BMJ Open

Implementation of dementia care management in routine care (RoutineDeCM): a study protocol for process evaluation

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To cite: Purwins D, Fahsold A, Quasdorf T, *et al*. Implementation of dementia care management in routine care (RoutineDeCM): a study protocol for process evaluation. *BMJ Open* 2023;**13**:e072185. doi:10.1136/bmjopen-2023-072185

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2023-072185).

Received 31 January 2023
Accepted 02 August 2023

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ABSTRACT

Introduction Dementia care management is a complex intervention intended to support persons with dementia and their (caring) relatives in home-based care arrangements. Dementia care management was developed in the federal state of Mecklenburg-Western Pomerania in Germany and subsequently adapted for the German region of Siegen-Wittgenstein, where it will now be implemented. Four different service providers will carry out the implementation process. This study protocol describes the planned procedures for the parallel evaluation of the implementation process.

Methods and analysis A multiple embedded case study design was chosen for the planned process evaluation. Data collection and analysis will be informed by the Consolidated Framework for Implementation Research, the Expert Recommendations for Implementing Change, the Medical Research Council framework for conducting process evaluations of complex interventions and the Taxonomy of Outcomes for Implementation Research. Information (qualitative and quantitative) will be collected from all stakeholders involved in the dementia care management intervention (ie, dementia care managers, general practitioners, people with dementia).

Ethics and dissemination The process evaluation is conducted in accordance with the Declaration of Helsinki, the recommendations on good scientific practice, the research ethics principles of the Code of Ethics of the German Society of Nursing Science, and on the basis of ethical approval from the Clinical Ethics Committee of University Medicine Greifswald (BB 110/22). The results of the process evaluation will be disseminated through reports to the funders of the study and also as a summary of recommendations for the sustainable implementation of dementia care management for future implementers. We also plan to publish the results of this process evaluation in an international peer-reviewed journal.

Trial registration number NCT05529277, Registered 7 September 2022, https://beta.clinicaltrials.gov/study/NCT05529277.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of the planned study is the theory-informed logic model which was developed to guide and plan the process evaluation.
⇒ The multiple embedded case study design with consideration of various perspectives will allow the generation of recommendations for an implementation strategy of the intervention in different settings.
⇒ Due to the design of this process evaluation, the focus is narrowed to specific evaluation outcomes, not including the reach of the intervention.
⇒ The significance of the results is limited by the fact that the process evaluation is restricted to one region and four service providers.

INTRODUCTION

Rationale

The goal of improving the care, health and well-being of people affected by dementia is a worldwide pursuit.[1] To achieve this objective, a national dementia strategy was adopted in Germany in 2020. One action line in this strategy is to improve guidance and support for people with dementia and their (caring) relatives, focusing on managing the interface between different care services and service providers in the German healthcare system. This also includes the establishment of dementia care management (DeCM) as an intervention pertaining to needs-based medical, nursing and psychosocial care planning and realisation for people with dementia and their (caring) relatives at home.[2] DeCM was developed in the German state of Mecklenburg-Western Pomerania as a German concept to address the effectiveness of collaborative primary care[3] and case management[4] for people with dementia as demonstrated in other countries.[5 6] DeCM is a care concept according to which a specifically qualified nurse (the dementia care

manager) assesses the medical, nursing and psychosocial (care) needs of people with dementia and their (caring) relatives. Dementia care managers have received special training for their specific tasks related to the intervention within a further training course additional to their basic training as a nurse and practical work experience.[7 8] The assessment of needs is performed using a 'computer-assisted intervention management system'.[5] This intervention management system was developed to promote planning and documentation.[5] Based on the needs thus assessed, the dementia care manager develops an individual care plan, if possible, in cooperation with all stakeholders involved in treatment and care.[7] In so doing, the dementia care manager works closely with general practitioners (GPs), since in the German healthcare system, these figures bear the main responsibility for the whole treatment process. The care plan is then implemented in a coordinated manner by the dementia care manager, and the care is monitored.[7] For more details regarding DeCM, see the detailed description of the intervention in Dreier *et al*.[7]

