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Title Page

Title of the article

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol of an exploratory cluster-randomised trial

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ABSTRACT

Introduction

Older age is associated with multi-morbidity, chronic diseases and acute deteriorations and leads to complex care needs. Nursing home residents are more often unnecessarily transferred to emergency departments or hospitals than community dwellers - largely due to a lack of qualified staff and diffusion of responsibility in the institutions. In Germany, only few academically trained nurses work in nursing homes, and their potential roles are unclear.

Therefore, we aim to explore feasibility and potential effects of a newly defined role profile for nurses with Bachelors' degree or equivalent qualification in nursing homes.

Methods and analysis

A pilot study with a cluster-randomised controlled design will be conducted in 11 nursing homes (cluster) aiming to include 15 residents per cluster. Nurses in the intervention group will receive training to perform role-related tasks such as case reviews and complex geriatric assessments. We will collect data at three timepoints (t0 baseline, t1 three months and t2 six months after randomisation). We will measure on residents' level: health services use and quality of life; clinical outcomes (e.g. symptom burden), physical functioning and delivery of care; mortality, adverse clinical incidents and changes in care level. On nurses' level we will measure perception of the new role profile, competencies, and implementation of role-related tasks as part of the process evaluation. An economic evaluation will explore resource use on residents' (health care utilisation) and on nurses' level (costs and time expenditure).

Ethics and dissemination

The ethics committees of the University of Lübeck (Nr. 22-162) and the University Clinic Hamburg-Eppendorf (Nr. 2022-200452-BO-bet) approved the Expand-Care study. Study protocol and results will be published in open access, peer reviewed journals, at conferences and in local healthcare providers' networks. A stakeholder advisory board including patient representatives discusses study procedures regularly.

Registration

German Registry for Clinical Trials (DRKS00028708).

Manuscript based on protocol version V1.3, 25th of September 2022.

Strengths and limitations

- The intervention was developed systematically based on a root cause analysis of unplanned hospital admissions or emergency service utilisation and participatory workshops with patient representatives and other stakeholders.
- A logic model including assumed causal mechanisms, distinct distal and proximal (mediating) outcomes and potentially relevant moderators (context factors) guides the evaluation, including a comprehensive process evaluation.
- Outcomes will be assessed at patient and staff levels and include patient-reported outcome and experience measures as well as objective measures such as hospital admissions.
- A potential limitation is the risk of early drop out of whole clusters (nursing homes) due to tensed staff capacities in the German elderly long-term care sector.

- The pilot study will have an exploratory character based on a small sample size.

Keywords: nursing homes, complex care needs, graduate nursing education, pilot project, cluster-randomised trial

INTRODUCTION

Background and rationale

Older age and aging processes are associated with multi-morbidity, including both acute and chronic diseases. Symptom control in long-term illnesses, cognitive impairment, an overall high degree of dependency or need for end of life care lead to increasingly complex care needs.[1,2] Nursing professionals in nursing homes (NH) are often the first to decide whether the use of emergency medical services is necessary when residents' health status deteriorates. These decisions are influenced by diverse contextual factors, among them unclear expectations of responsibilities of the NH regarding primary care, limited availability of qualified staff and the fear of exceeding one's scope of responsibilities. Inadequate access to multidisciplinary outpatient care, as well as poor communication with other decision-makers may also contribute to hospital admissions although in principle they might be avoidable.[3] Consequently, NH residents are significantly more often transferred to hospitals compared to community-dwellers. 90% of these hospital transfers are unplanned, and between 4% and 55% are considered avoidable.[4] For these residents, skills of academically qualified nurses could create a meaningful benefit.[5]

With the introduction of the new Nursing Professions Act (PflBG) 2020, academic nursing education is now implemented as a regular primary nursing qualification in Germany. Work areas of Bachelor graduates are predominantly in direct patient care, but include taking over process responsibility in complex or unclear situations in care.[6] However, surveys show that Bachelor graduates rarely find satisfyingly suitable job profiles.[7] Especially in the long-term care setting, defined work areas and competency-oriented differentiation of tasks and responsibilities for Bachelor-qualified nurses are lacking.

In the Expand-Care project, we developed a role profile for nurse specialists in a participatory research process:[8] PEPA (German acronym for nurse specialists with expanded competencies for person-centred elderly care, [Pflegefachperson mit erweiterten Handlungskompetenzen für personenzentrierte Pflege in der Altenpflege]). The PEPA covers competence areas with a focus on residents' needs regarding management of chronic and geriatric diseases, and empowerment and communication. Comprehensive implementation strategies target educational, supervisory and organisational levels.

Trial objectives

The objective of this trial is to explore feasibility, safety and resident-relevant benefits of the Expand-Care intervention programme promoting person-centred care in NH residents.

To assess safety and potential patient-relevant benefits, we will examine:

(1) What are potential effects of the programme on

a. patient-relevant indicators of quality of care (distal outcomes) like hospital admissions, emergency service utilisation, residents' out-of-hour physician contacts, and quality of life within 6 months of follow-up?

b. intermediate (proximal) outcomes regarding residents' clinical wellbeing and functioning and the delivery of care?

(2) What is the risk of adverse effects of the programme on residents' health, e.g. with regard to mortality?

To assess programme feasibility, we will conduct a process evaluation addressing a) nurses' ability to acquire, maintain and apply the desired competencies for expanded care tasks; b) implementation (reach and dose); c) nurses' perception of feasibility and fidelity of the intervention; d) adaptations to intervention care tasks; e) changes to care processes induced by the intervention; and f) changes to subjective professional roles, self-concept and self-efficacy of nurses.

With an economic analysis we will assess implementation costs of the programme and consequences for health care resource utilisation.

Trial design

The Expand-Care trial is an exploratory bicentric cluster-randomised trial (cRCT). Nursing homes (clusters) will be randomly assigned either to the implementation of the Expand-Care intervention programme (intervention group) or to usual care (control group). Follow-up measurements take place 3 (t1) and 6 months (t2) post randomised allocation. For the process evaluation, the trial includes a parallel mixed methods study which is described in detail in Supplement 1.

METHODS AND ANALYSIS

Study setting and participants

The trial will take place in 11 NH in Northern Germany. Eligible residents living in the participating NH will be invited to participate. Each NH has to nominate a qualified nurse specialist who will perform the intervention if randomised to this group (Table 1, eligibility criteria).

Table 1: Eligibility criteria for nursing homes, residents and nurse specialists

Participants	**Eligibility criteria**
Nursing homes	*All of the following conditions apply:* – provides in-patient long-term care services – provides a minimum of 50 beds – does not participate in other research projects on prevention of hospital admissions and emergency service utilization
Residents	*One of the following conditions applies:* – receives care services at the care level 3 or higher – receives care services at the care level 2 *and* fulfils at least one of the following conditions:

	… *multimorbidity confirmed by suffering from three or more co-existing chronic diseases (DEGAM 2017)[9]* … *hospital admission or utilisation of out-of-hour physician contacts or emergency services within the previous eight weeks.*
Nurse specialists	*One of the following conditions applies:* – academic qualification (Bachelor degree) and at least one year of job practice after professional licensing – 3 years vocational training and additional qualification in geriatric, gerontopsychiatric or palliative care after professional licensing – 3 years vocational training and additional qualification (300 h cumulative in the last 2 years) after professional licensing – 3 years vocational training and above average performance, assessed by head nurses based on pre-specified criteria (e.g. knowledge and skills, open-mindedness for innovation and improvement of nursing practice, and personal competencies)[10]

DEGAM: Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin e.V. (German association for primary care);[9] German care levels (range from 0 to 5) are assessed by expert raters of the German statutory health care insurance and can be described as low (0/1/2), medium (3/4), high (5).

Interventions

Control group residents will receive optimised usual care: we will offer a 1,5 h workshop on principles of person-centred care to control group NH.

Intervention group residents will receive person-centred care through the implementation of a new role profile for nurses with expanded competencies (PEPA). The role profile addresses four competence areas: 1) managing chronic diseases; 2) empowerment and communication; 3) person-centred care network; 4) organisation (Figure 1, logic model).

[Insert Figure 1]

In practice, PEPAs will perform specific intervention components (PEPA activities) which are defined as core (obligatory) and optional activities on direct care (resident-related) and organisational levels (Table 2).

Table 2: Intervention components

Core activities	**Optional activities**
Direct care level	
– Implementation of a structured care plan – Structured conversations with residents and relatives – Case conferences – Joint visits with physicians – Hospital visits – Geriatric assessments – Pain management	– Short checklist for external care providers (residents' essential information)
Organisational level	
– Introduction of ISBAR for handovers and communication with general practitioners – Nurse led staff training on ISBAR – Monitoring of residents' advance care planning status	– Nursing research activities – Supervision and consultation for colleagues

ISBAR: Structure for interprofessional communication consisting of Identification, Situation, Background, Assessment, Recommendation.

Parallel to the intervention development, we have designed implementation strategies targeting areas of *education*, *supervision/evaluation* and *organisation*.[11,12] Detailed information on rationale, target groups, mode of delivery and materials for each intervention component and implementation strategy is described according to the TIDieR template (Supplement 2).[13]

The main *educational strategy* is a 300-hour training for participating nurses (PEPA training programme) led by lecturers of the University of Lübeck. This is outlined in a detailed curriculum containing two modules: 1) management of chronic and geriatric illnesses, and 2) empowerment and communication with patients and person-centred care. Training methods comprise classroom and online teaching, training on the job and self-study time (about 100 hours each). Training will start immediately after randomisation and last for three months.

Supervision and evaluation strategies will be performed by members of the research team via on-site or online mentoring sessions. By target agreement talks with PEPAs and nurse managers, a shared goal for the implementation will be established. Supervisors will review

and give feedback on PEPAs' performance of the implementation of intervention components in practice.

Organisational strategies aim to strengthen NHs' commitment to the study: formal cooperation agreements between the university and participating NH comprise responsibilities regarding recruitment of residents and granted worktime for PEPAs. NH are allowed to adapt the intervention locally to their needs to a defined degree (optional activities, Table 2). A detailed description of the intervention development and the PEPA training programme will be published elsewhere.

Outcomes

Trial outcomes are based on the programme's logic model (Figure 1) and comprise distal and proximal outcomes. Distal outcomes include patient-important indicators of the quality of care that are assumed to be influenced by the Expand-Care intervention and are highly critical to residents' wellbeing (e.g. hospital admissions, need for emergency services, and health-related quality of life). Proximal outcomes are variables targeted by the intervention and deemed to mediate its effects on distal outcomes. They include clinical outcomes (e.g. falls and fall-related injuries, pressure ulcers category ≥2 and patient-reported symptom burden), outcomes on physical functioning (self-care and/or health behaviour and management), and outcomes on delivery of care in terms of patient-reported experiences and use of potentially inappropriate medication. For the assessment of safety, we consider mortality of residents, other adverse events not captured by distal or proximal outcomes, and increased care needs of residents (care level). Outcomes will be followed-up until 6 months post randomisation (Figure 2).

[Insert Figure 2]

Sample size

Sample size is calculated for the purpose of planning a confirmatory trial rather than any confirmatory efficacy analyses (Supplement 3, statistical study plan). Initially, 12 NH had consented to participate. One NH declined participation before recruitment of residents had started and we revised the sample size calculation. Now, in total, 11 NH shall be included with at least 15 participating inhabitants for a total of 75 (5x15) and 90 (6x15) individual participants per study arm. We will not replace institutions or residents lost to follow-up.

Recruitment

We will apply two recruitment strategies for NH: 1) eligible facilities already collaborating with the study centres (Universities) will be invited to participate and 2) public lists of NH in the target regions will be screened and eligible facilities (Table 1) invited to participate. Invitations will comprise written material (per post and email) and follow up phone calls by the research team.

Recruitment of residents will start after NH directors' written confirmation of participation. Ward nurses will screen residents' eligibility following the given eligibility criteria. If residents (or their legal guardians, if applicable) have confirmed their willingness to participate, research staff will check eligibility based on information from residents' charts.

Allocation (*Sequence generation, Allocation concealment mechanism, Implementation)*

NH (unit of randomisation) will be randomised with an allocation ratio of 5:6 to the intervention or control group. Investigators in charge of the respective NH will initiate randomised allocation after completion of baseline assessment (t0). The random sequence will be generated by permutation with validated software.

Registration and randomisation of NH are carried out centrally at the Institut für Medizinische Biometrie und Statistik of the Universitätsklinikum Schleswig-Holstein, Campus Lübeck, at the Universität zu Lübeck. This ensures the concealment of allocation until the intervention commences (Supplement 3, statistical study plan).

Blinding

Due to the intervention's nature, blinding of residents and nursing staff against the allocated intervention will not be feasible. Information provided to participants contains no specific hypotheses about possible directions of effects in measured outcomes. Study assistants blinded to allocation will collect distal outcome data (hospitalisation). The trial statistician will be unaware of assignments until after blinded review and data base closure (Supplement 3, statistical study plan).

Data collection methods

Baseline assessment

At resident level, we will extract data on age, sex, date of moving into the NH (length of stay), current medical diagnoses and treatment, nomination of legal guardians and existence of agreements for advance care planning from residents' records.

Additionally, NH directors will provide baseline information about NH characteristics (e.g. sponsorship, number of care places, wards, residents, nursing staff capacity, medico-technical infrastructure, and mode of collaboration with external health care providers) in a written standardised questionnaire.

Potential benefits and safety outcomes

We will extract data from residents' record using instruments which have been successfully applied in other studies.[14,15] To collect self-reported data, we will conduct standardised interviews with residents and/or proxies (Table 3, outcomes and data sources).

