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Development of a complex intervention to prevent delirium in older hospitalized patients by optimizing discharge and transfer processes and involving caregivers: A multi-method study

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ABSTRACT

Background: Delirium is a common yet challenging condition in older hospitalized patients, associated with various adverse outcomes. Environmental factors, such as room changes, may contribute to the development or severity of delirium. Most previous research has focused on preventing and reducing this condition by addressing risk factors and facilitating reorientation during hospital stay.
Objective: We aimed to systematically develop a complex intervention to prevent delirium in older hospitalized patients by optimizing discharge and transfer processes and involving caregivers during and after these procedures. The intervention combines stakeholder and expert opinions, evidence, and theory. This article provides guidance and inspiration to research groups in developing complex interventions according to the recommendations in the Medical Research Council framework for complex interventions.
Design and methods: A stepwise multi-method study was conducted. The preparation phase included analysis of the context and current practice via focus groups. Based on these results, an expert workshop was organized, followed by a Delphi survey. Finally, the intervention was modeled and a program theory was developed, including a logic model.
Results: A complex intervention was developed in an iterative process, involving healthcare professionals, delirium experts, researchers, as well as caregiver and patient representatives. The key intervention component is an 8-point-program, which provides caregivers with recommendations for preventing delirium during the transition phase and in the post-discharge period. Information materials (flyers, handbook, videos, posters, defined "Dos and Don'ts", discharge checklist), training for healthcare professionals, and status analyses are used as implementation strategies. In addition, roles were established for gatekeepers to act as leaders, and champions to serve as knowledge multipliers and trainers for the multi-professional team in the hospitals.
Conclusions: This study serves as an example of how to develop a complex intervention. In an additional step, the intervention and implementation strategies will be investigated for feasibility and acceptability in a pilot study with an accompanying process evaluation.
Tweetable abstract: Delirium prevention can benefit from optimizing discharge and transfer processes and involving caregivers of older patients in these procedures.
Study registration: DRKS00017828, German Register of Clinical Studies, date of registration 17.09.2019.

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What is already known

- Changing environmental factors as a result of hospital admission or room changes may contribute to the development of delirium, but discharges and transfers have so far been neglected as a possible risk factor.
- Multicomponent non-pharmacological interventions addressing modifiable risk factors have been shown to reduce delirium incidence in older patients during a hospital stay.
- Currently, there are few exemplary publications demonstrating the application of the Medical Research Council framework for complex interventions.

What this paper adds

- This study offers valuable guidance and inspiration for the development of complex interventions by demonstrating the utilization of methodological approaches that integrate a variety of data, as well as expert and stakeholder opinions.
- The developed intervention aims to optimize the discharge and transfer processes of older inpatients and to actively involve caregivers in delirium prevention strategies during and after discharge/transfer.

1. Background

More than one in five hospitalized older patients develop delirium (Bellelli et al., 2016), rendering it a growing challenge for healthcare professionals. Delirium is associated with increased care needs, longer hospital stays, falls (Hshieh et al., 2015), hospital readmissions, nursing home admissions (Gleason et al., 2015; LaHue et al., 2019; Park and Kim, 2019), and increased mortality (Park and Kim, 2019; Witlox et al., 2010). The duration of this condition varies, and it may persist even weeks after discharge (Cole et al., 2009; Dasgupta and Hillier, 2010).

There is a wealth of research on delirium prevention and management during hospital stay in older hospitalized patients, focusing on multicomponent interventions such as cognitive stimulation (e.g. reminder of time and day), mobilization, nutrition, hydration, non-pharmacological sleep promotion, medication review, and facilitating reorientation in the unknown hospital environment (Eckstein and Burkhardt, 2019; Inouye et al., 2014; Lee et al., 2021; Zhao et al., 2023). Family caregivers have also been involved in interventions, e.g. by providing orientation and bringing family photos, facilitating communication, and reminding patients to use glasses and hearing aids (Rosenbloom-Brunton et al., 2010). These interventions address both *predisposing* and *precipitating* risk factors for delirium. Known *predisposing* risk factors include older age, pre-existing cognitive impairment or dementia, sensory and functional impairments (e.g. problems in vision/hearing and activities of daily living), frailty and malnutrition (Bramley et al., 2021; Mattison, 2020). *Precipitating* factors include surgery, adverse drug reactions and acute illness (Wilson et al., 2020). In addition to these well-known mechanisms, the potential role of iatrogenic and environmental factors, such as sleep disturbance, immobilization, physical restraints, and bed or ward changes has recently been underscored (Ormseth et al., 2023). Some studies have indicated that frequent room changes are associated with increasing delirium incidence and severity (Goldberg et al., 2015; McCusker et al., 2013). This association arises not only from delirium symptoms such as agitation triggering room changes or transfers. It has also been established that delirium occurs after room changes (Goldberg et al., 2015).

While room changes and transfers within the hospital have previously been studied, transfers to other healthcare facilities (e.g. rehabilitation hospitals, nursing homes) or returning home after prolonged hospital stays have hitherto been neglected as risk factors for the onset of delirium.

To address this research gap, the project TRAnsport and DElirium in older people (TRADE) was initiated to develop and pilot a complex intervention for delirium prevention in older people, optimizing discharge and transfer processes and encouraging active involvement of caregivers during and after these procedures (Leinert et al., 2021).

This study serves as an example of how to develop a complex intervention following the recommendations in the Medical Research Council framework for developing and evaluating complex interventions (Craig et al., 2008; Skivington et al., 2021).

2. Methods

A multi-method study was conducted to comprehensively address the elements of the development phase described in the Medical Research Council framework for complex interventions (Craig et al., 2008; Skivington et al., 2021). Specifically, we analyzed the current context, developed a program theory, made efforts to engage stakeholders at all levels, and sought to identify and describe uncertainty. The study was carried out in a stepwise process: Step 1, the preparation phase, includes the analysis of the context and current practice (focus groups with different stakeholders). Based on these results, a first draft of the intervention components and implementation strategies was developed and validated in step 2 (a multi-professional expert workshop and Delphi survey). The process and envisioned outcomes of the development phase were finally modeled in step 3 (program theory and overview chart for practitioners). An overview of the development phase with the corresponding methods and aims is shown in Fig. 1.