DeCM was tested in Germany (federal state of Mecklenburg-Western Pomerania) in a study (the DelpHi trial) regarding its efficacy and efficiency.[8] It was shown to be a model of care that has the potential to improve relevant outcomes for people with dementia and their (caring) relatives.[9] Since that time, DeCM has been adapted for implementation in the German region of Siegen-Wittgenstein in the participatory pilot study DelpHi-SW (Dementia: Life- and person-centred help in Siegen-Wittgenstein).[10] Within the framework of DelpHi-SW, DeCM was prepared for implementation in the model region via a process featuring four steps. In the first step, all intervention-related components of the existing DeCM standard were adapted to regional care structures and resources via an iterative, participatory process that featured five local healthcare experts from four different healthcare sectors as coresearchers. For example, care processes were conceptualised to recognise dementia in time or to ensure palliative care, and interventions for wound management were developed—all these topics had not previously been considered in the context of DeCM. Furthermore, existing interventions for dementia-specific medication management were expanded to include a holistic concept of medication review. The inclusion of regional resources not only led to the expansion of areas in which DeCM could be concretely applied, such as in the field of psychosocial support (eg, housing counselling, technical assistance systems and social or legal counselling). In addition, regional networks were identified that may improve future regional intersectoral cooperation in home-based dementia care and strengthen the prospects of the successful implementation of the adapted DeCM. In the second step, the adapted preliminary DeCM model was subjected to a barrier analysis, in which further local care experts, acting as reviewers, assessed the facilitating and inhibiting factors that might be associated with the future implementation (for the results of this assessment, see Seidel *et al*[10]). In the third step, the new DeCM model was modified once again based on these analysis results, and an implementation strategy was defined. In the fourth step, the adapted DeCM was pilot tested on a small sample to prove whether the regional-related adaptations of the intervention and its strategies could be feasible for future implementation of DeCM. Following these steps, the intervention is now being implemented in the region of Siegen-Wittgenstein within the RoutineDeCM project.

DeCM meets the criteria of a complex intervention.[11] The complexity of this intervention is due to its numerous components and its integration into complex social systems.[12] The implementation of such interventions in clinical practice is challenging and often unsuccessful.[13] Therefore, the literature strongly recommends not only evaluating the effectiveness of newly developed interventions, but also to conduct process evaluations

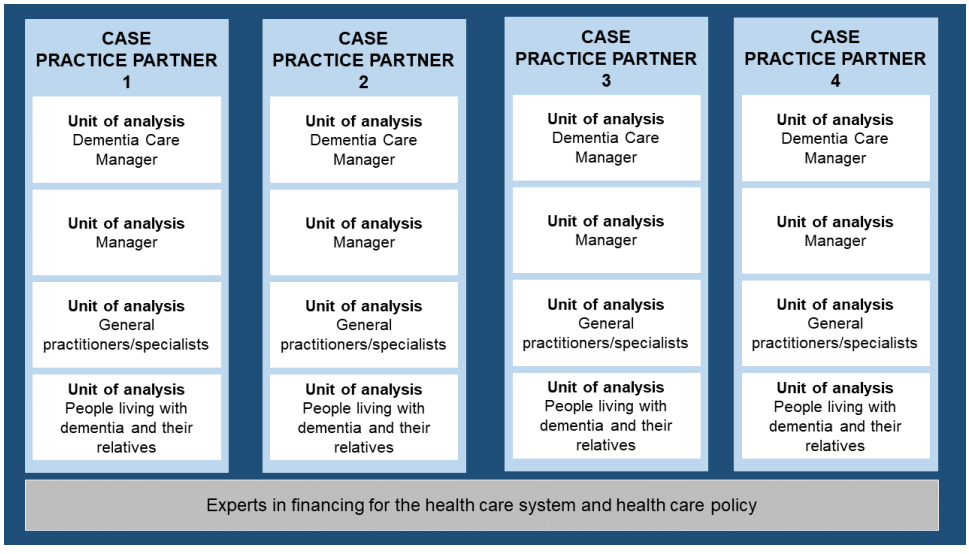

Figure 1 Data analysis based on within-case and cross-case perspectives.