Table 3: Outcomes, measurements and metrics for the evaluation of potential benefits and safety of the Expand-Care intervention

Outcome	Specific measurement	Specific metric	Time point		
			t0	t1	t2
Distal outcomes (extracted from residents' record)					
Hospital admissions (primary outcome)	Number of admissions	Within 3 months	X	X	X
	Number of hospital days	Within 3 months	X	X	X
	Reason for admission, initiator, discharge diagnosis	Within 3 months	X	X	X
Out-of-hour physician contacts	Number of contacts	Within 3 months	X	X	X
	Number of contacts	Within 3 months	X	X	X
	Kind of contacts: telephone, visit to nursing home	Within 3 months	X	X	X
	Reason for admission, initiator	Within 3 months	X	X	X
Emergency service use	Number of service utilizations	Within 3 months	X	X	X
	Kind of services used: (emergency) ambulance, emergency control centre, emergency room	Within 3 months	X	X	X
Distal outcomes (self-reported by resident or proxy assessment by nursing staff)					
Health-related quality of life	EuroQol-5 Dimension-5 Level (EQ-5D-5L)	At the day of data collection	X		X
Proximal outcomes (data extracted from residents' records)					
Falls and fall-related injuries	Number of falls and fall-related injuries	Within 3 months	X	X	X
Pressure ulcer category ≥2	Number or newly developed pressure ulcers per category	Within 3 months	X	X	X
Incontinence-associated dermatitis (IAD)	Number or newly developed IAD	Within 3 months	X	X	X
Potentially inappropriate medication	Prescribed medication and dosage, evaluated according to PRISCUS criteria	Current medication	X	X	X
Contacts with GP	Kind of contact (remote via fax, phone or other electronic form, visit in nursing home or GP office)	Within 3 months	X	X	X

	Reason for contact, initiator	Within 3 months	X	X	X
	Planned vs unplanned	Within 3 months	X	X	X
Proximal outcomes (self-reported by resident)					
Symptom burden	Four-dimensional Symptom Questionnaire (4DSQ) Dimensions: distress, depression, anxiety, somatisation	Within the last seven days	X		X
Self-care/ health behaviour and management	LTCQ-8, German version	Within the last 4 weeks	X		X
Person-centredness of care	Dimensions: safety climate and everyday living climate		X		X
Safety outcomes (harms) (data extracted from residents' records)					
All-cause mortality	Death (date, reasons)	Within 3 months		X	X
Level of care	Current level of care based on the Nursing Care Insurance Act (Sozialgesetzbuch XI)	Current level	X	X	X
Resource use (data extracted from residents' records)					
Other health care utilisation	FIMA categories of resource use (e.g. medical specialists, physiotherapy, occupational therapy, speech therapy, rehabilitation)	Within 3 months	X	X	X

4DSQ: Four-dimensional Symptom Questionnaire; EQ-5D-5L: EuroQol-5 Dimension-5 Level; FIMA: [Fragebogen zur Inanspruchnahme medizinischer und nicht-medizinischer Versorgungsleistungen im Alter] Questionnaire for Health-Related Resource Use in an Elderly; GP: General practitioner; IAD: incontinence associated dermatitis; LTCQ-8: Long-term conditions questionnaire short form; PRISCUS: List of potentially inadequate medication for elderly people.

Distal outcomes

Hospital admissions as primary outcome is defined according to Müller et al.[15] For each hospital admission, we will collect information about the kind (elective versus unplanned), initiator, reason, length of stay, and discharge diagnoses, similarly for each episode of general practitioner, medical specialists, out-of-hour physician or emergency services utilisation.

Health-related quality of life will be measured using the EQ-5D-5L (EuroQol Group).[16] The EQ-5D-5L measures health-related quality of life on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. It uses 5-point-ordinal scales ranging from 1 (no problems) to 5 (unable to/extreme problems). Dimensions are combined into a 5-digit

code that represents the unique health state. This code can be transformed into an index value between 0 and 1 using standard value sets. The EQ-5D-5L contains a visual analogue scale (EQ VAS) ranging from 0 to 100 (worst to best possible health status).[17-19] We will apply German versions of the EQ-5D-5L for self-reported quality of life to all residents with a Dementia Screening Score <4, else, we will perform the EQ-5D-5L proxy instrument with nurses in charge of residents at data collection.[14,20]

Proximal outcomes

Residents' records will provide data on falls, fall-related injuries and care activities responding to falls, pressure ulcers and IAD. Reported fall-related injuries will be categorised as: no injuries, minor injuries, moderate injury, major injuries, death or unclear/not reported.[21] For pressure ulcers, we will extract categories at first observation and at data collection as well as successive medical treatments (hospital admission, outpatient surgical treatment) from residents' records. All record entries classifying observed skin damages as IAD or describing perianal/perigenital skin damages associated with urinary or faecal incontinence and information about progression or healing since first observed will be extracted.

We will document current medication prescriptions (permanent and on-demand) and classify them as potentially inadequate according to the PRISCUS list relevant for the German healthcare system.[22]

The Four-Dimensional Symptom Questionnaire (4DSQ) is a 50-item self-report questionnaire designed to measure common expressions of psychological problems in primary care patients. Items are distributed over four scales: distress, depression, anxiety and somatization. With a reference period of the last 7 days it offers a 5-point Likert scale (scored 0 (no); 1 (sometimes), and 2 (regularly, often, and very often or constantly)). Corresponding item scores are summed up for scale scores.[23,24] Each dimension is interpreted in itself. We will use the cross-culturally validated German version of this instrument.[24]

We will use the long-term conditions questionnaire short-form (LTCQ-8) to measure self-care comprising health behaviour and management. The LTCQ-8 is an 8-item questionnaire assessing the impact of long-term health conditions on people's lives and their support needs.[25,26] A long-term condition is defined as any health issue that has lasted, or will last, for at least 12 months. It uses a 5-point Likert-scale (never – rarely – sometimes – often – always). Each question is scored with values ranging from 0 to 4 or 4 to 0 (depending on the question's meaning) to a single composite measure. A higher score indicates a higher health-related quality of life. We will generate a German version of this instrument prior to this trial following the translation and evaluation protocol of the original scale's authors.

With the German Person-centred Climate Questionnaire – Patient version (PCQ-P-G) we will assess residents' perception of person-centredness of experienced care delivery.[27,28] PCQ-P-G is a 14-item self-report questionnaire measuring person-centredness of care in the dimensions: a climate of safety, a climate of everydayness and a climate of community. It uses a 6-point Likert scale ranging from 1 (no, I totally disagree) to 6 (yes, I totally agree). Items are summated to an overall score and one sub score for each dimension. For the present study,

we will use only dimension-wise summated items on a climate on safety and a climate of everydayness.

Safety outcomes

We will extract residents' current need of nursing care (care level) based on external assessment of residents' care needs according to criteria laid down in the Nursing Care Insurance Acts (Sozialgesetzbuch XI). Criteria cover functional impairments (e.g. regarding mobility, communication and cognitive abilities), behavioural and psychological wellbeing, self-care (e.g. eating and drinking, personal hygiene, elimination), coping with illnesses and treatment requirements, and social participation. Care levels range from one to five, higher levels indicating larger need of (professional) care support.

NH continuously record residents' mortality. In case of death, we will extract information about date, place and reasons of death from residents' records.

Resource use

We will use the FIMA questionnaire (FIMA: Questionnaire for Health-Related Resource Use in an Elderly) to measure health care utilisation (monetary value by standard unit costs).[29,30] The FIMA is adapted to the German health care system and specialised for elderly populations. It measures utilisation of health care providers (e.g. hospital stays, outpatient visits to physicians and non-physicians, use of pharmaceuticals or out-of-hour care).

Data management

All resident-related data will be documented with patient identifiers. (Sub-)investigators will keep patient identification lists and NH identifiers under lock at the respective study centre, separated from resident data, and data will be archived for ten years.

Worksheets used for data collection in NH are defined as source data. Source data will be transferred to an eCRF (electronic case report form), which the (sub-)investigator will check and sign digitally.

We will manage data with the study management tool secuTrial®. The database programmer will in cooperation with the responsible biometrician and the documentarists check the study database for errors before use and afterwards release it for use. Data of the worksheets are entered into the secuTrial®-database via input masks. Data will be analysed using SAS 9.3 or higher. We will implement editing checks in the electronic data capture system (EDC) and use SAS 9.3 or higher for manual programming.

A daily complete backup of all data will take place. Correctness of data is checked by further range, validity and consistency checks. Implausible or missing data are queried at the test centre (query management) and corrected or supplemented if necessary. We will document any changes to the data, e.g. due to the incorporation of answered queries, in the database via automatic change tracking system (audit trail). A hierarchical access concept based on

roles makes unauthorised access to patient data impossible. Anonymity of data within the scope of evaluations is ensured.

We will use the Medical Dictionary for Regulatory Affairs (MedDRA) to code database entries on prior diseases, co-morbidities, and diagnoses and the anatomical, chemical and therapeutic classification (ATC) for drugs to code medication. Minimal objective is the first level of those hierarchical classifications.

After final analyses the data base will be closed and data handed over to the study management for archiving.

Statistical methods

To prepare a confirmatory clinical trial that will be adequately powered, this pilot study will yield two-sided 95%-confidence intervals for the 6-months incidence of hospitalisation that extend <10% in either direction. All participants are analysed by allocated intervention disregarding all intercurrent events following the treatment policy strategy. Absorbing endpoints like death are considered as competing risk or worst possible assessment by the composite strategy, so that other missing observations may be considered missing at random. The primary estimand of the marginal rates in treatment groups is estimated by mixed logistic regression from the occurrence of hospitalisation within 6 months on treatment and occurrence of hospitalisation within 3 months prior to the trial (both fixed factors with two levels) and institution (random effects). The primary treatment effect estimand is the marginal odds ratio in that model fit. It has two sensitivity estimands: the hazard ratio from Cox regression and the marginal rate ratio from Poisson regression. Proof of mechanism is tested at multiple significance level 0.05 in a Bonferroni-Holm procedure for sixteen endpoints of the nine variables of formal process evaluation. All other analyses are adjusted for the respective baseline measurement in mixed models without imputation. Safety, exploratory and sub-group analyses are pre-specified in the statistical study plan (Supplement 3). The true allocation list will be used only after all analyses will have been coded and the code tested.

Process evaluation

We will conduct an embedded parallel mixed methods study to examine processes at the cluster level (nursing facilities) and at the individual level (nursing staff, residents) in the participating NH. Target groups are NH managers, PEPAs, other NH nursing staff, residents and relatives. Written informed consent is a prerequisite for participation in the study. Qualitative methods of data collection are guideline-based semi-structured interviews, focus groups and observation or recording of practice supervision, which we will evaluate by qualitative content analysis. Quantitative methods of data collection are questionnaires, which we will analyse using descriptive statistics. We will triangulate data at the analysis stage using joint displays. The process evaluation study design and procedures are outlined in Supplement 1.

Health economic analyses

The economic evaluation covers two aspects: 1) Analysis of implementation costs, and 2) Analysis and modelling of incurred health care expenditures.

Analysis of implementation costs

Economic analysis will focus on the main implementation strategy, the PEPA training programme. This comprises time expenditures and costs for the programme (e.g. lecturer and expert fees), employers' expenses for time off (release of human capital), and time spent on PEPA training including self-study time. Considering potential government support and funding opportunities, we will develop a preliminary cost figure to estimate implementation costs in case of a positive evaluation of the intervention.

Analysis and modelling of incurred health care expenditures

Health care expenditure and savings comprise 1) avoidance of empty journeys during ambulance service missions, and 2) billable inpatient stays.

We will analyse occurring rescue service interventions (ambulance, emergency ambulance, control centre, transport to the emergency room) regarding projected costs incurred by the service, including initiators, reason for initiation and empty runs.

Reasons for inpatient stays will be derived from patients' diagnosis and discharge letters. We will therefore rate data on usage of medical services monetarily with standardised cost unit rates.

Data monitoring

A qualified Clinical Research Associate (CRA) of the ZKS (centre for clinical studies Lübeck) will conduct risk-based monitoring according to ICH GCP and written SOPs to ensure patients' rights and safety as well as reliability of trial results. Initiation visits and two regular on-site visits per study centre are planned. Recruitment of residents requires centre initiation by a CRA. Closeout visits will be conducted by telephone. Details of the monitoring, such as key data, will be defined and documented in a monitoring manual. The principal investigator will receive a monitoring report after each visit.

Harms

We will collect comprehensive data on potential harms throughout the trial to allow valid assessment of the intervention's safety. The research team will continuously supervise and follow-up implementation of the Expand-Care programme to strengthen fidelity. We will discuss any concerns due to unintended changes to care procedures or care outcomes observed and report to the Ethics Committee with a suggestion for amendments to the trial plan, if required.

Patient and public involvement

Representatives of the senior citizens advisory council and of NH resident boards participated in the intervention development. We will capture perspectives of residents, their family/ surrogates and NH staff on acceptability and feasibility of the intervention through process evaluation. Results will be presented and discussed at conferences with local health care providers and relevant stakeholders. The project's advisory board comprises representatives for patient and public, nursing science and education, nursing practice and medical law.

ETHICS AND DISSEMINATION

Research ethics approval

This trial adheres to the Declaration of Helsinki in the current version. The ethics committees of the University of Lübeck (Nr. 22-162) and the University Clinic Hamburg-Eppendorf (Nr. 2022-200452-BO-bet) approved the study protocol.

Protocol amendments

Principal investigators and the affected collaborators will consent to any amendments to this protocol before submission to ethics review. Protocol deviations are documented in writing and filed with the coordinating investigator and the trial biostatistician together with the rationale.

Consent or assent

Eligible residents and / or their authorised surrogates will receive written information about objectives and scope of the study from ward nurses. If residents are interested in further information, researchers of the study centres will provide further oral and written information (Supplement 4).

