-Burden Inventory (ZBI-7; [18,19]) will be used. The revised version ZBI is a caregiver self-report measure to examine burden, which is associated with functional/ behavioural impairments and home care situation. It contains 7 items using a 5-point scale. Response options range from 0 (Never) to 4 (Nearly Always). Total scores range from 0 indicating low burden to 28 indicating high burden.

(iv) Other outcomes used to examine moderating or modifying factors include cognition (DemTect), frailty (Edmonton Frail Scale, [20]) and health-related quality of life (EQ-5D-5L, [21].

Study procedure

Study staff will approach eligible participants during routine visits in their respective institution. After providing written informed consent, the baseline assessment will be conducted at the participant's home. Upon finishing baseline, the intervention will be conducted during an approximate period of 6 months. Based on the number of needs and their priorities for the participant, the number and duration of home visits differs and additional telephone contacts can be scheduled. The follow-up assessments will be conducted in person at the participant´s homes. The time taken for the assessments differs based on the cognitive capacity of the participant and the number of care needs. It is up to the judgement of the trained interviewer to postpone assessments to a later date if it is too burdensome in one date. (see table 1: SPIRIT: Schedule of enrolment, interventions, and assessments). Furthermore, the trained interviewer will ask caregivers or try to retrieve information from other sources in case the participant´s cognitive ability seems to be insufficient for providing valid information.

Table 1. Schedule of enrolment, interventions, and assessments

	Study Period				
	Enrolment	**Allocation**	***Post allocation***		***Close-out***
TIMEPOINT**	$-t_1$	**0**	t_0	t_1	t_2
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTION:					
Dementia Care Management			⟷	⟷	
ASSESSMENTS:					
Eligibility criteria	X				
Sociodemography, health status			X	X	X
Primary outcome: care needs			X	X	X
Secondary outcome: antidementia drug treatment			X	X	X
Secondary outcome: neuropsychiatric symptoms			X	X	X
Secondary outcome: caregiver burden			X	X	X
cognition			X	X	X
Frailty			X	X	X
health related quality of life			X	X	X

Sample size

The estimation of number of participants was based on previous literature about the efficacy of DCM and number of participants that can be served given the human resources available for the

intervention per year. One full time staff conducting DeCM is expected to manage n=60 persons with cognitive impairment. This number is sufficient to show a statistically significant reduction of unmet needs by two unmet needs.

Based on an empirical number of unmet needs and their standard deviation in a study of community dwelling people in Germany [22] a sample size of 56 achieves 90% power to detect a difference of -2,0 between the actual mean of 6,8 and the null hypothesized mean of 8,8 with an estimated standard deviation of 5,0 and with a significance level (alpha) of 0,050 using a one-sided one-sample t-test. A total of 4 people were assigned to deliver the intervention with a total working time of 1.5 full time equivalents, thus we expected to have n=90 participants in the study.

Recruitment

Participating partners in this study deliver the regular health care to people with cognitive impairments and their informal caregiver. As such, they are aware of the number of people served per year and the estimated n=60 per year and full-time person was rated to be doable before applying for the grant. The grant itself provided sufficient funding for 1.5 full time equivalents delivering the intervention and the additional work resulting in a total sample expected of n=90). A legal contract was put into place, where recruitment and provision of service is written down, too

Data collection and management

Plans for assessment and collection of outcomes

Data is assessed and documented by professionally trained study staff using the study specific software IMS. Base data (e.g. contact information, family doctor, health insurance) is initially recorded for each participant at baseline assessment and optionally updated at FU1 and/-or FU2. Each assessment includes several modules, such as questionnaires or diagnostic tools, for either People with dementia or caregivers. For each module technical data such as the duration, interviewer information, IMS version and change log is stored. In case of diagnostic tools, scores are calculated and displayed in real time by IMS and scores of previous test are displayed in FU1 and/ or FU2. As quality control, mandatory fields are used in IMS whenever applicable. Individual modules need to be completed before synchronization is possible and an incomplete status is highlighted by IMS. Monthly meetings between Dementia Care Managers and the scientific study team are conducted to discuss recruitment and progress, intervention and data collection issues.