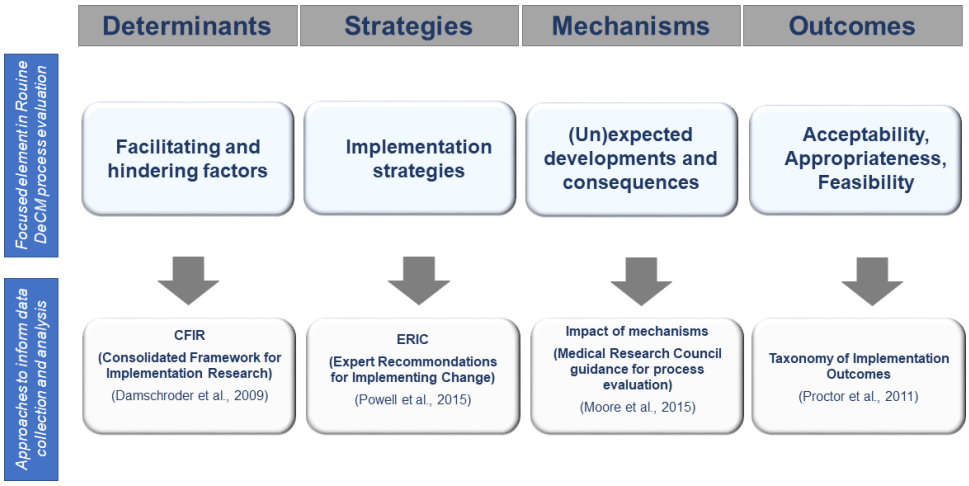

Figure 2 Logic model of process evaluation for the study RoutineDeCM (Smith *et al*[19] adjusted to the requirements of the project). DeCM, dementia care management.

to assess various aspects of the implementation process and to gather information on the causal mechanisms and contextual factors associated with the resulting variation in outcomes.[11 14–16] The implementation of the adapted DeCM in routine care in the region of Siegen-Wittgenstein is the subject of the current study (RoutineDeCM) with the described process evaluation as one part of the project. Within this process evaluation, we will focus on the fidelity of implementation of DeCM by four different healthcare providers to understand which components of the intervention may be critical when implementing DeCM, which are additional, and which may be developed during the project due to specific needs of the target group and regional specificities. Patient outcomes will also be recorded as part of the overall study. Although not part of the process evaluation, it is intended that the results of both substudies will be used for cross-interpretation. To avoid bias, the process evaluation and outcome evaluation are conducted separately.

Objectives and research questions

The focus of RoutineDeCM is to evaluate the process of DeCM implementation in Siegen-Wittgenstein and the effect of DeCM on its participants. Four different service providers (Alzheimer Gesellschaft Siegen e.V., Gesundheitsregion Siegerland eG, Caritasverband Siegen-Wittgenstein e.V., Klinikum Siegen) with different professional backgrounds, main tasks and sources of funding will carry out the process of implementing DeCM in routine care in this region. As these service providers offer their services for diverse problems and needs (eg, counselling vs medical support) of potential users of DeCM, it may be relevant to conduct an evaluation of the implementation process in relation to the specific determinants of each service provider. We want to understand how the implementation and routinisation of DeCM in Siegen-Wittgenstein can be successfully and sustainably supported. In addition, we intend to identify the elements and processes that are promising for the implementation of DeCM in other regions. Accordingly, we will focus on the following research questions within a multiple embedded case study:

1. What factors facilitated or inhibited the implementation of DeCM?
2. How was the implementation of DeCM planned and realised?
3. What (un)expected developments and consequences emerged during the DeCM implementation process?
4. How did stakeholders and target groups accept the DeCM intervention? Which recommendations did they provide for (future) implementation?
5. Was the implementation of DeCM successful (in terms of feasibility, appropriateness, acceptance)?
6. Which refinancing options for DeCM do stakeholders (implementing service providers and experts in financing regarding the healthcare system and healthcare policy) see with regard to sustainable implementation in routine care?