Residents will only be enrolled in the trial if they or their authorised surrogates have provided written informed consent. Residents can end participation at any time either orally or in writing, regardless of written confirmation by the surrogate. NH directors will inform the facility's residents' board, NH staff and employee representation about the objectives of the trial.

Confidentiality

For this study, we developed a comprehensive data protection concept in collaboration with the data protection official of the University of Lübeck. The concept comprises study information including information on data protection, forms for written informed consent for participants, descriptions of all data processing processes, and measures to protect data and participants rights according to the General Data Protection Regulation (Datenschutzgrundverordnung).

Access to data

The Sponsor (UKSH, Universitätsklinikum Schleswig-Holstein, nursing research unit) will retain records until 10 years after the publication of the article on the primary endpoint. Anonymised individual patient data used for all analyses reported in the article on the primary

endpoint will be made available on reasonable request for medical research purposes in easily machine-readable format.

Dissemination policy

We will publish study protocol and results following the CONSORT statement in open access, peer reviewed journals, and at conferences. A stakeholder advisory board including patient representatives discusses study procedures regularly. Furthermore, we will present results in local networks of relevant healthcare providers.

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AUTHORS CONTRIBUTIONS

Roles and responsibilities

Trial sponsor: University hospital Schleswig-Holstein, Katrin Balzer; principal investigator: Katrin Balzer (KB); sub-investigators: Katharina Silies (KS), Janna Sill (JS), Tilman Huckle (TH), Simone Inkrot (SI); collaborating partners and sub-investigators: Nadine Pohontsch (NP), Dagmar Lühmann (DL), Martin Scherer (MS); health economics: Fabian Frielitz (FF); biostatistics: Reinhard Vonthein (RV), Inke König (IK); monitoring: Denise Olbrich (DO); data management: Maren Vens (MV).

Contributions

KB, SI, RV, IK, MS and DL developed the study design; RV and IK designed the statistical analysis plan for the study. FF and KB designed the economic evaluation. KS, KB, JS, NP and DL designed the process evaluation plan. KB, KS, TH, NP and DL developed the intervention. RV and MV developed the database and pilot-tested it. KS, JS, TH, NP, MV and DO were responsible for data collection, -entry and controls. Analysis and interpretation of data will be performed by RV, IK, KB, KS, NP, and DL. KS, RV and KB drafted the manuscript, all authors contributed to the writing of the report and read, provided important revisions and approved the final version of the manuscript.

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COMPETING INTERESTS STATEMENT

The authors declare that there are no conflicts of interests.

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We would like to thank all members of the Expand-Care advisory board for their valuable advice and guidance in the development of the intervention and the study design, as well as nursing homes, residents, family, staff, general practitioners and other stakeholders for participation in the intervention development phase.

Supplements

Supplement 1 Process evaluation

Supplement 2 Description of the intervention's components and implementation strategies

Supplement 3 Statistical study plan

Supplement 4 Informed consent materials

Abbreviations

CRA	Clinical Research Associate
cRCT	Cluster randomised controlled trial

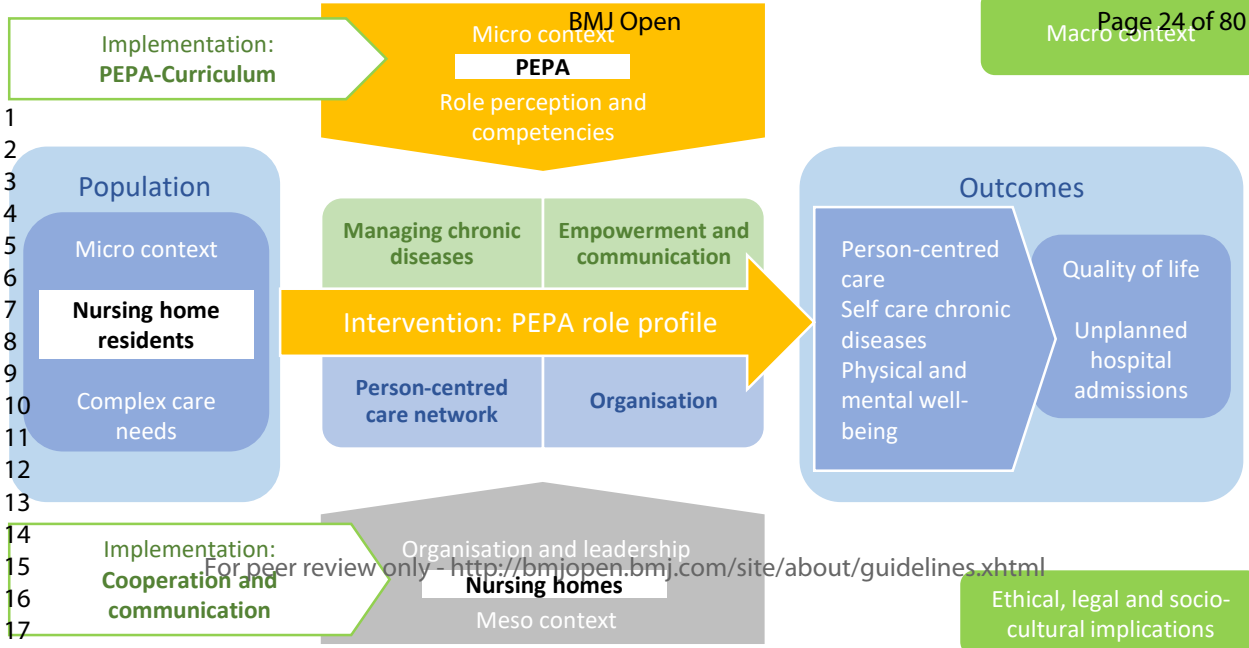
DEGAM	[Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin e.V.] German association for primary care
DM	Data management
eCRF	Electronic case report form
EDC	Electronic data capture
4DSQ	Four-Dimensional Symptom Questionnaire
EQ VAS	Visual analogue scale developed by the EuroQol Group
EQ-5D-5L	Tool to measure health-related quality of life developed by the EuroQol Group
FIMA	Questionnaire for Health-Related Resource Use in an Elderly population
HH	City of Hamburg
HL	City of Lübeck
IAD	Incontinence associated dermatitis
ICH GCP	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – Good Clinical Practice
ISBAR	Introduction, Situation, Background, Assessment, Recommendation
LTCQ-8	Long-term conditions questionnaire short-form
NH	Nursing home
PCC	Person-centred care
PCQ-P-G	German Person-centred Climate Questionnaire – Patient version
PEPA	[Pflegefachperson mit erweiterten Handlungskompetenzen für personenzentrierte Pflege in der Altenpflege] Nurse specialists with expanded competencies for person-centred elderly care
PflBG	[Pflegeberufegesetz] Nursing professions law
PREM	Patient-reported experiences measures
PROM	Patient reported outcomes measures
SAP	Statistical analysis plan
SIS®	Strukturierte Informationssammlung
SOP	Standard operating procedure

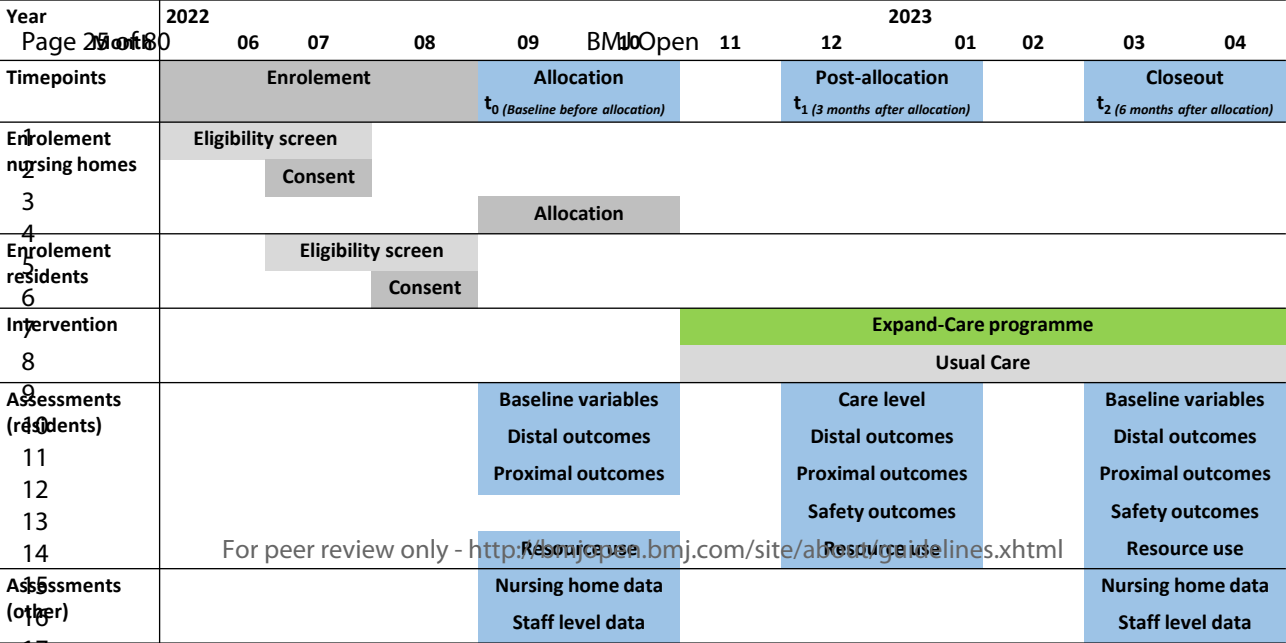
TIDieR	Template for Intervention Description and Replication
UKSH	[Universitätsklinikum Schleswig-Holstein] University hospital Schleswig-Holstein
ZKS	[Zentrum für klinische Studien] Centre for clinical studies

Legends

Figure 1: Logic model of the Expand-Care intervention and implementation strategies. PEPA: German acronym for nurse specialists with expanded competencies for person-centred elderly care.

Figure 2: Participant timeline





Supplement 1 to

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol of an exploratory cluster-randomised trial

Expanded nursing competencies to improve person-centred care for residents with complex care needs (Expand-Care): **study protocol for the process evaluation** of an exploratory cluster-randomised trial

Based on the process evaluation study protocol version: 1.0, August 12th, 2022

Synopsis

Study title	Expanded care competencies to improve person-centred care for nursing home residents with complex care needs (Expand-Care): **process evaluation**
Short title of the study	Expand-Care
Study no.	DRKS00028708
Ethical approval	Approval of the main study: 22-162, decision on 05/05/22 Approval of the process evaluation amendment: decision on 22/08/22
Study design	Mixed methods study for the process evaluation (main study: cluster-randomised, parallel, bicentre, national, open, controlled)
Indication	Nursing home residents with complex care needs
Aim	Exploration of feasibility, related to the implementation of the intervention and implementation of the study procedures, as well as evaluation of the intervention, mechanisms of action and contextual factors.
Sponsor	University Medical center Schleswig-Holstein
Principal investigator	Prof. Dr Katrin Balzer Section for Research and Teaching in Nursing, Institute for Social Medicine and Epidemiology, University of Lübeck
Inclusion criteria for care facilities	Hamburg or Lübeck region, >50 resident places, long-term care according to §43 SGB XI
Inclusion criteria for residents	Care level 3 or Care level 2 and either >2 chronic conditions or care level 2 and one unplanned acute medical care event within the last 8 weeks.
Intervention	Role profile for nursing professionals with expanded competencies. Intervention components are the planning and evaluation of residents' care based on the structured information collection (SIS) and tasks individually adapted to participants needs, e.g. structured conversations, participation in general practitioners' visits, case conferences and geriatric assessments. To support implementation, nursing professionals participate in a comprehensive training programme (300 hours in three learning formats: Contact hours, self-study, training on the job).
Observation period	6 months
Process evaluation outcomes at cluster level	Recruitment of institutions and nurses, implementation and learning outcomes of the training programme (Kirkpatrick model), contextual factors of nurses and organisations.
Process evaluation outcomes at resident level	Recruitment of residents, acceptance of intervention components and contextual factors among residents and relatives.
Sample	11 facilities from two regions (Hamburg and Lübeck area). In total approx. 12 residents, 6 care managers, 6 PEPAs ("Pflegefachperson mit erweiterten Kompetenzen für personenzentrierte Pflege in der Altenpflege"), 42 members of nursing staff (focus group), 120 members of nursing staff (questionnaire), 12 relatives, 6-8 lecturers.
Start & Duration	Total project duration: 01/04/21 to 31/03/24, inclusion of first participants in the cluster-randomised trial: August 2022
Funding agency	Federal Ministry of Education and Research FKZ: 01GY2003A (UzL/UKSH); 01GY2003B (UKE)

Content

Abstract

Background

Older people with complex care needs living in nursing homes (NH) are more likely to receive unplanned emergency or acute inpatient care than those living at home. The frequency of these care needs can be reduced through the employment of nurses with expanded competencies. In the Expand-Care study, a newly developed nursing role profile comprising expanded competence areas and tasks (intervention components) is tested in an exploratory cluster-randomised trial (DRKS00028708). Outcomes at residents' level are quality of life and unplanned acute medical care. The intervention is implemented by nursing professionals with above-average qualification profiles (German level DQR 6, equivalent to Bachelor's degree). To support implementation, these nurse specialists will receive a specifically developed training programme.

The intervention is complex, as it contains several components, targets micro and meso level and addresses several target groups. Following the UK-MRC framework for the development and evaluation of complex interventions in health, this warrants a comprehensive process evaluation.

Aim

Through the process evaluation, the implementation of the new role profile (intervention), its mechanisms of impact and relevant contextual factors will be investigated. Thus, insights into the feasibility as well as specific barriers and facilitating factors for the implementation in long-term care will be gained.