Plans to promote participant retention and complete follow-up

In case of a discontinuation of participation, the reason for dropping out of the study is noted. The deletion of previously assessed data is possible but has to be requested specifically by the participant in question.

Data management

Data will be pseudonymized after completion of the study, but no later than one year after the end of data collection, and will be retained in this form for at least 10 years in accordance with guidelines for Good Research Practice [23]. During the study the data can be accessed by selected personnel only: the Dementia Care Managers conducting interviews and intervention, IT-staff and study coordination personnel to ensure data quality and to create data monitoring reports. The monitoring reports, which

only include pseudonymized data, are discussed between coordination staff and Dementia Care Managers regularly. Any corrections on missing/ implausible values are incorporated either directly into the IMS or coded in the data procession software [R core Team, 2022].

Confidentiality

The collected data is assessed using a password secured tablet or computer in an additionally password secured software. The data is then transferred using a password protected personal VPN connection to a local server run by the German Center for Neurodegenerative Diseases. Data sharing with research institutions outside of the consortium is not envisioned at this time, but may be made possible upon reasonable request. In this case, only anonymized data would be shared.

Adverse event reporting and harms

No adverse events related to the participation in this study are expected or likely. The intervention has proven to be safe. However, adverse events and harms can happen unrelated to but while being in the study. The study staff with contact to participants is specifically trained and experienced in the working environment of the health care system and know how to react in medical emergencies. They do have access to the relevant health institutions as part of the study team.

Statistical methods

Pre-post analyses will be performed using descriptive methods like differences in means and proportions and appropriate regression models like logistic regressions and general linear models. A more detailed analysis plan will be written. Additional analyses are planned for subgroups based on demographic and clinical data. Data imputation is not planned at this point.

Study status

Protocol version 1.0; February 27th, 2024. Recruitment: September 1, 2022, to September 30th, 2023. Approximate end of study: September 30th, 2024.

The study protocol was submitted for publication before the end of data assessment. An earlier submission could not be accomplished due to an unexpectedly increased workforce during the study period with less human resources than anticipated. However, the study was registered before recruitment started and the study protocol submitted for publication was in principle not altered in comparison to the registration.

ETHICS AND DISSEMINATION

The Ethics Committee of University Medicine Greifswald, Germany, reviewed and approved the study on August 9th, 2022 (BB110/22). All eligible patients are informed about the study orally and in writing in routine care visits with the stakeholders. Information covers the aim of the study, the procedures, handling of data, expected results, and contact persons. Upon invitation to participate and giving written informed consent, they are included in the study as participants. In participants with cognitive impairment who have legal representatives, written informed consent is provided by the legal representatives. Participants are informed that participation is voluntary and that they can withdraw at any time without explanation.

The results will be disseminated in regional workshops, press, online media and talks. They will be submitted to international peer-reviewed scientific journals for publication and presented at scientific meetings and conferences. Furthermore, results will be discussed with the funder and presented to the steering committee of the National Dementia Strategy.

DISCUSSION

The study will deliver empirical evidence for the implementation of Dementia Care Management into routine care for a geographical region in Germany. The results are expected to be transferable to other regions as well and thus serve as a blueprint to implement Dementia Care Management nationwide. While changing health care is a joint endeavour of various stakeholders and not solely up to a research consortium, the results will show (a) whether the heath care related outcomes of an adapted Dementia Care Management are comparable to clinical trials. (b) Inform about differences between a clinical trial and the implementation study, that influence implementation. (c) Generate evidence and knowledge for further refinement and improvement of efficacy of Dementia Care Management, and (d) will generate expertise about dementia care and Dementia Care Management in a region that will be sustainable even after the funding for the study ends and thus improve the regional health care system.

The strength of the study is its basis in evidenced-based practice, participatory development and its implementation close to routine care. The intervention has proven its efficacy and efficiency in a cluster-randomized controlled trial. From very early on stakeholders have been involved in the design and implementation of the study, which is implemented in real life, making the results easily transferable to routine care.