METHODS

Design

The RoutineDeCM study started on 1 September 2022 and is expected to end on 30 June 2024. For the process evaluation, we chose a multiple embedded case study design.[17 18] The four service providers implementing DeCM are defined as cases with embedded units of analysis (see figure 1). Each stakeholder group represents a unit of analysis, except for the financing experts who are included to provide an overall view of the implementation of DeCM in routine care from a health policy perspective. All research questions will be answered both for each service provider independently (within-case analysis) and, in a second step, generally in order to derive overarching implementation strategies and mechanisms (cross-case analysis).[18]

Patient and public involvement

The adaptation of the scientific concept for the implementation in the local routine took place with the active

Table 1 Inclusion criteria

Participants	Inclusion criteria
Dementia care manager	► Written informed consent ► Experience as a dementia care manager in the application of dementia care management during the RoutineDeCM project period
Manager of service providers The following practice partners are involved in the RoutineDeCM project: ► Alzheimer Gesellschaft Siegen e.V. ► Caritasverband Siegen-Wittgenstein e.V. ► Gesundheitsregion Siegerland eG ► Klinikum Siegen.	► Written informed consent ► Manager most intensively involved in the implementation of dementia care management at the practice partners ► Knowledge of (A) the intervention and (B) the implementation of the intervention
General practitioners and specialists	► Written informed consent ► General practitioners and specialists caring for participants who receive dementia care management during the project period ► In contact with the dementia care manager and able to provide information related to DeCM and the collaboration with the dementia care manager
Experts in financing with regard to the healthcare system and healthcare policy	► Written informed consent ► Persons who address questions regarding the refinancing of dementia-specific care services in Germany with respect to health insurance and legislation bodies ► Sound knowledge of the refinancing of dementia-specific care services with regard to the German Code of Social Law (Sozialgesetzbuch V) and the German Code of Social Law (Sozialgesetzbuch XI)
People with dementia	► Written informed consent ► A cognitive impairment as determined by a standardised screening instrument (DemTect)[38] ► Receiving dementia care management as part of the 'RoutineDeCM' study ► Living in the region of Siegen-Wittgenstein ► Sufficient communication skills to be able to participate in the data collection process
Main caregivers of people with cognitive impairments living independently.	► Written informed consent ► Self-defined the primary caregiver for people with cognitive impairments receiving DeCM during the RoutineDeCM project period ► Primary caregivers who were present when dementia care management was administered and as a result feel able to answer questions regarding the provision of dementia care management

DeCM, dementia care management.

participation of the cooperation partners, with participation of people with dementia and their relatives, as well as the implementing persons (dementia care managers). Therefore, workshops were held, the results of which were incorporated into the implementation concept. In the development of our process evaluation study, which is built on adaptation study,[19] no patients or public were involved.

Application of theoretical approaches

We planned our process evaluation according to the Implementation Research Logic Model developed by Smith *et al*,[19] which integrates the following core elements of implementation: (1) determinants, (2) implementation strategies, (3) mechanisms and (4) outcomes. We aimed to plan data collection and analysis using established implementation science tools and guidelines to inform our instrument sets and interpretation of results. In doing so, we also hope to create comparable datasets for each of the individual service providers for cross-case analysis.