Methods

Parallel triangulation design embedded into the main trial: Processes at the cluster level (nursing facilities) and at the individual level (nursing staff, residents) in the participating nursing facilities of the Expand Care study will be examined. Target groups are nursing home managers, nurse specialists, other nursing staff of participating facilities, residents and relatives. Written informed consent is a prerequisite for participation in the study. Qualitative methods of data collection are guideline-based semi-structured interviews, focus groups and observation or recording of practice supervision, which are evaluated by qualitative content analysis. Quantitative methods of data collection are questionnaires, which are analysed using descriptive statistics. For the parallel mixed methods design, data is triangulated at the analysis stage using joint displays.

Expected results

The results of the process evaluation provide an important basis for interpreting the feasibility and effectiveness of the newly developed role profile for nurses with expanded competencies. They will be the basis for the development of study design and methods of a future effectiveness study.

Abbreviations

DQR	German Qualifications Framework
EL	Head of nursing home
IG	Intervention group
CG	Control group
GP	General practitioner
LTCQ	Long Term Conditions Questionnaire
LZP	Nursing home
PCQ	Person-centred Climate Questionnaire
PDL	Nurse manager
PEPA	PEPA: nurse with expanded competencies in person-centred care for the elderly
SHURP	Swiss Nursing Homes Human Resources Project (questionnaire)
UK-MRC	United Kingdom Medical Research Council

1. Background

1.1. Introduction

Older age is associated with increasing multimorbidity, which can include both chronic and acute illnesses and leads to increased care needs. Symptom control to prevent exacerbation of chronic diseases, cognitive impairment, frailty and high levels of care dependency increase the complexity of care needed for this population (Chadborn et al. 2019, Kiljunen et al. 2017). To meet these demands, a need for more highly qualified care professionals has been identified. Academic training for nurses has been established in Germany since 2003/2004. So far, only few academically trained nurses work in nursing homes, and role profiles are unclear. The aim of the Expand-Care research project is to develop a clear role profile for academically trained nursing professionals in nursing homes as an intervention and to test its possible effects and feasibility.

1.2. Expand-Care Intervention

The intervention is addresses two target groups: Residents with complex care needs in long-term care and nursing professionals with a qualification level equivalent to level 6 of the German Qualifications Framework (DQR, Deutscher Qualifikationsrahmen). The intervention is defined as a role profile of a nursing professional with extended competencies: PEPA (German acronym for nurse specialist with extended competences for person-centred care in long-term care). It focuses on four competence areas: 1) dealing with chronic and geriatric diseases, 2) empowerment and communication with residents, 3) building and maintaining a person-centred care network, and 4) organisation/institution. These areas comprise fields of action and goals. In order to implement these, various intervention components (see Table 1) were developed on resident related level as well as on organisational level. For the implementation of the intervention in nursing homes (NH), a distinction is made between core components and optional components (Tab. 1). The optional components include activities that are to be prioritised and adapted within the facility depending on their specific needs.

Table 1: Intervention components

	Core components of the intervention	Optional components
Resident related	• Planning and evaluating care • Structured conversation with residents • Structured conversation with relatives/ surrogates • Geriatric assessments • Joint visits with physician • Case conference • Hospital visit • Pain management	• Short form resident information
Organisation related	• Handover according to ISBAR • Structured fax communication according to ISBAR • Nurse-led staff training • Monitoring of Advance Care Planning	• Nursing research • Supervision • Collegial counselling

Various implementation strategies were developed to support the introduction of the intervention. These are measures to enable the implementation of the intervention or to overcome barriers to implementation. These strategies include a comprehensive additional training programme for the nursing professionals (PEPA training), monitoring and evaluation of the intervention by means of a PEPA manual and target agreement meetings, as well as measures on the organisational level, for

example a cooperation agreement with the LZP and possibilities to adapt the intervention (Figure 1, logic model).

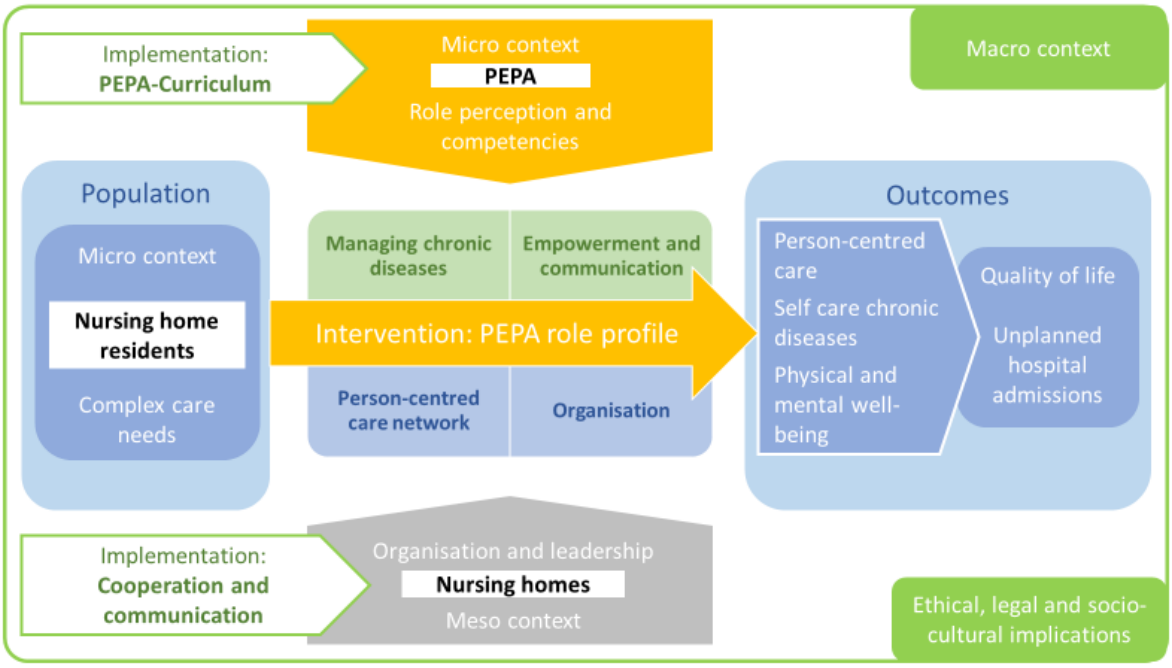


Figure 1: Logic model of the Expand-Care intervention

1.3. Expand-Care pilot study

A pilot study with a cluster-randomised controlled design will be conducted in 11 care facilities with the aim of including 15 residents and one caregiver per facility. Data collection will take place at three time points: t0 (baseline, September 2022), t1 will take place three months (+92 days) and t2 six months (+184 days) after randomisation. Key outcome domains at residents' level are utilisation of care, such as hospitalisation and emergency services, and quality of life (distal outcomes). Proximal outcome domains are clinical outcome parameters (e.g. symptom burden), physical functioning (e.g. self-care and health behaviours and management) and care delivery (person-centredness of care). Safety-related outcome measures at the resident level are mortality, adverse events and changes in level of care. The intervention is to be defined as complex, as it contains several components, starts at several levels and addresses several target groups.

In order to explain change mechanisms of complex interventions and to appropriately interpret the effects on patient-relevant outcomes, a comprehensive process evaluation is required in addition to the evaluation of these effects. Therefore, the process evaluation described here will be carried out embedded in the main trial, based on established, scientific frameworks for the development and evaluation of complex health interventions (Moore et al. 2015, Grant et al. 2013). The aim of the process evaluation is to evaluate the actual implementation of the trial/intervention, the implementation strategies and the intervention as well as their mechanisms of change in the specific context of the Expand Care trial. Thus, conclusions can be drawn regarding the feasibility of the intervention and the study procedures in order to subsequently prepare an effectiveness study. In addition, the process evaluation helps to understand how interventions can be transferred from research to practice and into other settings.

2. Methods

2.1. Process evaluation of complex interventions

In the context of process evaluation, processes are distinguished at the cluster level and the individual level. Furthermore, the context, the maintenance of the intervention, possible effects on the main target variables and unexpected events are observed (Grant et al. 2013, Fig. 1). In the Expand Care study, nursing homes are defined as clusters. The individual level in the Expand Care study refers to residents and nursing professionals (PEPAs). Contextual factors are considered at these levels (micro level) as well as at facilities' level (meso level) and at a supra-organisational level (macro level). After implementation (PEPA qualification phase), the intervention, its maintenance and overarching changes that influence the distal targets at the resident level are monitored.

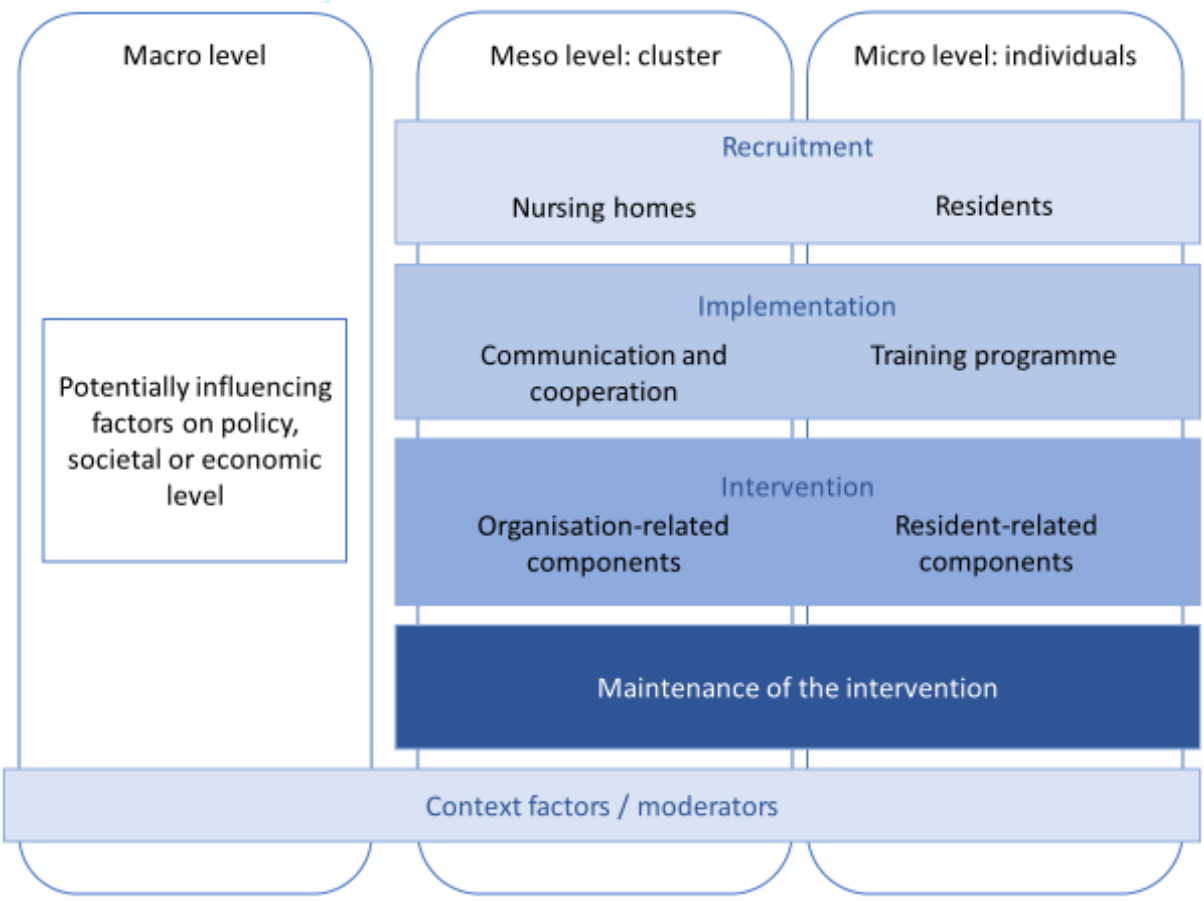


Figure 1: Process evaluation within the framework of cluster-randomised studies. Own representation based on Grant et al., 2013, p. 4.

2.2. Mixed Methods

The process evaluation is conducted in a parallel triangulation design ("convergence model", Creswell & Plano Clark, 2007). Integration of data obtained by means of qualitative and quantitative survey methods takes place at the outcome level using a mixed methods matrix/joint display (O'Cathain et al. 2010).

2.3. Outcomes of the process evaluation

Process evaluation outcomes are organised according to the given structure (Figure 1 and Tables 2 a-2d). The methods listed are used to collect data on several outcomes (for an overview of data collection methods for specific target groups, see Table 4 in Chapter 2.4.2 Sampling). The focus of the process

evaluation is on qualitative methods (interviews, focus groups). Quantitative data, for example characteristics that can be assigned to the context of the residents, such as care level and socio-demographic information, are already partially included in the data collection of the main study. The process evaluation data are collected at different points in time during the preparation of the study (recruitment of facilities and residents, t-1) and during the entire course of the study (tables 2a-2d).

Table 2a: Outcomes, methods and measurement times of the process evaluation - recruitment

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
Recruitment of nursing homes	Procedure Recruitment success Reasons for non-participation	**Study teams:** documentation of contacts and conversations	X				/
	Motivation for participation	**PDL:** Guided semi-structured interviews				X	IG
Recruitment of residents	Procedure Recruitment success Reasons for non-participation	**Contact person for Expand-Care Study:** Documentation of recruitment	X				IG, CG
	Characteristics of the target group	**Residents:** Quantitative: Data collection main study		X	X	X	IG, CG

Shaded grey: Part of the main study. CG: Control group; IG: intervention group; PDL: nurse manager.