2.1. Methods – step 1: preparation

2.1.1. Focus groups (1)

The aim of the focus groups involving healthcare professionals and transport service employees was to explore contextual factors. In

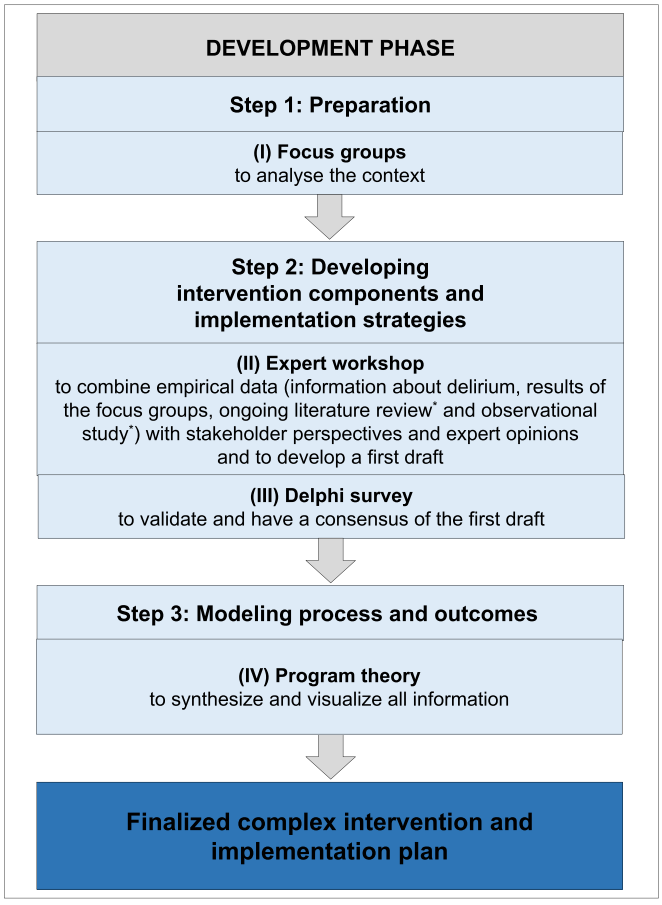

Fig. 1. Development phase with the methods and aims.
Note. *Reported separately.

particular, we focused on existing practices, challenges, and requirements associated with the transfer/discharge of patients, and those factors associated with the management of older patients with delirium/at risk of delirium.

Study design

Semi-structured, guide-based focus groups with relevant professional stakeholders were conducted by an independent external researcher.

Study population, recruitment and sampling

We aimed for a sample size of 25 healthcare professionals and employees of transport services divided into five focus groups, including a balanced mix of nurses, physicians, social workers, discharge/bed managers, ward secretaries, therapists, and transport service staff. Four hospitals and two transport services were approached. Due to the distances between the participating hospitals and transport services, separate focus groups were necessary. Participants were included if they were at least 18 years old, legally fully competent, and fluent in German. The focus groups with healthcare professionals in the hospitals included those with at least one-year experience in caring for patients aged 65 or older. To capture the views of all transport service employees, individuals with varying work arrangements were selected, including those with little experience (under two years) and those in permanent or long-term employment. Team leaders were also invited for participation. All interested individuals meeting the inclusion criteria received prior written and verbal information regarding the content of the study, the study aim, and data protection regulations via email and telephone.

Data collection and processing

The semi-structured interview guides were based on the pre-defined research aims and German expert standard for discharge management in nursing (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege, 2019). For both healthcare professionals working in hospital and employees of the transport services, two different guides were developed and tested (see Supplementary file 1). The focus groups took place in the participating hospitals and in one transport service. They were conducted with systematic moderation by one researcher (ND), aiming to maximize inter-interviewer reliability. Field notes were taken during all focus groups. All focus groups were conducted in German, audiotaped and transcribed verbatim with the transcription software "f4transkript" (dr. dresing & pehl GmbH, 2019). Data protection was respected in accordance with the requirements of the EU General Data Protection Regulation.

Data analysis

Data were analyzed using qualitative content analysis (Kuckartz and Rädiker, 2023) to identify common themes arising in local discharge, transitional care and transportation procedures, existing practice, needs, problems, and facilitators. MAXQDA 2018 (VERBI Software, 2017) was used for data handling. A trained researcher experienced in qualitative methods (ND) created a first draft of a coding manual with inductive and deductive codes (based on German expert standard for discharge management in nursing (Deutsches Netzwerk für Qualitätsentwicklung in der Pflege, 2019)). This draft was tested by a second trained, experienced researcher (StS) and subsequently discussed. After first coding by ND, the second researcher (StS) checked the codes. Both discussed coding to achieve high intercoder reliability. Data saturation was defined as the point when no additional information was obtained. This was defined by a consensus between the two researchers involved and discussion with the principal investigator (MM).

2.2. Methods – step 2: developing intervention components and implementation strategies

2.2.1. Expert workshop (II)

The expert workshop provided a platform for the collaborative design and development of intervention components and implementation strategies, and enabled key uncertainties to be addressed.

Study population, sampling and recruitment

We aimed to involve all relevant stakeholders in the workshop: Clinical and research experts on delirium and discharge processes, interviewees from the focus groups, other healthcare professionals involved in the discharge process of patients 65 years and older, patients and their caregivers, representatives of affected individuals, and the association of caregivers' self-help organizations were all invited to participate in a two-day workshop via a personal request and a cover letter. Professionals, patients, and caregivers were approached by the study team in the hospitals and recruited by the researchers. The workshop was led by a senior researcher (MM) with extensive experience in workshops for intervention development (Regauer et al., 2021; Saal et al., 2018).

Study design, data collection and analysis

A stepwise modeling process was conducted in the expert workshop, which is displayed in detail in Table 1.

Knowledge and clinical practices: Starting with a shared common understanding of the topic, the project and the concepts of cognitive impairment and delirium were introduced, followed by a comprehensive presentation of relevant previous project findings (focus group findings, preliminary results of an ongoing systematic review and an ongoing observational study).

Identification of challenges and development of solutions and goals: The aim of the first phase of the workshop was to identify further challenges from the perspective of the workshop members and to develop feasible solutions for managing patients at risk of delirium during transfers and discharges. For this purpose, creativity techniques, such as "imagination of the situation in five years", "reversal method" and task assignments to develop implementation solutions were used in plenary and group sessions.