The Consolidated Framework for Implementation Research (CFIR) will be used to inform the determinants section of the logic model. The CFIR can be defined as a meta-theoretical framework that builds on established theories and provides consistent taxonomies, terminologies and definitions that can guide an implementation project.[20 21] When planning our process evaluation, all elements of the CFIR were discussed in terms of whether they could be applied to the implementation of DeCM or whether they could be omitted when collecting and

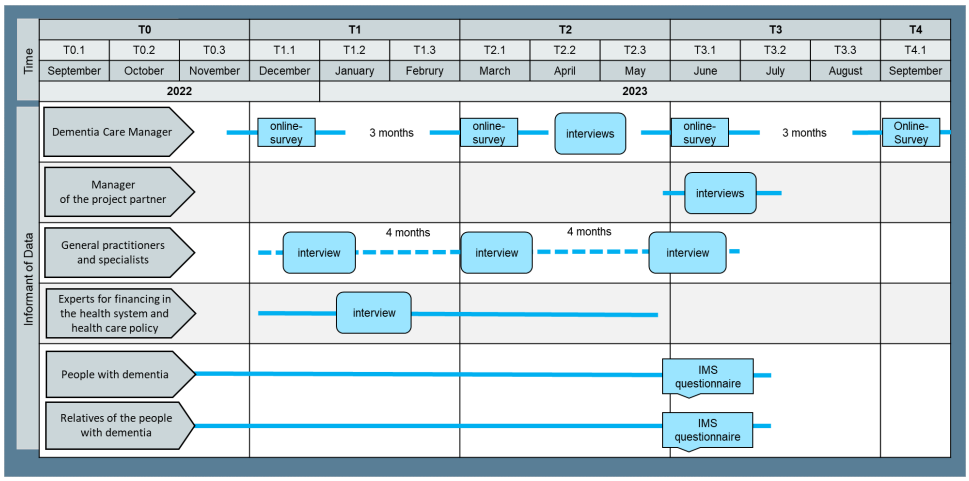

Figure 3 Scheduling of the data collection process. (IMS = Intervention Management System)

analysing process data (see online supplemental information file 1).

With regard to implementation strategies, we use the Expert Recommendations for Implementing Change (ERIC) to support data collection and analysis in our process evaluation (see online supplemental information file 1) that occur during the implementation process and that have an impact on implementation outcomes. We will use an exploratory qualitative approach as emphasised by Grant *et al*.[22] Finally, the Taxonomy of Outcomes for Implementation Research[23] informed the selection of appropriate outcomes of the DeCM implementation and will guide the investigation of those outcomes. Figure 2 shows the logic model and illustrates how its individual sections are represented by the theoretical approaches mentioned above. The theoretical approaches will guide data collection, data analysis and the interpretation of results throughout the process evaluation.

Participants

Several groups of people are usually responsible for or affected by the implementation of programmes rooted in research-based evidence,[24] such as the DeCM intervention. These stakeholder groups will be involved in the process evaluation. Table 1 provides an overview of the stakeholder groups that are considered to be relevant to the process evaluation and the corresponding criteria for their inclusion in the study.

Based on the inclusion criteria (table 1), the recruitment of the dementia care manager, the managers of the practice partners, the people with dementia, their main caregivers and the GPs and specialists will be conducted by the practice partners. Experts in financing with regard to the healthcare sector will be recruited by the study team.

Data collection

Data collection from the different stakeholders involved in the implementation of DeCM in Siegen-Wittgenstein will take place at overlapping times. Ways of general collaboration between stakeholders during delivery of the intervention will be included in the interviews with dementia care managers. Stakeholders directly involved in the provision of services (dementia care managers, GPs/specialists) will be interviewed several times during the course of the study. Stakeholders who describe their perspective in an overall manner and independent of the implementation progress will be interviewed once (see figure 3).