Table 2b: Outcomes, methods and measurement points of the process evaluation - implementation

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
Implementation at facility level: cooperation and communication	Perceived support in the implementation of the intervention	**PEPA:** semi-structured qualitative interviews				X	IG
PEPA training	Implementation of the training programme	**Lecturer:** Documentation Contact hours, practice supervision **PEPA:** Documentation PEPA Manual			X	X	IG
PEPA training	Experiences with the training programme	**Lecturer:** Focus group (online)			X		IG
PEPA training	Perception of implementation: Kirkpatrick Level 1	**PEPA:** Semi-structured qualitative interviews				X	IG
		Focus group			X		IG

	Learning Success: Kirkpatrick Level 2 and 3	**PEPA:** Learning success checks, practical support, focus group, reflection discussion			X		IG
PEPA training	(Change) in professional self-image, understanding of roles: Kirkpatrick Level 4	**PEPA:** Semi-structured qualitative interviews				X	IG
		Quantitative: Questionnaire Role Understanding: (SHURP)			X	X	IG
		Focus group, reflection meetings			X		IG

SHURP: Swiss Nursing Homes Human Resources Project (Schwendimann et al, 2014; https://shurp.unibas.ch/). ***PCQ: person-centred climate questionnaire; PEPA: nurse with expanded competencies in person-centred care for the elderly; PDL: nurse manager.***

Table 2c: Outcomes, methods and measurement times of the process evaluation - intervention

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
Implementation of the intervention: resident related and organisation-related components	Implementation of intervention components: Kirkpatrick Level 3	**Lecturer:** Focus group				X	IG
		Practical support, observation			X		IG
		PEPA: Focus group				X	IG
		Reflection talks, PEPA manual			X	X	IG
		Nursing staff: Focus group				X	IG
Implementation of the intervention as quality indicators: resident related and organisation-related components	Quality indicators: structured handover and fax communication, joint physician visits, case conferences, geriatric assessments, hospital visit, awareness of the study	**Nursing staff:** Quantitative: Questionnaire quality indicators		X		X	IG, CG
	Perception of the intervention and of changes	**Residents, relatives, nursing staff:** Semi-structured qualitative interviews/focus group				X	IG

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
	Perceived person-centred care climate, Self-Care Participation, empowerment	**Residents** Quantitative: Data collection form (PCQ, LTCQ-8 (main study)		X		X	IG, CG
		Semi-structured qualitative interviews				X	IG
	person-centred care climate	**Nursing staff:** Quantitative: Questionnaire (PCQ-Staff)		X		X	IG, CG
Implementation of the intervention	Maintaining implementation after the end of implementation / qualification	**PEPA, PDL:** Semi-structured qualitative **interviews**				X	IG
Course of studies	Perception of the study process as a whole	**PDL and PEPA:** Guided semi-structured interviews				X	IG

Shaded grey: Part of the main study. PCQ: person-centred climate questionnaire; PEPA: nurse with expanded competencies in person-centred care for the elderly; PDL: nurse manager.

Table 2d: Outcomes, methods and timepoints of the process evaluation - contextual factors

Domain	Outcomes	Target group/method	timepoints				Group
			t-1	t0	t1	t2	
Micro level / PEPA	Characteristics of PEPA (qualification, experience)	**PEPA:** Quantitative: Questionnaire			X	X	IG
	Motivation for participation	**PEPA:** Semi-structured qualitative interviews				X	IG
		Quantitative: Questionnaire			X	X	IG
Micro level / residents	Characteristics of residents (e.g. sociodemographics, care level	**Residents** Quantitative: Data collection form (main study)		X		X	IG, CG
	Attitudes, expectations	**Residents** Guided semi-structured interviews				X	IG
Meso level / organisation	Characteristics of the facility (skill mix, staffing ratio, size of the facility, sponsorship, care level	**PDL/EL:** Quantitative: Data collection form nursing facility (main study)		X		X	IG

Domain	Outcomes	Target group/method	timepoints				Group
			t-1	t0	t1	t2	
	of residents, special care services)						
	Willingness and ability of team members to participate in implementation	**PEPA:** Guided semi-structured interviews				X	IG
Macro level / political, legal, ethical	ELSI as perceived problems or barriers	**PDL and PEPA:** Guided semi-structured interviews				X	IG
Macro level / other events	Overarching factors / changes that may have had an influence on the intervention	**PDL and PEPA:** Guided semi-structured interviews				X	IG

Shaded grey: Part of the main study. ELSI: Ethical, legal and social implications; LTCQ-8: Long-term conditions questionnaire short form; PCQ: person-centred climate questionnaire; PEPA: nurse with expanded competencies in person-centred care for the elderly; PDL: nurse manager.

2.4. Target groups

2.4.1. Inclusion criteria

Participants will be recruited from the main study's sample. Inclusion criteria for participants in the process evaluation therefore are the same as the criteria for participation in the main study. All persons entrusted with nursing tasks and permanently employed in the facility can participate as members of the nursing team. In this study, relatives/surrogates are persons who consider themselves to be related to a participating resident (Table 3). Participation in the process evaluation means an additional burden, especially for residents. It is therefore voluntary with an additional declaration of consent and targets only residents who are able to consent to participation independently.

Table 3: Inclusion and exclusion criteria for participation in the process evaluation

Target group	Inclusion	Exclusion
Relatives	Person close to or associated with a study participant (named as primary caregiver by resident or on file)	/
Residents	Participants of the main study	Dementia Screening Scale Score > 3, residents who are unable to give their own consent
Nursing staff	Staff members of the facility who are involved in direct care	Worktime less than 50% of fulltime
Nurse/ PEPA*	Nurse who has been designated as a potential participant or is a PEPA after randomisation.	/
Nurse manager	Person who assumes the function of care manager.	/

**PEPA: nurse with expanded competencies for person-centred care for the elderly*

2.4.2. Sampling

The selection and number of participants will be determined according to the research question and respective methods (Table 4, Sample size, methods and timepoint of measurement). For the description of the clusters (facilities, n=11) and for qualitative and quantitative questions directed at the PEPAs (n=6), a 100% sample is aimed.

At the level of the residents, the sample will be selected according to the criteria of care facility affiliation and gender. One male and one female resident from each of the care facilities participating in the intervention group will be included (n=10-12). Only persons who can independently consent to the additional qualitative survey will be included (Kelle & Kluge, 2010).

Relatives are selected independently of the residents participating in the process evaluation. The aim is to include two relatives per cluster (IG): one relative of a resident without cognitive impairment (able to give consent him/herself) and one of a resident with cognitive impairment (not able to give consent him/herself), in order to generate a heterogeneous sample (purposive sampling).

The review and evaluation of the qualitative data already takes place during the data collection process, so that recruitment of representatives of additional target groups can be considered, for example general practitioners or specialists (purposive sampling).

Table 4: Sample size, methods and timepoint of measurement

Target group	Method	N t-1	N t0	N t1	N t2	Group
Residents	semi-structured qualitative interviews				12	IG
	Data collection sheet: context, intervention		75-90		90	IG, CG
	Data collection sheet: Notes on the survey		75-90		90	IG, CG
Nursing management	semi-structured qualitative interviews				6	IG
	Data collection form Institution: Recruitment		10-12			IG, CG
	Documentation sheet for recruitment of residents	10-12				IG, CG
Nurse / PEPA	Semi-structured qualitative interviews				6	IG
	Focus group			6		IG
	PEPA Manual*				6	IG
	Decision support / planning*				6	IG
	Reflection talk (protocol)*			6		IG
	Learning success checks*					
	Questionnaire			6	6	IG
Nursing staff	Focus group[1]				~ 42	IG

Target group	Method	N t-1	N t0	N t1	N t2	Group
	Questionnaire		120		120	IG, CG
Relatives	Guided semi-structured interviews				12	IG
Lecturer	Focus group (online) Documentation Contact hours*, Practice supervision*, Observation*.			6-8		-
Family doctors	Guided semi-structured interviews (optional)				6	IG
Medical specialists	Guided semi-structured interviews (optional)				6	IG

[1]One focus group per cluster (á n= 6-8 carers)

BW: resident:in; IG: intervention group; CG: control group; PCQ: person-centred climate questionnaire; PEPA: nurse with advanced competencies in person-centred care for the elderly; PDL: nurse manager. Blue shading: Audio recording/transcript. Grey shading: Part of the main study.

Marked with an asterisk: Work tools that are used as part of the training programme and are only evaluated in aggregated and anonymous form.

2.5. Data collection

Individual interviews will be conducted with residents, relatives, nursing staff, PEPAs and care managers (Table 4). PEPAs will be interviewed in a focus group at the end of the training programme. One focus group will be conducted with nursing staff and one with lecturers (online). If necessary, general practitioners (GPs) and other specialists will be additionally interviewed, either in the facility or by (video) telephone.

Residents will be visited in the care facility for data collection. Relatives, nursing staff, PEPAs and nursing service managers will be visited according to their preference or, if necessary, interviewed (by video) telephone. Video-telephonic interviews will be conducted via Cisco Webex (licence of the University of Lübeck). The focus group with PEPAs will be conducted at the end of the training programme, on the premises of the University of Lübeck.

The written survey will be conducted by means of paper-based questionnaires. Nursing staff will be invited to participate in writing. The completed (anonymous) questionnaires will be collected centrally by the nursing home and then handed over to the university.

All interviews and focus groups will be conducted by experienced study staff specifically trained for data collection for the Expand Care study. The conduct of the interviews and focus groups will be supported by a semi-structured guide (Helfferich, 2011, table 5).

Table 5: Overview of topic guides for qualitative interviews and focus groups

A) PEPA /head of nursing homes/nursing managers (T2, interviews)	***B) Focus group with teaching staff (T1)***
1. Motivation for participation 2. Overall impression of the study 3. Changes due to study participation regarding a. professional role perception b. care processes c. communication with residents and relatives d. interprofessional collaboration e. team work 4. Implementation barriers, facilitators, hindering factors 5. Perception of support 6. Perspective of maintenance 7. Adverse events 8. Other aspects 9. Implications for further research	1. Overall impression of the teaching programme 2. Satisfaction a. of participants b. own satisfaction 3. Hindering and facilitating factors 4. Impression of participants: a. Fit of participants' qualification with performance requirements of the educational programme b. Usefulness of the training programme's content for participants c. Participants' performance during supervision visits in the facility d. Maintenance of the intervention 5. Overall impression of the training programme 6. Need for adjustments for future implementation of the training programme 7. Other aspects
C) Residents (T2, interviews)	***D) Relatives (T2, interviews)***
1. Introduction ("tell me something about yourself") 2. Motivation for participation 3. Changes due to study participation regarding a. Relationship with nurse b. Care processes c. Contact with general practitioner d. Contact with other health care professionals e. Contact with relatives 4. Other aspects/ negative experiences with care	1. Introduction ("tell me something about yourself and your relationship with [resident]") 2. Motivation for participation (proxies who consented in participation as surrogates) 3. Perception of the study in the nursing home 4. Changes due to study participation regarding a. Care processes b. Contact with nurses c. Contact with general practitioners d. Contact with other health care professionals e. Negative changes 5. Other aspects

Table 5, continued

E) Focus group nursing staff (T2)	*F) Focus group PEPAs (T1)*
5. Overall impression/knowledge of the study	Satisfaction
6. Impact on training courses and (team) meetings	Transfer of knowledge
7. Changes in own everyday working life	Effort-benefit-ratio
8. Changes in everyday working life of the PEPA	a. individual
9. Changes in care processes	b. in general
10. Changes in the team	other aspects
11. Positive/negative consequences	

2.6. Data management

Interviews and focus groups will be audio recorded. Audio recordings will be transcribed by study assistants and checked by research assistants. Transcripts will be stored and analysed pseudonymously under a personal ID (letter-digit combination). During transcription, all names or places mentioned in the interview will be deleted and replaced by an anonymous description of the function (e.g. [facility management], [clinic]). Audio recordings will be deleted after the study is completed.

Questionnaire data will be collected, stored and evaluated anonymously. The assignment of the questionnaires to the cluster (institution) is maintained by marking them with a cluster ID (letter-digit combination) on the questionnaire.

The programmes MAXQDA (Verbi Software) and Microsoft Office applications will be used to process the data.

The processes described in the study protocol of the main study and the associated appendices apply to the storage and backup of data.

2.7. Data analysis

The transcripts of the qualitative surveys (interviews, focus groups) will be analysed according to the principles of qualitative content analysis by Kuckartz (Kuckartz, 2012). Both deductive categories, derived from the research questions, and inductive categories, emerging from the material, will be formed. The primary analysis is carried out by a team of two researchers. The results are also discussed (anonymously) in an interdisciplinary working group in order to ensure the intersubjective comprehensibility of the evaluation. The software MAXQDA will be employed for processing and analysing qualitative data. Quantitative data will be analysed descriptively (frequencies, means, range, median). Triangulation of data will be performed on the level of results.

2.8. Information and consent

Information and consent will be based on processes described in the study protocol of the main study. Participation in the process evaluation is voluntary. Written informed consent is a prerequisite for participation from nursing staff. For participation in the written survey of the nursing staff, submission of the questionnaire is considered as written informed consent.

For participation in focus groups and/or an interview, participants receive an expense allowance of 20€.

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Supplement 2 to

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol of an exploratory cluster-randomised trial

Description of the Expand-care intervention components and implementation strategies based on the TIDieR template (Template for Intervention Description and Replication, Hoffmann et al. 2014[1])

In the following, the Expand Care intervention is presented in terms of the rationale, the target group, the way of implementation and the materials used. The intervention is defined as a new role profile for nurses with expanded competencies for person-centred care. This role is specified by intervention components (activities) at a resident-related and an organisation related level, which are additionally differentiated as core and optional elements (Fig. 1, Table 1).

Additionally, strategies to ensure the implementation of the intervention are presented according to the same scheme (Table 2).