Contextualization: The results obtained thus far provided the basis for subsequent steps. The moderator and the research team picked up on these results along with any new insights that emerged during the process, and reintroduced them into the workshop when necessary. To identify potential barriers to the implementation and to select implementation strategies, the Consolidated Framework of Implementation Research 1.0 (CFIR) (Damschroder et al., 2009) and the Expert Recommendations for Implementing Change (ERIC) (Powell et al., 2015) were used in the second phase of the workshop. Participants weighted and prioritized the 39 constructs of the Consolidated Framework of Implementation Research. The constructs with the highest scores were used for the matching tool "Consolidated Framework of Implementation Research-Expert Recommendations for Implementing Change Barrier Busting Query Tool V 1.0" (CFIR Research Team-center for Clinical Management Research, 2019; Waltz et al., 2019). This tool was applied to generate a weighted order of recommendations for potentially appropriate implementation strategies. The twelve strategies with the highest weights were selected and further developed in the participants' own context, using the 6–3–6–brainwriting-method (adapted version of 6–3–5–method of Rohrbach (1969)). The experts were able to select, specify and discuss which strategy would be appropriate for implementation based on their experience. It was also possible to deselect a strategy if it did not match the implementation context.

Intervention and implementation plan: As the final step, a summary of the results of steps one and two was presented and discussed by the participants, leading to a first version of the intervention and an implementation plan.

2.2.2. Delphi survey (III)

The initial draft of the intervention and implementation plan was reviewed and discussed by the research team. The results of this review were presented in an online-Delphi survey (Wilkes, 2015) to the participants of the workshop and additional external experts on delirium, patients, caregivers, and members of a German association of caregivers' self-help organization. The participants were asked to make comments or suggestions for further development of the interventions and implementation strategies.

Table 1
Modeling process of the expert workshop.

Aim	Content	Methods and materials
Knowledge and clinical practices	- Introduction, explanation of the expert workshop and project information - General information on cognitive impairment and delirium (epidemiology, pathophysiology, diagnosis, assessments, treatment) - Research results (perspective of healthcare professionals/employees of transport services arising from focus groups, preliminary results of ongoing review and observational study)	- Presentation in plenum - PowerPoint slides
Identification of challenges and development of solutions and goals	- Situation in five years ("How will the living situation of people aged 65 and older, and the healthcare system/situation develop in the next 5 years?") - Reversal method: Worst case and ideal case scenarios structured according to three phases: pretransfer, inpatient stay, after transfer ("Imagine that your loved one – who has an increased risk of delirium – has to be hospitalized — what are the three worst scenarios from the perspective of the patient? What would perfect care look like in an ideally-run system, and what could be a feasible solution in the current healthcare system?") - Realistic implementation solutions (including opportunity–risk-analysis: high opportunity/high risk, low risk/high opportunity, low opportunity/high risk, low risk/low opportunity)	- Creative techniques - Discussion in plenum and small working groups - Pinboards and mind maps
Contextualization	- Identifying and weighting potential barriers (CFIR) - Weighting an order of recommendations ("CFIR-ERIC Barrier Busting Query Tool V 1.0") - Further development of ERIC: Implementation strategies in context (6–3–6–method: Six participants produce three ideas, which are further developed in six rounds)	- Creative techniques - Working in small groups, alone, and in plenum - Discussion in plenum and small groups - Pinboards, CFIR 1.0, ERIC, software matching tool "CFIR-ERIC Barrier Busting Query Tool V 1.0"
Intervention and implementation plan	- Summary of all results - Consensual definition of first draft of the intervention and implementation plan	- Discussion in plenum - Pinboards

Note. CFIR = Consolidated Framework of Implementation Research, ERIC = Expert Recommendations for Implementing Change.

2.3. Methods – step 3: modeling process and outcomes

2.3.1. Program theory (IV)

A program theory was developed to represent why, how, and under which conditions the developed intervention could work, and to obtain a common understanding of the intervention (Skivington et al., 2021). To synthesize and visualize all information together with the theoretical fundamentals of the development phase, the Program Logic Model was established (W.K. Kellogg Foundation, 2004). In addition, we applied the Normalization Process Theory (NPT), an empirically derived theory and analytical tool to understand the dynamics of implementing complex interventions. We integrated the Normalization Process Theory core elements ("coherence", "cognitive participation", "collective action" and "reflective monitoring") into our logic model to enhance our understanding of the intervention and the related change processes (May et al., 2018; May and Finch, 2009). This theory will serve as the theoretical basis for the process evaluation in the later feasibility study (May et al., 2022).

Study registration and ethics

The study is registered in the "German Register of Clinical Studies" (ID: DRKS00017828, date of registration 17.09.2019). Ethical approval was obtained by the relevant ethics committees of the participating hospitals (University of Ulm (# 84/19 and 265/20), University of Heidelberg (# S-443/2019 and S-692/2020), University of Tübingen (# 352/2019BO2)).

3. Results

3.1. Results – step 1: preparation

3.1.1. Focus groups (I)

Characteristics of the participants

Between September and October 2019, a total of 21 hospital employees (n = 13 healthcare professionals, n = 8 discharge management/social services) from four different hospitals took part in four focus groups (three focus groups with five participants and one with six). Four employees of the transport services also participated in one focus group.

The focus groups were conducted face-to-face in the participating hospitals and at a transport service station, and lasted between 47 and 60 min (total 268 min). The characteristics of all participants are shown in Supplementary file 2.

Perspective of healthcare professionals and transport service employees

The following themes were identified:

Risk assessment: Standardized cognition tests and delirium screening were reported to be rarely performed in hospitals due to a shortage of time.

"*Unfortunately not on a regular basis. (…) We lack the time for screening and assessment in addition to the routine activities (…).*"

[Hospital 2, Physician, 70–71]

Discharge planning: Participating professionals reported different discharge planning processes, which varied according to the professionals responsible for discharge planning in each location (such as discharge managers or social workers). Frequently, discharge planning was only offered for patients with projected increased care needs after hospitalization (e.g. requiring rehabilitation or nursing/caring support, or displaying altered cognition such as delirium or dementia). Multi-professional team meetings and early discharge planning were reported to facilitate an optimal discharge process in hospitals with longer stays. In some cases, unplanned discharges were conducted (e.g. due to lack of beds and transfer to another institution). Particularly in the larger hospitals, discharge times are difficult to plan, and changes occur frequently, creating a barrier to an optimal discharge process. Generally, the discharge process is

reported to be a considerable challenge for patients with cognitive impairment, with discharges often delayed due to additional examinations. In most cases, the patients' beds are needed, so they are sometimes asked to wait in the corridors for discharge. Healthcare professionals are aware of the issue of delayed discharges, particularly in patients who have already showed cognitive impairment, and make efforts to keep them in their rooms for as long as possible.