Limitations include: (a) the budgetary constraints not allowing to roll out the intervention systematically, thus the risk to recruit a somewhat selective sample. (b) The restriction to one region with certain specifics that might limit the generalization of the results to other regions and the whole country. (c) The assessment of very few variables, limited by time available with the patient and focus on use of the variable for care rather than for scientific purposes.

Results of the study will be shared with the general public, the funder, the participating stakeholders, the participants and the scientific community using various methods. Among other avenues, a homepage will be set up, (scientific) reports will be published, and talks will be given. There are no publication restrictions.

Abbreviations

BMFSFJ	Federal Ministry of Family, Senior citizens, Women and Youth
BMG	Federal Ministry of Health
DCM	Dementia Care Management
DeCM	adapted Dementia Care Management for regional implementation
FU1	Follow-up 1, 6 months post baseline
FU2	Follow-Up 2, 12 months post baseline
HMR	home medication review
IMS	computer-assisted intervention management system
NDS	National Dementia Strategy
NPI	Neuropsychiatric Inventory
ZBI	Zarit Burden Interview

Contributors

RT is the Principal Investigator; he conceived the study and designed the study together with JH. MB and KS contributed to the study design, adapted the intervention and are responsible for the acquisition of data. MB, KS and ATS coordinate the training and discussion meetings of study staff. ATS is responsible for data monitoring, monitoring reports and analyses. CB, AHP, SK and MG contributed to the acquisition, the concept adaptation and provided the infield study staff. RT Wrote the manuscript, MB, JH and ATS contributed significantly to the manuscript text. All authors have reviewed the work critically, have approved of the final version to be published and have agreed to be accountable for all aspects of the work.

Data availability statement

The study team will have access to the final study dataset, which is regulated in a cooperation agreement. Upon reasonable request, the data set will be made available to other scientists after completion of the study.

Competing interests

The authors declare that there is no conflict of interest.

Funding

This study is funded by the Federal Ministry of Health (BMG); grant# ZMI1-2521FSB907. The funding body does not have any influence on the design of the study, the collection, analysis, and interpretation of data and in writing the manuscript.

References

1. Blotenberg I, Hoffmann W, Thyrian JR. Dementia in Germany: Epidemiology and Prevention Potential. Dtsch Arztebl Int. 2023(Forthcoming).

2. BMFSFJ, BMG. National Dementia Strategy [Nationale Demenzstrategie]. In: Bundesministerium für Familie S, Frauen und Jugend (BMBF) &, (BMG) BfG, editors. Berlin2020.

3. Thyrian JR, Hoffmann W. Dementia care and general physicians--a survey on prevalence, means, attitudes and recommendations. Cent Eur J Public Health. 2012;20(4):270-5.

4. Thyrian JR, Fiss T, Dreier A, Bowing G, Angelow A, Lueke S, et al. Life- and person-centred help in Mecklenburg-Western Pomerania, Germany (DelpHi): study protocol for a randomised controlled trial. Trials. 2012;13:56.

5. Thyrian JR, Hertel J, Wucherer D, Eichler T, Michalowsky B, Dreier-Wolfgramm A, et al. Effectiveness and Safety of Dementia Care Management in Primary Care: A Randomized Clinical Trial. JAMA Psychiatry. 2017;74(10):996-1004.

6. Nikelski A, Keller A, Schumacher-Schonert F, Dehl T, Laufer J, Sauerbrey U, et al. Supporting elderly people with cognitive impairment during and after hospital stays with intersectoral care management: study protocol for a randomized controlled trial. Trials. 2019;20(1):543.

7. Klein OA, Boekholt M, Afrin D, Dornquast C, Dreier-Wolfgramm A, Keller A, et al. Effectiveness of a digitally supported care management programme to reduce unmet needs of family caregivers of people with dementia: study protocol for a cluster randomised controlled trial (GAIN). Trials. 2021;22(1):401.