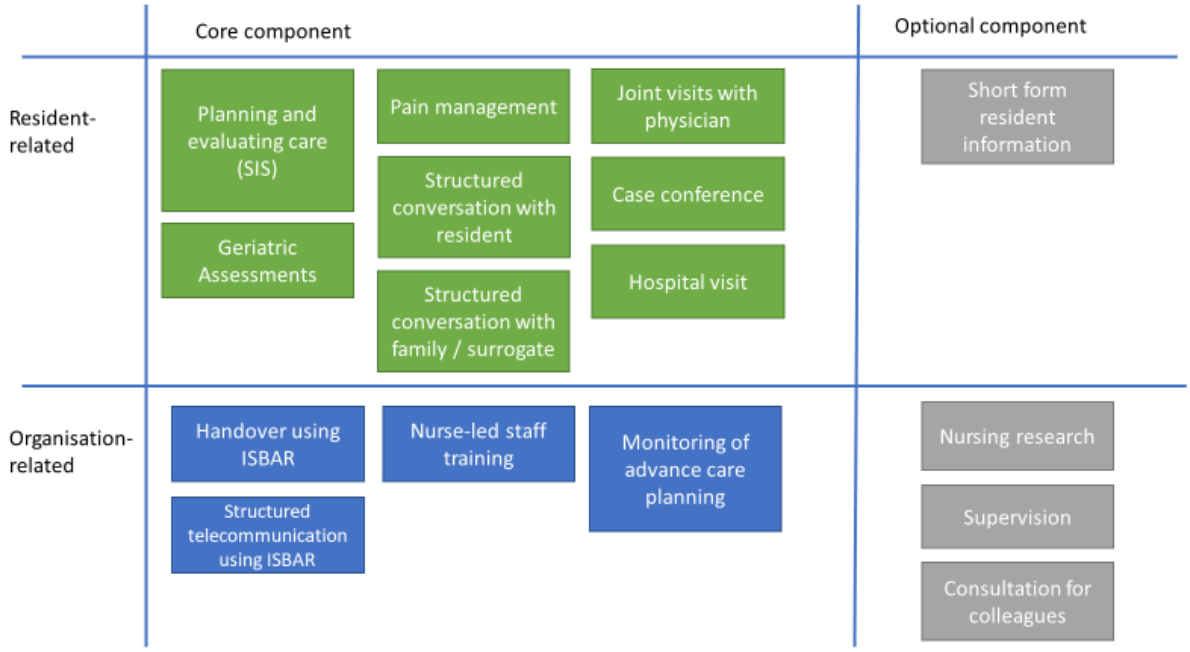

Figure 1: Core and optional components of the Expand-Care intervention. SIS: Structured Information Collection®.

[1] Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687.

Table 1: Intervention components

Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
Resident-related activities						
Planning and evaluating care	Residents Place: nursing home (NH)	Through targeted planning that considers the long-term course of defined events, changes in the condition are better perceived and activities/services can be derived in advance and initiated or adapted in a timely manner. The planning and evaluation of the care situation is the central element for deciding on the use and linkage of different intervention components. Structured according to the SIS® [strukturierte Informationssammlung] (structured assessment plan), all elements of a complex nursing assessment are mapped and the component is linked to the existing system of care planning so that integration is supported.	PEPA	PEPA carries out planning and evaluation of care by means of a decision algorithm. Based on the results, nursing measures (as well as intervention components such as assessments or structured conversations) are implemented or medical measures are initiated. Guiding points for the decision algorithm are key events that are defined on the basis of the resident's transition through the course of care in the care facility (e.g. moving in, settling in, increase in care needs, health deterioration, hospitalisation).	Defined by (key) events related to the individual situation of the residents (e.g. moving in, settling in, increase in care needs, health deterioration, hospital stay).	SIS-based decision algorithm: planning and evaluation tool
Structured conversation with resident	Residents Setting: NH (residents' room or counselling room)	Structured discussions ensure that residents have the opportunity to reflect and express their needs and that these are considered in their care. Residents perceive that their right to make decisions is taken seriously.	PEPA	Personal structured conversation with residents in an undisturbed setting. Topics are life in the facility; self-care, chronic illnesses; nursing care; communication with	At regular intervals and at key events defined in the SIS-based decision algorithm (e.g. moving in, deterioration in health, hospitalisation).	Interview guide for structured conversation with residents (linked to the SIS).

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
		Guiding questions ensure that all relevant topics are considered. The component is linked to the SIS and thus to the existing system of care planning, so that integration is supported.		doctors, therapists, relatives; advance care planning (status).		
Structured conversation with relatives	Relatives / surrogates Setting: NH (residents' room or counselling room)	Structured discussions ensure that the perspective of relatives and important information from them are considered in care. The organisation of medical care and social support can thus be coordinated with the relatives. The conversation's structure is based on the structure of the conversation with residents, so that it is possible to link results with the documentation.	PEPA	Personal structured conversation with relatives, if necessary together with the resident.	At regular intervals and at key events defined in SIS-based decision algorithm (e.g. moving in, deterioration in health, hospitalisation).	Interview guide for structured conversations with relatives (linked to the SIS).
Joint visit with General practitioner (GP)	General practitioners and specialists Residents Relatives Setting: NH	By accompanying physicians' ward rounds, current observations, questions and needs of the residents can be clarified directly and more efficient communication (differentiated use of ward rounds, fax and telephone calls) can be promoted. The ISBAR scheme promotes the complete and focused transfer of information. The continuous and structured approach promotes regular evaluation and adjustment of the care situation. The	PEPA (or nurse in charge)	Time for joint visits is scheduled in the PEPA's or supervising professional's duties for visits that are scheduled in advance or regularly. Beforehand, the accompanying person compiles information based on the ISBAR scheme.	Depending on onsite visits by the supervising physicians	Template for structured transfer of information in handovers (ISBAR scheme, Identification, situation, background, assessment, recommendation).

Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
		involvement of residents (and relatives) promotes regular communication between the parties involved. In addition to joint visits, the organisation, coordination and evaluation of the visit with GPs within the NH is beneficial for interprofessional collaboration.				
Case conference	Residents Relatives General practitioners and specialists Other parties involved in residents' medical care and nursing Setting: NH or virtual conference	Through direct communication of all those involved in resident's care, needs and care can be directly coordinated and timely and needs-based care can be ensured. Participation of residents and relatives supports the person-centred perspective of care. Residents perceive that their right to decide is taken seriously and that care measures address their own wishes. The care situation is evaluated and adapted interprofessionally. By taking a longitudinal view, undesirable events can be anticipated and preventive measures can be taken. The joint holistic and comprehensive view promotes the professional and personal competence of those involved.	PEPA	PEPA organises appointment and carries out preparatory care planning, collects information in advance if necessary, including current or long-term issues.	One case meeting per 6 months	Guideline for case conferences If applicable, video conferencing system and hardware
Hospital visit	Residents Acute care ward team	By visiting residents during inpatient treatment, questions that arise due to acute	PEPA or nurse in charge	Visit the clinic, obtain authorisation in advance to obtain	For hospital stays lasting longer than 3 days.	

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
	Setting: Hospital	changes in care after the hospital stay can be clarified and prepared in advance. The acute care ward team can be supported in dealing with residents' special needs.		information about the resident's care.		
Pain management	Residents Setting: NH	Residents' quality of life is promoted through the individual support of the pain therapy.	PEPA	Procedure and instruments according to the recommendations of the S3 guideline "Pain assessment in older people in full inpatient care for the elderly" (German Pain Society & German Centre for Neurodegenerative Diseases 2017)	According to the needs of the resident(s)	Templates for instruments according to the S3 guideline "Pain assessment in older people in full inpatient care for the elderly".
Geriatric assessments	Inhabitants:in Setting: NH	Through geriatric and nursing assessments, changes in residents' condition are recognised and documented at an early stage, can be adequately communicated and used to support the initiation and evaluation of individual measures.	PEPA or trained professional	Depending on the assessment method	Regularly depending on the assessment and on an ad hoc basis (according to the result of SIS-based decision algorithm)	Assessment tools, for example: • Mobility • Fall • Cognition • Delir • Nutritional status • Pain • Skin condition • Continence • Change in medication
Organisation-related activities						
Care handover according to ISBAR	Nursing team General practitioners and specialists	The ISBAR structure ensures complete and efficient communication about the current care needs of the	PEPA, professionals	The handover of care is structured using the ISBAR scheme.	At every care handover	ISBAR scheme and information materials explaining the application

Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
	Other parties involved in residents' medical care and nursing Setting: NH	residents. Important information is prioritised.				
Structured (fax) communication	General practitioners and specialists Other parties involved in residents' medical care and nursing Setting: NH	Structured communication ensures that information is passed on in full and that there is an adequate basis for decision-making for GPs and physician specialists, so that decisions can be made more quickly.	PEPA, professionals	A pre-structured fax form is used for the transmission of information or enquiries to general practitioners and specialists.	For all fax communications with general practitioners and specialists.	Fax form with ISBAR scheme
Training (on ISBAR)	Nursing team Setting: NH	Through the training, the nursing staff members are introduced to the structured handover and the implementation is practised so that it can be adopted in the handovers without guidance.	PEPA	PEPA organises the training for nursing staff on ISBAR. The training includes information and exercise modules as well as supporting information materials	Once in the study period on the topic of ISBAR	ISBAR scheme and information materials explaining the application Training concept prepared by PEPA as part of the PEPA curriculum.
Monitoring of Advance Care Planning	Nursing team General practitioners and specialists Setting: NH	The monitoring of ACP should ensure that existing plans are documented and known. This will improve the conditions for implementing the wishes of the residents.	PEPA	The PEPA checks whether advance care planning or health care planning exists and is documented. PEPA checks the consistency of entries on ACP in the analogue and digital documentation. In case of discrepancies, their PEPA	Regularly and on an ad hoc basis, e.g. after a stay in hospital or health deterioration	Existing documentation of information on ACP in the facility (digital and analogue).

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
				initiates clarification, e.g. in cooperation with the ACP facilitator of the nursing home.		
Peripheral elements (optional)						
Participation in evidence-based practice development	Organisation / Facility Setting: NH	Through specified impulses from practice for research, questions relevant to the institution can be worked on in cooperation with nursing scientists. Thus, further development of nursing practice in an evidence-based manner can be supported and quality of care care can be improved.	PEPA	PEPA identifies needs for quality development or research and initiates cooperation with quality management or the University.	On demand.	
Supervision	Nursing team Setting: NH	The targeted discussion of cases from practice that are experienced as difficult on the one hand promotes learning from experience. On the other hand, situations experienced as stressful can be worked through in the team to enhance mutual support and reduce stress.	PEPA	PEPA offers supervision in the form of structured case discussions of about 1 hour. Cases that are experienced as difficult or stressful are selected.	On demand	Background information given as part of the curriculum. Guiding questions for structuring a supervision session.
Collegial counselling	Nursing team Setting: NH	Through the possibility of an individual conversation, topics can be addressed that are not suitable for supervision. In particular, professional uncertainties or one's own mistakes can be discussed and thus learnt from experience.	PEPA	PEPA is available for one-to-one meetings on an ad hoc basis with a focus on professional discussion.	On demand	Background information given as part of the curriculum.

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
Short info sheet	Care team, external health care providers Setting: when care is provided outside the NH, e.g. clinic	Important information about the resident is briefly summarised on an information sheet so that care outside the nursing home can be tailored to residents' individual needs.	Nursing team	The PEPA creates and presents the information sheet and makes sure that the nursing staff implement it.	Initially with all residents [of the study], then event-related (as part of the planning and evaluation of the care situation).	Information Sheet Template

GP: General practitioner; ISBAR: Information, situation, background, assessment, recommendation, template to ensure structured and complete information transfer in handovers; NH: Nursing home; PEPA: German acronym for nurse specialist with expanded competencies for person-centred care; PDL: nurse manager; SIS®: [Strukturierte Informationssammlung] structured plan for the professional assessment of residents' care needs, containing a broad question (What is important to you at the moment?) and six assessment topics (1. Cognitive and communicative abilities; 2. Mobility and agility; 3. Health related requirements and burden; 4. Self-care; 5. Living in social relationships; 6. Living environment) as well as a matrix for the assessment of nursing-sensitive risks within the assessment topics.

Table 2: Implementation strategies

Implementation strategy	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
Education						
PEPA Curriculum (training programme)	PEPA Setting: University of Lübeck, online, NH	The training programme ensures the PEPAs' knowledge of person-centred care. They are supported in developing their understanding of their role and develop competences for transferring the knowledge into care. The learning objectives and learning target checks are documented in the curriculum.	Lecturers from the participating universities, learning in working groups, supervision by the university.	Different learning formats according to the curriculum.	A total of 300 hours of teaching (10 ETC), consisting of contact time, self-study and on-the-job training. The qualification takes place in the first three months after randomisation.	Learning materials and tools according to the curriculum. Manual for documenting learning objectives, presentations, digital learning platform (Moodle), assignment descriptions, materials individually designed by lecturers.
Monitoring / Evaluation						
PEPA Handbook	PEPA Setting: University of Lübeck, NH	A detailed manual for documenting participation in courses and other learning activities, as well as for documenting learning objectives, increases the commitment to implementation and shows PEPAs their learning progress.	Study centres	The study centres introduce the handbook during contact time and provide a print version. Attendance is documented in the courses. PEPA maintains the handbook and collects the documentation.	According to curriculum. The handbook is kept during the three months of the training programme (implementation).	Print version of the manual.
Target agreement talks	PEPA Nurse manager (PDL) Setting: NH	The aim of the conversation is to talk about a shared idea of good care and how the intervention (role of PEPA) can support this. This will involve the PDL more in the project and thus support the implementation of the intervention components. Hindering and supporting factors	PEPA PDL If applicable, researchers from the university	PEPA and PDL meet to discuss study participation and implementation and document the outcome of the discussion in writing.	Meetings of 45-60 min, time points: 1. After randomisation, before the start of the training programme. 2. 4 weeks after randomisation.	Interview guide and protocol template.