"*With delirious patients or those who have cognitive impairments, the aim is to bring a sense of calm because on the day of discharge, most of them become quite anxious, unsure of where they are going, and it simply unsettles them. So, we attempt to keep the patients in their rooms for as long as possible and not have them in the hallway. This approach varies depending on the day and the level of bed pressure, sometimes working better and sometimes not as effectively.*"

[Hospital 2, Nurse, 58–60]

Different transport services are provided, based on the patient's health: public taxis, non-medical transport or medical ambulance transportation. There is a lack of capacity in transportation, and transfers are sometimes carried out at night.

Involvement of patients and caregivers: Involving patients and caregivers in the discharge process was reported to be important for healthcare professionals. For example, ward rounds were rescheduled to allow contact with caregivers who visit patients. However, healthcare professionals also feel that caregivers are sometimes passive in terms of providing care and planning for the post-discharge period.

"(…) They always have the hope that ´it'll be okay, it'll be okay. (…) I won't do anything, (…) they will sort it out, he [the patient] will be fine, everything will be the same as before [the hospital stay]´. That's why they come relatively rarely, call relatively rarely."

[Hospital 3, Nurse, 45–46]

Sometimes, therapists act as a close carer due to the amount of time they spend together.

"*(…) I have the feeling that I am always very close to the patient and also always get told a lot of things, because the time spent with the patient as a therapist is simply more than as a doctor. Or that they sometimes pour out their hearts to me (…). So I think there are always very intense conversations with the patient.*"

[Hospital 3, Physiotherapist, 68–69]

Discharge report, conversation and intersectoral communication: Information about discharge, planned post-discharge actions and medication is usually written in the discharge report, which is mostly communicated by the physicians to patients and, if necessary, to caregivers.

"*All relevant information is included in the discharge report, which essentially documents the patient's progress, specific procedures performed, diagnostic tests conducted, therapies administered, and the crucial aspect of the prescribed discharge medication (…). This information is also briefly communicated to the patient and, if necessary, also to the caregivers in the discharge conversation.*"

[Hospital 1; Physician, 44–46]

The discharge conversation does not usually provide additional information on preventive and supportive measures, e.g. the topic of delirium in general, or reorientation after discharge or transfer, primarily due to time limitations.

For data protection reasons, taxi drivers and non-medical transport services are not permitted to receive the same information as those from medical transport services: They are informed about the patients' living conditions at their destination (stairs, elevator, etc.), but not about diagnoses or specific impairments (e.g. hearing, visual or cognitive impairment). Drivers have to explicitly ask about the patient's health situation and specifics.

"*We don't know what the patients have. We also don't know why they were in the hospital (…). If you don't ask, you probably won't get any information on your own.*"

[Transport, Driver, 87–88]

It was stated that it would be helpful for drivers to know as much as possible about the patient, as this would allow them to better assess the situation and facilitate a safe journey to the right destination.

Knowledge: Transportation drivers receive brief training, including driver safety training (mandatory), mobilization, and dealing with older people with dementia (voluntary).

"*When it comes to diseases like dementia, we are briefly told how to deal with it. What do I do when the person asks where to go for the two hundredth time? How should I react?*"

[Transport, Driver, 202–204]

New drivers are trained by experienced ones for at least two weeks. The drivers do not distinguish between delirium and dementia; they speak generally of confusion. Problems with confusion arise when patients unbuckle their seat belts while driving, give incorrect location information, and when drivers have to constantly repeat what they have said.

Involvement of patients and caregivers: Transport from hospital either to home or to another institution usually involves the patient only. Whether or not it is possible for caregivers to be taken along must be clarified when transportation is initially registered. However, when patients are transported from home to a physician's appointment, caregivers often want to accompany them on the journey with the transport service.

"*(…) because then the daughter is more interested in what's wrong with grandma than when she is discharged from the hospital.*"

[Transport, Driver, 115]

3.2. Results – step 2: developing intervention components and implementation strategies

3.2.1. Expert workshop (II)

Characteristics of the participants

The expert workshop was conducted on two days in January 2020. In total, 19 people participated in the workshop: n = 2 nurses, n = 3 social service staff, n = 2 discharge managers, n = 5 physicians, n = 1 person from a non-profit foundation for nursing, n = 5 researchers and n = 1 study nurse. Patients, caregivers, employees of transport services, and members of associations of caregivers could not be recruited. The most frequently named reason for non-participation was the two-day duration.

Course and results of the workshop

Knowledge and clinical practices: After presenting the overview of the project, cognitive impairment and delirium, and the focus groups, the preliminary results from the literature review were summarized as follows: Multicomponent interventions involving caregivers and patients (e.g. patient, caregiver, and staff education, exercises and mobility training) (Boltz et al., 2014; Martínez-Velilla et al., 2016), together with consideration of environmental risk factors (e.g., frequent room changes, modification of lighting, access to sensory and mobility aids) (Boltz et al., 2014; Goldberg et al., 2015; McCusker et al., 2001) may be effective, although evidence is limited. Preliminary results of an ongoing observational study on delirium incidence and current practice (Leinert et al., 2021) were also shared: Relatives did not systematically accompany hospitalized patients, and approximately one third of the patients

were continuously accompanied by a caregiver before, during and after discharge. We carefully elaborated the initial findings to avoid any inappropriate impact on decisions in the intervention development. Detailed reporting of the review and observational study will be published elsewhere.

Identification of challenges and development of solutions and goals: A desirable situation to ensure high quality care under current conditions would encompass: i) a reliable daily and discharge schedule, ii) consistent communication and education about delirium to healthcare professionals, and subsequently for patients and relatives, iii) avoidance of room and bed changes, iv) the possibility for patients to take personal belongings with them, v) the use of digital media for information dissemination like videos, and vi) a checklist for a well-organized discharge and transfer for older people.