Procedures to collect qualitative data

The collection of qualitative data will primarily take the form of semistructured interviews. Semistructured interviews will be conducted with representatives from all stakeholder groups except for people with dementia and their main caregivers with the aim of capturing the determinants of and strategies for implementation as well as the mechanisms underlying the implementation process. Interview guides will be developed based on the theoretical approaches mentioned above. They will include questions regarding determinants (barriers and facilitators for implementation based on the CFIR)[20 21] and implementation strategies (plan and adaptation during the process of implementation based on the ERIC).[25] The subsequent questions on (un)expected consequences and developments (based on the Medical Research Council guidance) will be extended according to the substance of the first structured questions (see online supplemental information file 1). Dementia care managers and managers of the service providers will be interviewed face to face, while GPs/specialists and financial experts will be interviewed by telephone. The semistructured interviews will be audiorecorded and transcribed verbatim by a transcription company. In addition, relevant sources (eg, emails) will be collected, minutes will be taken and conversation notes will be prepared by research assistants of the study team throughout the course of the project for inclusion in data analysis.

Table 2 Overview of data collection

Informant	Data collection					Research questions
	Method	Recording	Performed by	Number of instances data collection planned	Time point	
Dementia care manager (n=1 per practice partner)	Semistructured interviews	Audio recording	Research associates	One time	T2	1-4
	Online survey	LimeSurvey	Dementia care manager	Four times	T1–T4	4-5
Manager of service providers (n=1 per practice partner)	Semistructured interviews	Audiorecording	Research associates	One time	T3	1-4,5
	Fully structured interviews	LimeSurvey		One time		4-5
General practitioners and specialists (n=4–8)	Semistructured interviews	Audiorecording	Research associates	Three times	T1–T3	4-5
	Fully structured interviews	LimeSurvey		Three times		
Experts in financing for the healthcare system and healthcare policy (n=4–8)	Semistructured interviews	Audiorecording	Research associates	One time	T3	6
People with dementia and their (caring) relatives (n=60)	Fully structured interviews	Intervention management system	Dementia care manager	One time	After completion of the intervention	4-5
Dementia care manager, Managers of the project partner, research associates	Collecting relevant sources, preparing minutes and notes regarding conversations; requests from the managers		Research associates		Ongoing	1-3,5

Procedures to collect quantitative data

Quantitative data will be collected in the form of fully structured interviews and an online survey to capture implementation outcomes (acceptability, appropriateness and feasibility)[23] (figure 2). Individual items drawn from three standardised scales (the Acceptability of Intervention Measure, the Intervention Appropriateness Measure and the Feasibility of Intervention Measure) will be used to assess these implementation outcomes[26 27] (see online supplemental information file 2). The scales were published by Weiner *et al*[26] and translated into German and psychometrically tested by Kien *et al*.[27] These fully structured interviews will be conducted by two different groups of people. On the one hand, they will be conducted by research assistants. These answers will be entered into LimeSurvey.[28] On the other hand, they will be conducted by dementia care managers. These answers will be entered into the DeCM intervention management system.[5] The dementia care managers themselves will be invited to participate in the online surveys. The online survey will be conducted using the online survey tool LimeSurvey.[28]

Table 2 provides an overview of the planned data collection details.

Most data will be collected by the scientific staff of the study team. Only the data collection from people with dementia and their (caring) relatives is carried out by the dementia care managers to ensure that the potential burden corresponding to the data collection process remains as low as possible for this vulnerable target group.[29]To reconstruct and evaluate the whole process of DeCM implementation, data will be collected at different time points throughout the process (figure 3).