Implementation strategy	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
		are discussed and solutions are sought if necessary.				
Organisation						
Cooperation agreement with the NH	NH Universities Setting: University, NH	A formal declaration of commitment increases the binding nature of the respective tasks of the partners (nursing homes and universities) in the project and thus supports compliance with the project plan, in particular the recruitment of participants, granting PEPAs worktime to perform Expand-Care tasks and the implementation of the curriculum.	Study centres and NH	Study centres hold a cooperation agreement, authorised representatives of the university and the NH sign the agreement.	Before the recruitment of residents begins.	Draft contract for the cooperation agreement.
Adaptability of the intervention	NH, PEPA Setting: NH	The PEPA intervention comprises several sub-components, some of which can be implemented optionally, others are mandatory. The possibility to adapt the intervention to the individual circumstances and needs of the NH promotes identification with the intervention and subsequently implementation.	PEPA PDL Researchers at the university.	At the beginning of the implementation, it is determined which components the intervention should include in the respective NH (discussion with PEPA, PDL and university).	After randomisation. If necessary, further discussion during the study if it becomes apparent that there are deviations from the original planning.	Interview guide and protocol template.

GP: General practitioner; ISBAR: Information, situation, background, assessment, recommendation, template to ensure structured and complete information transfer in handovers; NH: Nursing home; PEPA: German acronym for nurse specialist with expanded competencies for person-centred care; PDL: nurse manager; SIS®: [Strukturierte Informationssammlung] structured plan for the assessment of residents' care needs, containing a broad question (What is important to you at the moment?) and six assessment topics (1. Cognitive and communicative abilities; 2. Mobility and agility; 3. Health related requirements and burdens; 4. Self-care; 5. Living in social relationships; 6. Living environment) and a matrix for risk assessment and care needs.

Statistical study plan for the study Expand-Care

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Universität zu Lübeck, Universitätsklinikum Schleswig-Holstein, Campus Lübeck
(Director: Univ.-Prof. Dr. Inke R. König)

Date: *23.09.2022*
Version: *2.0*

This document is valid for the study protocol (version: *V 1.3)* of the study mentioned above.

Confidential

Condition for the services of the IMBS described in this statistical study plan is a cost-covering funding from the sponsor of the study (third-party funds) on the basis of a budget plan to be made by the IMBS.

Table of content

This statistical study plan is part of the study plan.

1. General

All statistical analyses except for the health economics evaluations and process evaluation are carried out by the Institut für Medizinische Biometrie und Statistik (IMBS) at the Universität zu Lübeck. All analyses are described in detail in the statistical analysis plan (SAP), which will be finalised before the registration of the last patient in the study.

2. Purpose, objectives and hypotheses of the study

Purpose of the study is to prepare a confirmatory clinical trial that will be adequately powered. The objective is the necessary precision of estimates of variation. As a consequence, a confidence interval of predefined width replaces hypotheses.

2.1 Purpose

Purpose of the study is to prepare a confirmatory clinical trial that will be adequately powered, smoothly conductible, and may be augmented by the evidence generated in the pilot study.

2.2 Objectives

Objective of the study is a narrow confidence interval for both, the population summary measure and the standard deviation of the outcome variable. The 6-months rate of hospital admissions in each group shall be estimated with a two-sided 95%-confidence interval that extends no more than 10 percentage points in either direction, as this would effectively restrict the range of possible sample sizes of the subsequent confirmation study. The 6-months incidence of hospitalisation of nursing home residents is thought to be 25% (Leutgeb et al., 2019). Using a rate of 30% or 20% in the control group as a basis for planning, sample size of the subsequent confirmatory study to detect a difference of 15 percentage points would change by 50%. If that rate was 25%, but the risk difference to be detected was 15% or 10%, one possible sample size would be 250% of the other, so that an interim analysis of the subsequent confirmatory trial could be justified or not.

2.3 Hypotheses

This pilot study will be used to define the hypotheses of the subsequent confirmatory study. They will have the form: There is no difference in the 6-months hospitalisation rates of nursing home residents cared for according to current standards or with the Expand-Care programme versus the risk difference is P1 % with P1 to be determined by the pilot study to be a number of perhaps 10 or 15.
Sample size planning of the pilot study could be thought of as being for a test of the hypotheses that 6-months hospitalization rates of nursing home residents cared for according to current standards is 25% versus 15% and with the Expand-Care programme 15% versus 25%.

3. Design of the study

3.1 General

The study will be national, bicentric, cluster-randomised, open, in parallel groups

3.2 Randomisation, blinding, confounding

Randomisation will be central to ensure concealment of allocation and will be stratified by time to balance any seasonal effects. Blinding is not possible in this complex intervention, but will be observed during statistical analysis and data review.

3.2.1 Registration and randomisation

The randomised allocation will be initiated after completion of the baseline assessment (t0) in participating nursing home residents by the investigators responsible for the respective nursing

homes. Participating nursing homes (unit of randomisation) will be randomised with an allocation ratio of 5:6 to the intervention or the control group. The random sequence will be generated by the IMBS by permutation with validated software once two nursing homes have faxed their readiness. So, date has to be stated on the fax asking for randomisation.
The trial statistician will write and test SAS code like

```
/* randomisation.sas
Reinhard Vonthein 18.03.2022 nach
Kundu & Roy auf lexjansen.com/pharmsug/2007/ad/AD07.pdf
Per stratum 3 blocks of size 2 */

data _null_;
 x=round(ranuni(0)*10000000);
 call symput ('seed', x);
run;

title1 "Seed number = &seed.";
title2 " Blocks are times of randomization,";
title3 "subject means nursing homes within a block in the temporal
order of their registration for randomization";

proc plan seed=&seed.;
 factors block=6 ordered subject=2 ordered/noprint;
 treatments treatment=2 random;
 output out=out
treatment cvals=('Expand-Care' 'Usual care');
run;

proc print data=out noobs;
 var block subject treatment;
 format subject z3.;
run;
```

for the generation of the randomisation sequence by permutation within time – the latter is called a block in the code. The effective randomisation sequence is generated, tested for balance (5:6 in total), and kept confidential by another person. Assignment of an institution is disclosed to just the designated investigator and only after registration, i.e. written assurance that all baseline assessments detailed in the protocol and other necessary preparations have been completed.
Registration and randomisation will be done via fax (++ 49 (0) 451 500-50614) from Monday to Friday from 08:00 to 14:00. Exceptions in which no randomisation is carried out are holidays and the period from 27.12. until 31.12. every year. The randomisation procedure is based on IMBS internal standard operating procedures.
The statistical analysis is prepared using place-holders assuming alternating assignments, so that results may not be guessed. True assignments are inserted into the code only after blinded review and data base closure.

3.2.2 Blinding

Due to the nature of the Expand-Care intervention, blinding of the nursing home residents and the nursing staff against the allocated intervention will be not feasible. However, in the information provided to the nursing home residents no specific hypotheses about possible directions of effects in measured outcomes will be described. The distal outcome data on hospital admissions, out-of-hour physician contacts and emergency service utilisation in the nursing home residents will be collected by study assistants blinded to the allocated intervention. For the assessment of all distal outcome (i.e hospital admissions, out-of-hour physician contacts, emergency service use and HRQoL) and resource use data in the nursing home residents, standardised instruments and

procedures will be used which have been proven feasible and reliable in previous trials of the authors (Müller et al. 2019, Richter et al. 2019). The trial statistician will be unaware of the assignments until after blinded review and data base closure. To this end, tests of the program code for analysis use an alternating assignment instead of the true allocation. The randomisation list will be merged to the data as a last step. A test of that step will use the list with alternating assignments.

3.2.3 Confounding

The primary endpoint is an event within 6 months, and the individual baseline measurement for this is the occurrence of the same event in the 3 months prior to randomisation. This will be observed retrospectively for adjustment in statistical analysis.
All analyses need to consider institution or one of its features as a moderator. This is usually done in the form of random effects/frailty to adequately model correlations. One exemption to this rule are the median differences and Hodges-Lehman confidence intervals, that take care of the problem by the resampling-like mode of their computation.

3.3 Endpoints

The hospitalisation rate measures a relevant burden to nursing home residents and from a payer perspective. Other measurements of resource use are complemented by residents' reports on quality of life, and safety outcomes. Morbidity endpoints will be used to describe the mechanism behind treatment effects.

3.3.1 Primary endpoints and hypotheses

The endpoint used in sample size calculation is the binary variable, whether a resident is hospitalised at least once during the six months following randomisation of the nursing home. All hospitalisations qualify irrespective of urgency, reason, duration, and initiator.
The primary estimand directly linked with sample size calculation is the difference of the proportion of such residents.
The endpoint for the first sensitivity analysis is the individual mean time between hospitalisations. All episodes between randomisation and hospitalisation or censoring and between discharge and re-hospitalisation or censoring are entered in a recurrent event analysis.
The endpoint for the second sensitivity analysis is the individual rate of hospitalisations (number divided by days in institution) within 6 months. This is analysed by Poisson regression with number of days in institution defining the offset.

3.3.2 Secondary endpoints

The list of endpoints is a subset of clinical investigation plan Tables 1, 2, 4.
(P) Occurrence of hospital admission within last 3 months at 3 and 6 months
(C) Number of hospital admission within last 3 months at 3 and 6 months
(C) Number of hospital days within last 3 months at 3 and 6 months
(P) Occurrence of out-of-hours physician contact within last 3 months at 3 and 6 months
(C) Number of out-of-hours physician contacts within last 3 months at 3 and 6 months
(P) Occurrence of emergency service use within last 3 months at 3 and 6 months
(C) Number of emergency service uses within last 3 months at 3 and 6 months
(M) EQ5D subscales and summary at 6 months
(M) 4DSQ subscales at 6 months
(P) Occurrence of falls within last 3 months at 3 and 6 months
(C) Number of falls within last 3 months at 3 and 6 months
(P) Occurrence of fall related injury within last 3 months at 3 and 6 months
(C) Number of fall related injuries within last 3 months at 3 and 6 months
(P) Occurrence of pressure ulcer of degree 2+ within last 3 months at 3 and 6 months
(P) Occurrence of pressure ulcer of degree 2 within last 3 months at 3 and 6 months

(P) Occurrence of pressure ulcer of degree 3 within last 3 months at 3 and 6 months
(P) Occurrence of pressure ulcer of degree 4 within last 3 months at 3 and 6 months
(P) Occurrence of incontinence associated dermatitis within 3 months at 3 and 6 months
(P) Occurrence of potentially inadequate medication within 3 months at 3 and 6 months
(M) Self-care subscales at 6 months
(M) Person-centredness subscales at 6 months
(T) Mortality within 6 months
(P) Occurrence of general practitioner visit within 3 months at 3 and 6 months
(C) Number of general practitioner visits within 3 months at 3 and 6 months
(P) Occurrence of specialist visit within 3 months at 3 and 6 months
(C) Number of specialist visits within 3 months at 3 and 6 months
(P) Occurrence of physiotherapy visit within 3 months at 3 and 6 months
(C) Number of physiotherapy visits within 3 months at 3 and 6 months
(P) Occurrence of occupational therapy visit within 3 months at 3 and 6 months
(C) Number of occupational therapy visits within 3 months at 3 and 6 months
(P) Occurrence of speech therapy visit within 3 months at 3 and 6 months
(C) Number of speech therapy visits within 3 months at 3 and 6 months
(P) Occurrence of rehabilitation visit within 3 months at 3 and 6 months
(C) Number of rehabilitation visits within 3 months at 3 and 6 months

(M) Time for PEPA training at 3 and 6 months
(M) Costs of PEPA training at 3 and 6 months
(M) 5 PEPA quality indicators at 6 months
(M) Time for other training at 6 months
(M) Costs of other training at 6 months
(M) Time for PEPA training per institution at 3 and 6 months
(M) Costs of PEPA training per institution at 3 and 6 months
(M) Time for other training per institution at 6 months
(M) Costs of other training per institution at 6 months
(M) Costs of medical devices and apps per institution at 6 months

3.4 Analysis timing

The statistical analysis will be prepared during the follow-up period and performed after monitoring, blinded review, and data base lock. No interim analyses are planned, not even for safety data.

4. Statistical analysis

4.1 Analysis population

The primary analysis population is defined by the intention to treat for all analyses including safety data, as the intervention is empowerment of carers rather than the actual application of the resulting methods of care.

4.2 Intercurrent events

Discontinuation of the Expand-Care intervention or adoption of a policy meant to reverse consequences of the Expand-Care intervention would affect whole institutions. Failure at PEPA training in single carers or at policy implementation are possibilities. Implementation of different policies is another possible intercurrent event.
Intercurrent events that may affect the individual participants are absorbing endpoints (permanent hospitalisation, death).

4.2.1 Analysis strategy

The default analysis strategy is the treatment policy strategy, i.e. intercurrent events are irrelevant as a rule. Absorbing endpoints are considered as competing risks or worst possible assessment by the composite strategy.

4.2.2 Estimands

The primary estimand of the marginal rates in treatment groups is estimated by mixed logistic regression from the occurrence of hospitalisation within 6 months on treatment and occurrence of hospitalization within 3 months prior to the trial (both fixed factors with two levels) and institution (random effects). All participants in all institutions are analysed by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation.
For the treatment effect:
The primary estimand is the marginal odds ratio of occurrence of hospitalisation within 6 months after randomisation adjusted for the presence of hospitalisation within the 3 months prior to the trial among all participants in all institutions by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation.
First sensitivity estimand is the hazard ratio of a Cox regression of recurrent events with shared frailty from times to hospitalisation on treatment and occurrence of hospitalisation within 3 months prior to the trial among all participants in all institutions by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation instead of as a competing risk.
Second sensitivity estimand is the marginal rate ratio of hospitalisation within 6 months in a mixed Poisson regression on treatment and occurrence of hospitalisation within 3 months prior to the trial among all participants in all institutions by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation.
All estimands above should be complemented by additional sensitivity estimands that employ GEE for GLM instead of random effects.