Contextualization, intervention and implementation plan: In Fig. 2, we detail the selected weighted constructs of the Consolidated Framework of Implementation Research and the matched and ultimately selected Expert Recommendations for Implementing Change strategies. These strategies were further developed by the workshop participants. The most prioritized domain (in total, 129 points, 100 %) of the Consolidated Framework of Implementation Research was *inner setting* (33 points, 26 %), followed by *process* (30 points, 23 %), *intervention characteristics* (27 points, 21 %), *outer setting* (21 points, 16 %), and *individual characteristics* (18 points, 18 %). The most weighted constructs (see Fig. 2 "Selected most weighted constructs and their CFIR domains") were transformed into strategies (see Fig. 2 "Matched ERIC strategies"). In addition, participants suggested including the strategy "Distribute educational materials", although this was not included in the initial selection. After extensive discussions on the matched strategies, the participants further developed seven Expert Recommendations for Implementing Change strategies for implementation (see Fig. 2 "Final selected ERIC strategies with results of the further development in the workshop"). Finally, we defined an intervention and implementation plan.

3.2.2. Delphi survey (III)

An enhanced draft of the intervention was developed by researchers after the workshop. The draft received agreement in an online-Delphi survey involving all healthcare professionals who participated in the workshop, two additional experts in delirium (one nurse with a master's degree, one nursing PhD student), one person from an association of caregivers, two caregivers, and one patient. Only a few minor comments were made at this stage. For instance, it was recommended that champions should be chosen from different professional groups. It was also suggested that education sessions should be integrated into already established training sessions, or should be repeated to ensure that knowledge is continually refreshed, especially in the context of ongoing implementation. New staff members should also be included in the briefing process. It was emphasized that caregivers should receive thorough information and there should be a designated contact person available on the ward to address any additional questions or concerns. Comprehensive training for both champions and staff was also deemed necessary. Since there was already strong agreement on the first version of the draft in the first round, no second round was carried out.

3.3. Results – step 3: modeling process and outcomes

3.3.1. Program theory (IV)

A program theory was developed, and the program implementation is visualized in Fig. 3, outlining the resources/inputs, activities, outputs, short- and long-term outcomes, and the impact.

The principal intervention is an 8-point-program for delirium prevention given as guidelines for caregivers supporting patients through discharge and transfer processes. It encompasses the following points: (1) encourage caregivers to accompany patients during and after discharge and transfer processes, (2) create familiarity, (3) pass on information, (4) support orientation, (5) adapt communication, (6) structure everyday life, (7) promote exercise, and (8) encourage adequate nutrition (8-point-program: see Fig. 4).

This information will be conveyed to caregivers via a conversation with healthcare professionals at least 48, and at the latest 24, hours before discharge. It will be supplemented by informative flyers and videos available at the project website. Patients will also be apprised of discharge and any processes after discharge or transfer as early as possible.

In addition to caregivers, follow-up care providers (such as general practitioners, nursing homes, home care services) will be notified about the discharge date and relevant patient information will be passed on. Discharge reports and referral forms will also be handed out before discharge/transfer. Further, it will be ensured that all individuals involved in the discharge process and follow-up care are well informed about the risk of delirium and possible symptoms (including the transport service). Discharge should be scheduled between 7 am and 6 pm.

This discharge pathway will be presented in an overview for practitioners, which includes the stages "preparation for discharge/transfer" (patients, caregivers, hospital staff), "discharge/transfer day", and "arrival and following days in further institution/home" (see Supplementary file 3).

3.3.2. Implementation strategies

The following implementation strategies will be used to ensure successful integration of the intervention into practice.

Use of gatekeepers and status analysis

Nominated gatekeepers at each department of the participating hospitals will support the implementation using their influence as leaders, providing constant support and reminders throughout the intervention phase. Gatekeepers will be healthcare professionals (nurses, physicians, discharge managers, or social workers), and preferably in a leadership position, with at least three years of professional experience and at least two years on the ward or in the department. They will also select the champions, as they know which persons will be best suited for these positions, and will record the local structures and discharge processes at the beginning and the end of the intervention phase (status analysis).

Use of champions, mentoring, and trainings

Champions will be deployed for each profession at the participating wards as supporters and influencers of implementation. They should be healthcare professionals (nurses, physicians, discharge managers, or social workers), with at least three years of professional experience and at least two years on the ward or in the department.

They will assist in the implementation of the intervention and the accompanying implementation strategies by supporting implementation transfer and raising awareness of delirium and the planned intervention within the team. They will thus become knowledge multipliers for their teams. Before starting the intervention phase, all healthcare professionals identified as being involved in the discharge process will be trained: Champions and gatekeepers will receive a one-day training course conducted by the project team at least two weeks before starting the intervention. Other healthcare professionals will be informed about delirium and the interventions in a one and a half hour training session offered by champions. Champions will also serve as direct contact persons for team colleagues and the project team. Mentoring will be used to support champions through four-weekly video or telephone meetings with the project team. Together with the project team, gatekeepers and champions, site-specific lists of "Dos and Don'ts" for delirium prevention in hospitals will be created.

Information to stakeholders

The participating opinion leaders will be informed by the project leader and research team about the interventions and implementation strategies as they will serve as implementation support.

Materials for healthcare professionals

A handbook will be provided for each healthcare professional. It will include information about delirium (risk factors, differences between

Selected most weighted constructs and their CFIR domains			
1	Tension for Change (Inner setting)	13	Self-efficacy (Characteristics of individuals)
2	Relative advantage (Intervention characteristics)	14	Individual Stage of Change (Characteristics of individuals)
3	Peer Pressure (Outer setting)	15	Executing (Process)
4	Formally Appointed Internal Implementation Leaders (Process)	16	Champions (Process)
5	Reflecting and Evaluating (Process)	17	Patients/Customers (Process)
6	Knowledge and Beliefs about the Intervention (Characteristics of individuals)	18	Patient needs and resources (Outer setting)
7	Implementation Climate (Inner setting)	19	Relative Priority (Inner setting)
8	Leadership Engagement (Inner setting)	20	Structural Characteristics (Inner setting)
9	Intervention characteristics: Complexity	21	Tension for Change (Inner setting)
10	External Policies and Incentives (Outer setting)	22	Relative advantage (Intervention characteristics)
11	Adaptability (Intervention characteristics)	23	Peer Pressure (Outer setting)
12	Costs (Intervention characteristics)	24	Formally Appointed Internal Implementation Leaders (Process)