Data analysis

Data analysis will be carried out in two steps within the case study design[18]: (1) within-case analysis based on the individual units of analysis and (2) cross-case analysis based on the same units of analysis of all four cases. Convergent parallel methods will be used to analyse the

different data material.[30] Accordingly, qualitative and quantitative data will be analysed separately and will subsequently be merged during the interpretation of the results.[30] Synthesising the results of the within-case analysis as a cross-case analysis will allow us to derive generalisable findings regarding the regional adaptation and implementation of DeCM. Interview transcripts, minutes of meetings and conversations, email correspondence and other documents (see table 2) will be analysed using qualitative content analysis[31] applying a deductive-inductive approach to coding. The six research questions will inform the initial deductive main categories and generic categories. Detailed information found in the data material will lead to subcategories.[31] The process of coding will be carried out by at least two researchers to enhance intersubjective traceability. After these coding steps, the extracted information will be synthesised and interpreted in group sessions with all members of the research team. Elements of the CFIR[20 21] and the ERIC[25] will be used to inform and theorise our findings.[14] Qualitative data analysis will be carried out using the software MAXQDA.[32]

Procedure for the analysis of quantitative data

Information on implementation outcomes (accessibility, appropriateness, feasibility) collected in a standardised way–either through an online survey or structured interview questions–will be analysed using descriptive statistics. The analysis will focus on changes in these outcomes over time (within-case analysis) and on differences in evaluation between the four service providers (cross-case analysis). Quantitative analysis will be carried out using the software SPSS version 25.0.[33]

DISCUSSION

This process evaluation will provide in-depth information regarding the implementation of DeCM. Based on a theory-informed logic model, core aspects of the implementation process (including the determinants of, strategies for and outcomes of the implementation of DeCM) will be addressed and can be linked systematically. The results will provide information regarding the determinants of DeCM implementation that must be addressed and the strategies that are appropriate for implementing DeCM in home-based care arrangements. The development of programme theory for DeCM as a complex intervention can also be informed by the results of the process evaluation. Furthermore, the evaluation's focus on the mechanisms underlying the outcomes of DeCM implementation will provide insights into the extent to which DeCM has succeeded in terms of acceptance, appropriateness and feasibility as well as the extent to which setting-specific adaptations of the DeCM intervention are possible and permissible.

The multiple embedded case study design (in particular the cross-case analysis) will allow the generation of recommendations for an implementation strategy that can contribute to the routinisation of DeCM in the region of Siegen-Wittgenstein. Furthermore, this evaluation will provide insights into the elements and processes that are promising regarding the implementation of the DeCM intervention in additional regions in Germany.

ETHICS AND DISSEMINATION

The process evaluation is conducted in accordance with the Declaration of Helsinki,[34] the recommendations on good scientific practice,[35] the research ethics principles of the Code of Ethics of the German Society of Nursing Science,[36] the recommendations of Schnell and Dunger: People with dementia and their relatives can withdraw their consent to participate in the study at any time.[37] The written consent is obtained by the dementia care manager, who has received training for this step and has professional expertise in working with people with dementia. The RoutineDeCM study has received ethical approval from the Clinical Ethics Committee of University Medicine Greifswald (BB 110/22).

The results of the process evaluation are to be published in the form of scientific publications. In addition, it is planned to write practice-relevant reports and recommendations for action. In particular, an attempt will be made to generalise the implementation strategies investigated in the process evaluation in order to make them usable for other health service providers.

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Acknowledgements The authors would like to thank René Thyrian for his contribution to the conception of the RoutineDeCM project, Martina Roes, Franziska Laporte Uribe and Jan Dreyer for reviewing the manuscript and providing valuable feedback, and René Müller-Widmer for sharing and suggesting changes to figure 3.

Contributors BH conceived and led the process evaluation part of the RoutineDeCM project. TQ and BH conceptualised the process evaluation. The process evaluation was concretised by TQ, HB, TK, DP and BH. JH and KS led and coordinated the DeCM adaptation for implementation into routine care in Siegen-Wittgenstein. DP wrote the first draft of the manuscript. AF, TQ, HB, TK, BA, KS, JH and BH offered recommendations for modification. All authors read and approved the final manuscript.

Funding The RoutineDeCM project and thus also the process evaluation described in this study protocol is financially supported by the Federal Ministry of Health in Germany (funding number: ZMI1-2521FSB907).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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