8. Boekholt M, Nikelski A, Schumacher-Schoenert F, Kracht F, Vollmar HC, Hoffmann W, et al. Supporting elderly people with cognitive impairment during and after hospital stays with Intersectoral Care Management [intersec-CM] – results of a randomized clinical trial. submitted.

9. Dreier A, Thyrian JR, Eichler T, Hoffmann W. Qualifications for nurses for the care of patients with dementia and support to their caregivers: A pilot evaluation of the dementia care management curriculum. Nurse Educ Today. 2016;36:310-7.

10. Eichler T, Thyrian JR, Fredrich D, Kohler L, Wucherer D, Michalowsky B, et al. The benefits of implementing a computerized intervention-management-system (IMS) on delivering integrated dementia care in the primary care setting. Int Psychogeriatr. 2014;26(8):1377-85.

11. Eichler T, Thyrian JR, Dreier A, Wucherer D, Kohler L, Fiss T, et al. Dementia care management: going new ways in ambulant dementia care within a GP-based randomized controlled intervention trial. Int Psychogeriatr. 2014;26(2):247-56.

12. Thyrian JR, Eichler T, Pooch A, Albuerne K, Dreier A, Michalowsky B, et al. Systematic, early identification of dementia and dementia care management are highly appreciated by general physicians in primary care - results within a cluster-randomized-controlled trial (DelpHi). J Multidiscip Healthc. 2016;9:183-90.

13. Seidel K, Quasdorf T, Haberstroh J, Thyrian JR. Adapting a Dementia Care Management Intervention for Regional Implementation: A Theory-Based Participatory Barrier Analysis. Int J Environ Res Public Health. 2022;19(9).

14. Seidel K, Rupp L, Thyrian JR, Haberstroh J (2024) Adapting Dementia Care Management to a Regional German Context: Assessment of Changes in Acceptability, Appropriateness, and Feasibility. J Appl Gerontol, 7334648241258024

15. Purwins D, Fahsold A, Quasdorf T, Berthold H, Klas T, Albers B, Seidel K, Haberstroh J, Holle B (2023) Implementation of dementia care management in routine care (RoutineDeCM): a study protocol for process evaluation. BMJ Open 13, e072185.

16. Cummings JL, Mega M, Gray K, Rosenberg-Thompson S, Carusi DA, Gornbein J. The Neuropsychiatric Inventory: comprehensive assessment of psychopathology in dementia. Neurology. 1994;44(12):2308-14.

17. Cummings JL. The Neuropsychiatric Inventory: assessing psychopathology in dementia patients. Neurology. 1997;48(5 Suppl 6):S10-6.

18. Kühnel M, Ramsenthaler C, Bausewein C, Fegg M, Fodiamont F. Validierung der 7-Item Kurz-Version des Zarit Burden Interviews – Ein Fragebogen zur Erhebung der Belastung von Angehörigen von Palliativpatienten. Zeitschrift für Palliativmedizin. 2018;19(5):256-8.

19. Kuhnel MB, Ramsenthaler C, Bausewein C, Fegg M, Hodiamont F. Validation of two short versions of the Zarit Burden Interview in the palliative care setting: a questionnaire to assess the burden of informal caregivers. Support Care Cancer. 2020;28(11):5185-93.

20. Rolfson DB, Majumdar SR, Tsuyuki RT, Tahir A, Rockwood K. Validity and reliability of the Edmonton Frail Scale. Age Ageing. 2006;35(5):526-9.

21. EuroQol G. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy. 1990;16(3):199-208.

22. Eichler T, Thyrian JR, Hertel J, Richter S, Wucherer D, Michalowsky B, Teipel S, Kilimann I, Dreier A, Hoffmann W. Unmet Needs of Community-Dwelling Primary Care Patients with Dementia in Germany: Prevalence and Correlates. J Alzheimers Dis. 2016;51(3):847-55.

23. DFG. Guidelines for Safeguarding Good Research Practice - Code of Conduct [Leitlinien zur Sicherung guter wissenschaftlicher Praxis - Kodex]. Bonn: Deutsche Forschungsgemeinschaft (DFG); 2019.