Matched ERIC strategies			
1	Identify and prepare champions	7	Identify early adopters
2	Assess for readiness and identify barriers and facilitators	8	Create a learning collaborative
3	Alter incentive/allowance structures	9	Capture and share local knowledge
4	Conduct local consensus discussions	10	Conduct local needs assessment
5	Conduct educational meetings	11	Promote adaptability
6	Inform local opinion leaders	12	Distribute educational materials

Final selected ERIC strategies with results of the further development in the workshop		
Selected ERIC strategies	**Facilitators**	**Implementation strategies**
Identify and prepare champions	- Identify one person of each healthcare profession (train-the-trainer) - Identify local work groups	- Using champions/gatekeepers - Status analysis - Mentoring of champions
Alter incentive/ allowance structures	- Transfer local responsibility to subordinate employees - Feedback from project team - Define “No-Gos”	- Using champions/gatekeepers - Mentoring of champions - “Dos and Don´ts” (instead of “No-Gos”)
Conduct educational meetings	- Training of gatekeepers, champions and healthcare professionals - Videos and flyers for caregivers, and healthcare professionals - Training handbook	- Training - Information to transport services employees
Inform local opinion leaders	- Information and involvement of hospital management	- Written and oral information about intervention to stakeholders
Capture and share local knowledge	- Share knowledge from already implementing organization (via email, etc.) - Implementation process checklist - Identifying local responsibility	- Identifying gatekeepers/champions - Status analysis - Mentoring - Information about implementation processes to other organizations
Conduct local needs assessment	- Identify knowledge about delirium - Identify best person for implementation	- Status analysis - Identifying gatekeepers/champions
Distribute educational materials	- Internal: Revision of Standard operating procedures, Information via email, checklist for discharge - External: Flyers, videos/audio files/app, Pre-inpatient information on discharge management	- Checklist for discharge process - Videos, flyer, handbook - Conversation guide - Status analysis

Fig. 2. CFIR and matched ERIC with further development in context.
Note. CFIR = Consolidated Framework for Implementation Research, ERIC = Expert Recommendations for Implementing Change.

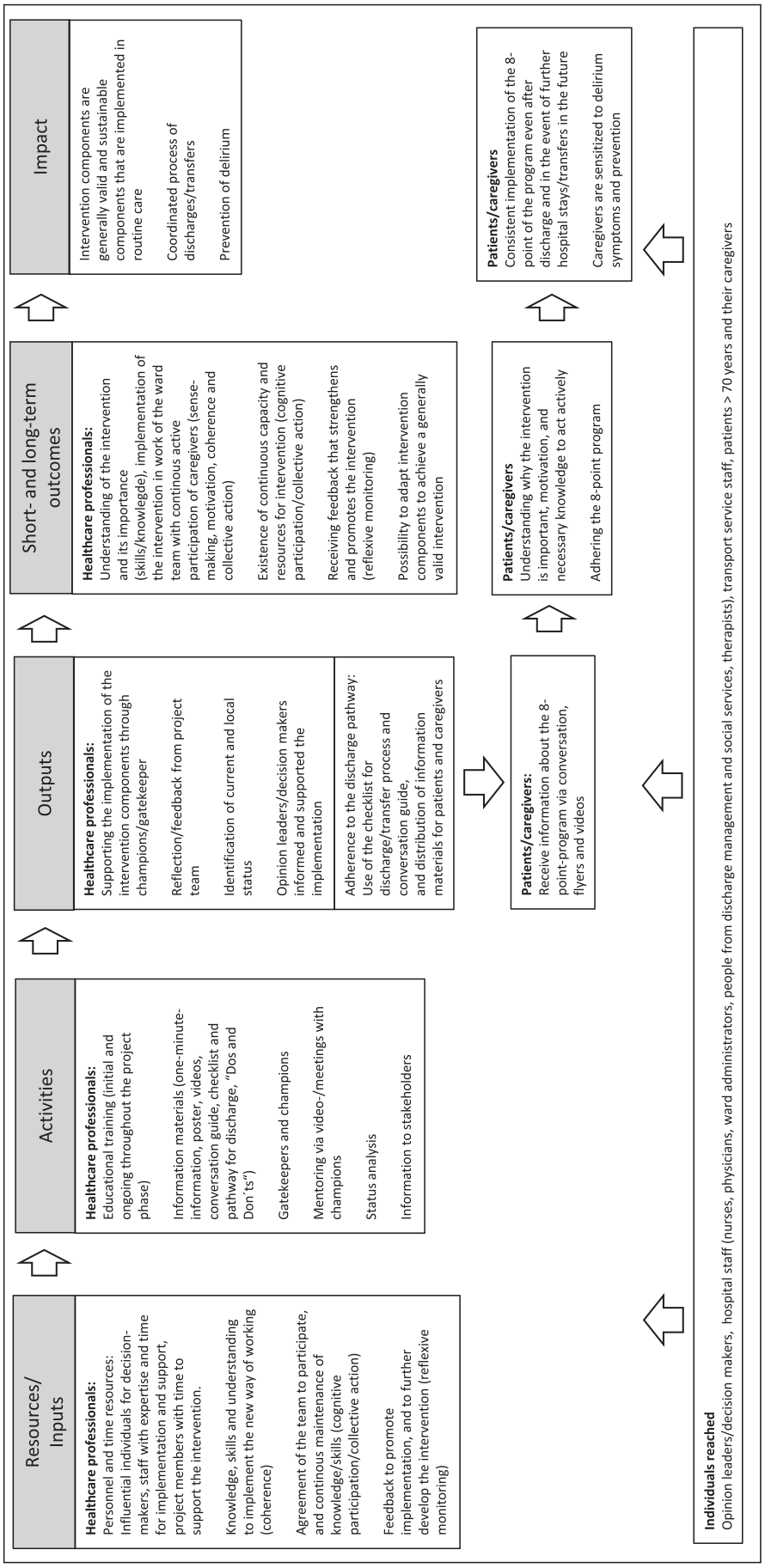

Fig. 3. Logic model for the program implementation.

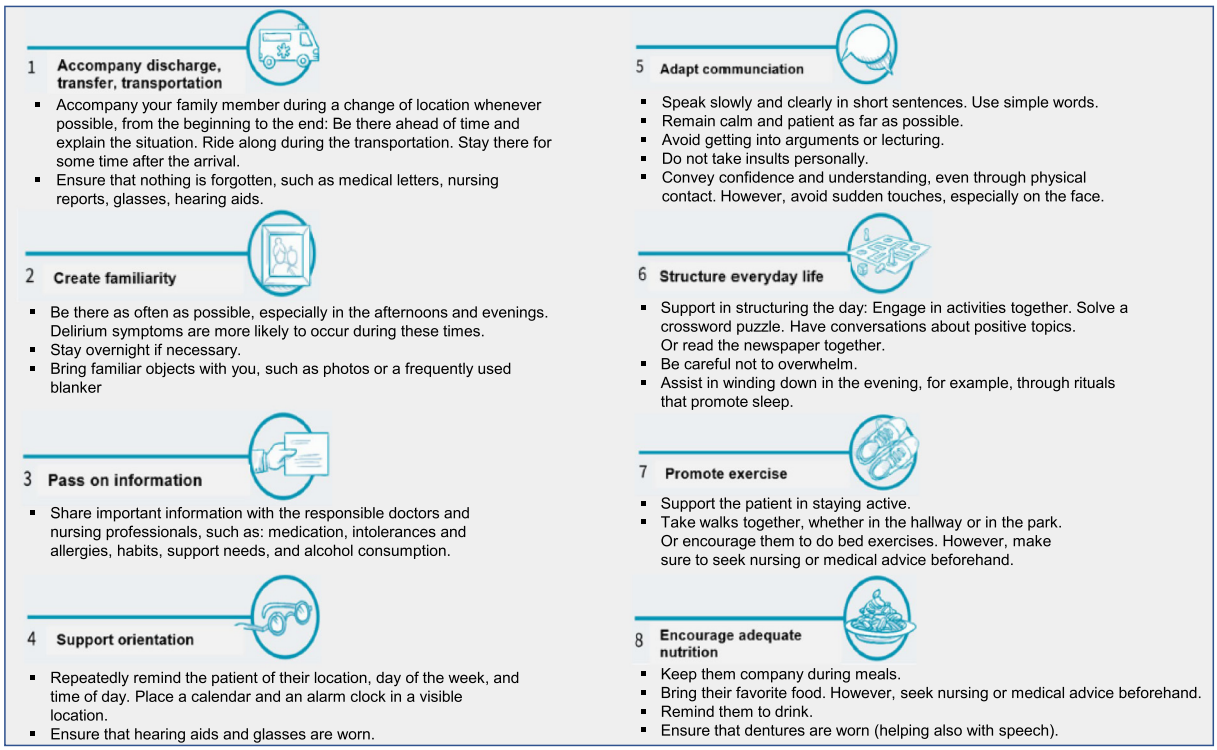

Fig. 4. 8-point-program for delirium prevention (German version translated into English).

delirium, dementia and depression), the 8-point-program, a structured conversation guide, and a checklist for an optimal discharge process. Posters will be created and provided, including a list of "Dos and Don'ts for prevention of delirium", and "1-minute-information" posters adopting the "One minute wonder" (Krüger et al., 2022) approach and providing brief information about delirium and the project TRAnsport and DElirium in older people intervention and implementation strategies for healthcare professionals. These "1-minute-information" posters should be positioned at highly frequented locations in the participating departments and in areas where people frequently wait for approximately 1 minute (e.g. elevator). They will be exchanged weekly to ensure ongoing attention to the project and to refresh relevant knowledge. Additionally, short videos providing brief information about delirium and the 8-point-program will be shown to healthcare professionals. These videos will also be presented on the study website.

A more detailed description of all components is presented in the Supplementary file 4.

4. Discussion

This article reports on the application of the Medical Research Council framework recommendations to develop a theory-based, practicable and implementable intervention. This intervention is designed to optimize discharge and transfer processes by educating caregivers and patients, and empowering caregivers in the prevention of delirium. This collaborative effort involved experts, healthcare professionals, and researchers in the entire process, as well as caregiver and patient representatives in the Delphi survey. An expert workshop followed by a Delphi survey was carried out to model the intervention and implementation strategies. As a result of this iterative process, an 8-point-program supporting delirium prevention by caregivers was generated. This program provides caregivers with recommendations to prevent delirium during the transition phase and in the post-discharge period. Training for healthcare professionals, training manuals and materials, deployment of gatekeepers and champions undertaking mentoring, information to stakeholders, and status analyses will be used as implementation strategies. The intervention components and implementation strategies will be applied in the setting of a clinical study (Leinert et al., 2021).

Numerous studies demonstrate that multiple intervention components in hospitals have a significantly stronger impact on delirium than single measures (Hshieh et al., 2015; Siddiqi et al., 2016; Zhao et al., 2023). Interestingly, few studies have focused on interventions starting in the hospital and continuing during transfer or after hospitalization. These few studies suggest that a multicomponent intervention approach e.g. through training caregivers and staff (Boltz et al., 2014; Martínez-Velilla et al., 2016) and mobilization and exercise (Bogardus et al., 2003; Boltz et al., 2014; Martínez-Velilla et al., 2016) could be helpful in delirium prevention. Due to the limited availability of strong evidence for strategies to be implemented during transfer and/or discharge, we decided to combine intervention components that have already demonstrated effectiveness in preventing delirium in hospital settings (rationale for intervention and implementation strategies see also Supplementary file 4). This assumes that the process of transitioning from home or an institution to hospital, as well as discharge from hospital back to home or to an institution require adjustment to the new situation and environment.

The inclusion of interprofessional teams in delirium prevention also appears to be common in intervention studies: Martinez et al. (2015) noted in their review and meta-analysis that of a total of seven included studies, six studies conducted delirium interventions together as a team consisting of nurses, physicians, social workers, and therapists.

The involvement of caregivers was identified as our central element of the developed intervention before, during and after the discharge and transfer process. However, this active involvement has so far been neglected, despite being helpful in providing care during and after discharge (Eskes et al., 2023), in reducing hospital readmissions (Levoy et al., 2022) and in the recognition and management of delirium in older individuals (Shrestha and Fick, 2020; Wang et al., 2020). Although caregivers often experience significant distress when caring for older individuals with or without delirium, they are still open to learning new options to support them. Caregivers not only recognize cognitive fluctuation better than healthcare professionals, but they also support patient

care (Carbone and Gugliucci, 2015). Caregivers benefit from different educational materials to convey knowledge about and understanding of delirium, such as conversations, flyers and brochures (Carbone and Gugliucci, 2015; Paulson et al., 2016; Wong et al., 2023). However, the limited availability of family members to provide post-discharge care for many patients poses a significant challenge. Therefore, it is beneficial to include both family members and/or close friends in the caregiving process and provide them with appropriate support (Eskes et al., 2023).

During the development process, we identified challenges in the discharge process that are known risk factors for delirium, such as sleep disturbances and stress (Ormseth et al., 2023) stemming from overnight transfers and spontaneous discharges. This led to recommendations to optimize discharge processes. Additionally, it is important to communicate and include relevant geriatric information for the general practitioner in the discharge letter (Bakker et al., 2014). This facilitates further measures outside the hospital (e.g. general practitioners visits, home care services) and raises awareness in institutions to implement additional delirium prevention interventions.

The absence of patients and caregivers in the workshop must be acknowledged as a potentially important limitation. The invited patients and caregivers found the two-day workshop too time-consuming, but shortening the process or holding an additional workshop for those groups was not possible. Ideally, the involvement of patients and their caregivers should take place as early as possible in the research process (Shippee et al., 2015). Caregivers, one patient, and one person from an association of caregivers' self-help organization did participate in the Delphi survey, meaning that the intervention and the implementation strategies have been validated from their perspective to some extent. We also planned in-depth involvement of patient and caregiver views within the process evaluation of the feasibility study.

Previous recommendations for developing complex interventions have highlighted the significance of program theories and logic models (Bleijenberg et al., 2018; Skivington et al., 2021). Our developed program theory, along with its logic model, played a crucial role in providing a comprehensive overview of our program planning and implementation: By synthesizing knowledge and steps from the development phase, we aimed to make our intervention transparent to all stakeholders involved in our study and to prospectively predict why our program can be successful (Bleijenberg et al., 2018; Skivington et al., 2021).

Our approach to developing interventions and implementation strategies using well-established implementation theories builds a strong basis for comprehending and elucidating the elements that contribute to the effective implementation in practice (Nilsen, 2015). In this regard, we employed the Consolidated Framework for Implementation Research and the Expert Recommendations for Implementing Change to select appropriate strategies tailored to our specific context. This approach helped us not only to identify potential barriers and select strategies in collaboration with workshop participants, but also to subsequently adapt our selected strategies to align with our study context (Powell et al., 2015).

To effectively implement the intervention, all healthcare professionals require knowledge about delirium as well as the skills to communicate that knowledge to caregivers and patients (Rosenbloom-Brunton et al., 2010). Various methods for knowledge transfer were chosen, such as face-to-face training and manuals, as well as microlearning methods such as short videos and 1-minute-information posters (Krüger et al., 2022). Microlearning methods are becoming increasingly common and appear to have great potential to communicate knowledge within a short time (Sankaranarayanan et al., 2022).

Another important component is the nomination of champions (Miech et al., 2018). However, the success of champions depends not only on the tasks they perform, but also on their skills. They should be selected based on their assertiveness, leadership and physical presence (Bonawitz et al., 2020). Therefore, certain inclusion criteria have been defined. For instance, champions should be selected jointly by the experienced gatekeepers and the project team.

4.1. Strengths and limitations

This study has several strengths. We chose a multi-method approach to consider a comprehensive perspective from different stakeholders and the contextual conditions.

One researcher (MM) had previously been involved in two similar development studies that adopted similar methods, opening up opportunities to exchange ideas with the researchers from these studies (Regauer et al., 2021; Saal et al., 2018) and to benefit from their experience in the detailed planning of the study. Further, O'Cathain et al. (2019) suggested being creative in developing interventions, and Kirk et al. (2016) recommended planning the scientific use and implementation of Consolidated Framework of Implementation Research carefully. Following these recommendations, a variety of different creativity techniques within the expert workshop were used, enabling in-depth conversations and discussions, considering different individuals and clinical processes, and ultimately selecting the most appropriate implementation strategies.

To date, few published examples describe a similarly detailed intervention and implementation development process using various designs in developing and combining all elements of theory, evidence, and involvement of stakeholders, patients, and caregivers (O'Brien et al., 2016; Regauer et al., 2021; Saal et al., 2018). Our intensive development of the intervention and implementation strategies has resulted in a highly promising approach for delirium prevention.

The Normalization Process Theory was only incorporated during the final development of the program theory, as we intend to use it for the process evaluation (May et al., 2022). For the sole development of the intervention, we did not necessarily need the Normalization Process Theory in addition to the Consolidated Framework of Implementation Research 1.0 and the Expert Recommendations for Implementing Change.

Due to the tight time frame of the project, we were unable to consider the final results of an ongoing systematic review on non-pharmacological interventions in the context of discharges and transfers and an observational study into the workshop, forcing us to rely on preliminary descriptive results. Final results would have made the evidence-based approach more straightforward. To adjust for this, we formulated the preliminary results with care, ensuring they did not inappropriately influence decisions.

5. Conclusions

This study presents the in-depth development of a complex intervention to prevent delirium in older hospitalized patients during discharge or transfer, with a specific focus on caregiver involvement. The derived intervention components and implementation strategies are to be implemented by a multi-professional team, including nurses, physicians, social workers, therapists, and clinical and research experts for delirium and discharge processes. As a next step, this intervention can be tested for its feasibility and acceptability in a pilot study accompanied by a comprehensive process evaluation according to the Medical Research Council framework.

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CRediT authorship contribution statement

Natascha-Elisabeth Denninger: Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation,

Formal analysis, Data curation, Conceptualization. **Simone Brefka:** Writing – review & editing, Investigation. **Stefanie Skudlik:** Writing – review & editing, Validation, Methodology, Investigation. **Christoph Leinert:** Writing – review & editing, Methodology, Conceptualization. **Thomas Mross:** Writing – review & editing. **Gabriele Meyer:** Writing – review & editing, Supervision. **Daniela Sulmann:** Writing – review & editing, Visualization, Conceptualization. **Dhayana Dallmeier:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Michael Denkinger:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Conceptualization. **Martin Müller:** Writing – review & editing, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Data availability

The data supporting the findings of this study are not publicly available for reasons of sensitivity, but can be obtained from the corresponding author upon reasonable request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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