4.3 Descriptive statistics

The type of descriptive statistics used in this study are described in the following:

Type C (count): Absolute frequencies of counts without adjustments and estimated marginal rates and 95% confidence interval for the marginal rate ratio from a mixed Poisson regression on allocated treatment with random institution effects (proc `genmod; ln log(n) model … / dist = poisson link = log offset = ln; repeated subject = institution / type = exch`).

Type M (measurement): Median and range with 95% confidence Hodges-Lehmann intervals for the difference of medians.

Type N (normal): Marginal means and total standard deviations (SD) for each treatment group and 95% confidence interval for the difference of marginal means all estimated using the mixed model with fixed treatment effect and random institution effects (proc `mixed; random`).

Type LN (log-normal): Type N statistics are computed for logarithms and converted back to geometric means, ratio of geometric means and coefficients of variation.

Type O (ordinal): Absolute frequencies without adjustments and estimated marginal probabilities and 95% confidence Wald interval for the odds ratio from a mixed ordinal logistic regression on allocated treatment with random institution effects (proc `glimmix; random intercept / subject = institution`).

Type P (proportion): Absolute frequencies without adjustments and estimated marginal probabilities together with 95% confidence score interval for the difference of marginal proportions using a mixed logistic regression (proc `glimmix; random intercept / subject = institution`)..

Type T (time to event): Unadjusted Kaplan-Meier-curves, marginal cause specific hazard ratio (HR) with 95% confidence interval estimated from Cox-regression with shared frailty (proc `phreg; random`), and cumulative incidence functions for competing risks where needed.

The disposition of patients will be described by a CONSORT flow chart.

4.4 Overall methods of analysis

4.4.1 Testing strategy

The primary estimands, proportions in treatment groups, will be estimated into 95%-confidence intervals. Their odds ratio will be estimated into a 95%-confidence interval, too. Additionally, to adjust for multiplicity, (1 – 0.05/2) = 97.5%-confidence for the three will be calculated, as the third is fixed, if two are known. These are the results needed to plan a confirmatory study with the full confidence. They will be superseeded subsequently, so that they are not part of the second testing strategy.

This pilot study is not meant to confirm any claims, but may confirm some, nevertheless. In contrast to the subsequent confirmatory study, this pilot study will not primarily aim at the distal endpoints relevant to the patient, but rather confirm the mechanism of action by tests of the proximal endpoints describing changes in care. No interim analysis is planned with the aim of terminating the study early for efficacy or futility. This formal process evaluation will employ the Bonferroni-Holm procedure for the sixteen endpoints of the nine variables without adjustments, as most moderators will be measured after randomisation. The multiple significance level is set at 0.05, the first local significance level is set at 0.05/16, both for two-sided alternatives. As there was no power calculation directed at these tests, results have to be interpreted as tests of significance rather than tests between alternatives.

Conclusions other than those formulated above cannot be statistically ascertained. Confidence limits may, however, indicate what reasonable expectations are.

4.4.2 Methods of analysis

All analyses are described in detail in the statistical analysis plan (SAP), which will be finalised before the registration of the last patient in the study. The analyses specified therein will be translated into computer code. The results of that code applied to the closed data base are the basis for the statistical study report, on which the clinical study report will be based.

Analyses like the ones in 4.3 will be adjusted for baseline measures of the same, if measured, or by age in the case of mortality. The mapping of endpoints to analysis type is indicated in the list 3.3.2 above by abbreviations of types in parentheses.

4.5 Sample size calculation

A total of 11 nursing homes are to be included, with an average of 15 participating residents. These will be randomised with chance 5:6 to the intervention group and to the control group, resulting in 75 and 90 study participants per study arm. With an assumed drop-out rate of max. 20% (Richter et al., 2019, Saal et al., 2019), data of 60 and 72 residents for each study arm are expected.

The sample size calculation is based on the following assumptions: With an average of 50 residents per nursing home (Statistisches Amt für Hamburg und Schleswig-Holstein, 2020) and an assumed rate of approx. 60% residents meeting eligibility criteria (clinical estimate based on epidemiological data on the incidence of hospital admissions (Leutgeb et al., 2019) and emergency room visits (Brucksch et al., 2018)), it is assumed that on average 60%, i.e. 30 residents, are potentially eligible for participation. Assuming a participation rate of 50% among these residents (Saal et al., 2019), an achievable mean cluster size of 15 residents is assumed. Considering an intra-cluster correlation coefficient of 0.021 (Adams et al., 2004, Richter et al., 2019), this mean cluster size results in a design factor (inflation factor) of 1.294, i.e. the assumed number of 60 and 72 residents with analysable

outcome data corresponds to an effective analysable sample of 46 and 55 residents per treatment group.
The aim of the present study is to estimate as precisely as possible the proportion of residents with at least one hospital admission during the six-month observation period in each of the two treatment groups. Based on empirical results on the annual incidence of hospital admissions among nursing home residents (Leutgeb et al., 2019), it is assumed that the proportion of residents with at least one hospital admission in the control group will be 25% (i.e. 0.25 rate of hospital admissions) for the six-month observation period in this study. Furthermore, it is assumed that the Expand-Care programme to be tested in the intervention group can realistically lead to a reduction in the incidence by a maximum of 10% to 15% (= 0.152 rate of hospital admissions) within the six-month observation period. The planned sample sizes allow these rates to be estimated with a confidence interval of +/- 0.115 or +/- 0.119 in the control group and +/- 0.095 or +/- 0.0985 in the intervention group. This is considered to be sufficient for a precise calculation of the required sample size for subsequent explanatory randomised controlled trials.

4.6 Interim analyses and design adaptions

4.6.1 Interim analyses

No interim analysis is planned, so that any interim analysis would be preceded by an amendment to the trial protocol.

4.6.2 Design adaptions

No design adaption is planned, so that any design adaption would be preceded by an amendment to the trial protocol.

4.7 Adjustment and stratification

The analyses of endpoints will be adjusted for the respective baseline observations and will correct for correlated observations within institutions by random effects models and by GEE as sensitivity analyses.

4.8 Subgroup analysis

The primary analysis will be complemented by subgroup analyses that are exploratory in nature. The results will be displayed as a forest plot of confidence intervals for odds ratios within subgroups, absolute frequencies, and descriptive P values of the statistical tests for interaction between the grouping variable and the treatment. Subgroups will be defined by the baseline values of binary outcome variables and some plausible predictors, if subgroup sizes reach at least 20:
Occurrence of hospital admission within last 3 months
Level of care needed (Pflegegrad) at baseline (care level 2 versus 3 or higher)
Number of comorbidities in classes of at least 20 participants
Dementia Screening Score </=4 versus >4 at baseline
Two classes of maximum number of persons cared for at the institutions
Degree of implementation of Expand-Care programme as quantified in the process evaluation pooled to groups of at least 3 institutions
Occurrence of out-of-hours physician contact within last 3 months
Occurrence of emergency service use within last 3 months
Occurrence of falls within last 3 months
Occurrence of fall related injury within last 3 months, if at least 20 participants
Occurrence of pressure ulcer within last 3 months
Occurrence of incontinence associated dermatitis within 3 months
Occurrence of potentially inadequate medication within 3 months
Occurrence of specialist visit within 3 months
Occurrence of physiotherapy visit within 3 months
Occurrence of occupational therapy visit within 3 months

Occurrence of speech therapy visit within 3 months
Occurrence of rehabilitation visit within 3 months
Sex
Region (HL or HH).
Interpretation of implementation groups would be even more tentative than the rest of the hypothesis generating subgroup analyses, as this happens after randomisation and groups are formed so as to be extreme. An exploratory mediator analysis should be tried instead.

4.9 Missing data

Missing observations in random effects analyses are not imputed. The only exception are "worst case" imputations of hospitalisations in case of death in the institution, when death is not a competing risk. That is a conservative assumption to prevent death from being a favourable outcome. Subjective assessments that were collected earlier than 77 days after randomisation or later than 207 days after randomisation will be set to missing, as the former could severely bias the treatment effect in case of a missing assessment at t2 and the latter would not capture the effect of the intervention that is considered discontinued by then.

4.10 Safety analyses

Medical treatments will be reported. Their frequency will be tabulated by treatment and kind rather than system organ class. The extraction from the eCRF is complex, as the information is scattered. Types are:

- Emergency service, if ambulance or emergency physician, but not just a phone call
- Contact with general practitioner,
- Unplanned visit of general practitioner,
- Visit at the general practitioner's,
- Contact with specialist,
- Physiotherapy,
- Ergotherapy,
- Logopaedic therapy,
- Osteopathy.
- others

Complications:

- Falls,
- Pressure ulcer,
- Dermatitis caused by incontinence
- Deterioration of care level

will be tabulated by randomised treatment and degree or damage. Duration of pressure ulcers and dermatitis will be described by treatment group.
Hospitalisations that are not planned will be tabulated by category (rather than system organ class), duration, outcome, and treatment. Mortality will be tabulated by treatment and cause of death.
Hospitalisations that could have a causal association with the intervention will be listed with all available data and additional information on mitigating treatment.

4.11 Health services research

Medical treatments and requests for these will tabulated by function of the person that initiated the contact, whether the need newly arose, whether the requested treatment was delivered, and the means used.

Complications:

Falls,
Pressure ulcer,
Dermatitis caused by incontinence,
Deterioration of care level
will be tabulated by randomised treatment and requested treatment of the complication.

4.12 Exploratory and sensitivity analyses

The effect of missing data on occurrences is explored by sensitivity analyses of individual incidence rates (Poisson Regression) and event times (Cox regression). This applies to the endpoints that may occur more than once:
Times to or number of out-of-hours physician contact within 6 months
Times to or number of emergency service use within 6 months
Times to or number of falls within 6 months
Times to or number of fall related injury within 6 months
Times to or number of pressure ulcer of category 2+ within 6 months
Times to or number of pressure ulcer of category 2 within 6 months
Times to or number of pressure ulcer of category 3 within 6 months
Times to or number of pressure ulcer of category 4 within 6 months
Times to or number of incontinence associated dermatitis within 6 months
Times to or number of potentially inadequate medication within 6 months
Times to or number of AE within 6 months
Times to or number of SAE within 6 months
Times to or number of general practitioner visit within 6 months
Times to or number of specialist visit within 6 months
Times to or number of physiotherapy visit within 6 months
Times to or number of occupational therapy visit within 6 months
Times to or number of speech therapy visit within 6 months
Times to or number of rehabilitation visit within 6 months

Further adjusted and mediation analyses should explore the need for more or less data in any subsequent trial.

5. Reporting and publication

Reporting will adhere to the CONSORT statement.
Results from the study will only be published after the database has been closed with the only exceptions being publications concerning the design of the study. Before, for methodological-statistical reasons, it must only be reported in general form without results, e.g. recruitment status or demographic characteristics of study participants (within the meaning of Table 1 of a study). There will be no publications or conference contributions on outcomes prior to the first publication on the primary outcome that encompasses the results from all participating institutions.
Any publication shall be consented among the authors and the coordinating investigator. All reports and publications concerning the study are agreed with the responsible biostatistician of the IMBS in order to avoid misinterpretations of statistical results. Conclusions or recommendations formulated in the publications for which a statistical assurance is claimed require the consent of the statistical co-authors. Conclusions or recommendations for which no statistical coverage is claimed are expressly designated as such at the request of the statistical co-authors (see, for example: Grundsätze für die ordnungsgemäße Durchführung der klinischen Prüfung von Arzneimitteln. 9.12.1987. Bundesminister für Jugend, Familie, Frauen und Gesundheit, Bundesanzeiger Nr. 243 vom 30.12.1987, S. 16167, Punkte 4.2. und 4.2.5, and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH-Efficacy Topic 3, Structure and Contents of Clinical Study Reports, Annex VIII, point A d) (ii)).

A study-assisting member of the IMBS or the ZKS is second on the authors list and the senior author of the IMBS or ZKS second to last in the authors list. Further co-authorships of the IMBS and ZKS are based on the Good Scientific Practice Guideline of the DFG and the four rules of the ICMJE.
The data from the respective centre will be made available to investigators upon request at the end of the study. Publication of this study data from individual centres is only possible after publication of the overall study results.

6. Literature

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Müller, C., Hesjedal-Streller, B., Fleischmann, N., Tetzlaff, B., Mallon, T., Scherer, M., Köpke, S., Balzer, K., Gärtner, L., Maurer, I., Friede, T., König, H. H., & Hummers, E. (2020). Effects of strategies to improve general practitioner-nurse collaboration and communication in regard to hospital admissions of nursing home residents (interprof ACT): study protocol for a cluster randomised controlled trial. Trials, 21(1), 913. https://doi.org/10.1186/s13063-020-04736-x

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Information on the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)".

(Translation based on Version 1.3, 09.07.2022)

Dear Ladies and Gentlemen,

we would like to invite you to participate in the study "Expand-Care". The study is being conducted by the Nursing Research Unit at the University of Lübeck and the Institute for General Practice at the University Medical Center Hamburg Eppendorf. The study is funded by the Federal Ministry of Education and Research (BMBF).

The study was reviewed by an independent ethics committee. This committee did not raise any objections to the conduct of this study.

Your participation in the study is voluntary. If you do not wish to participate or if you later withdraw your consent, you will not suffer any disadvantages as a result.

Please read this information carefully. If you have any further questions regarding the study, please contact us, the study team:

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Research assistant
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Tel.: 0451 500-52161

What is the aim of this study?

The aim of this study is to find out whether nursing professionals with special additional qualifications should take on additional tasks in the care of residents in nursing homes. The aim is to improve nursing care and health of residents and to adapt care to their needs. The employment of nursing professionals with additional qualifications in nursing homes is now to be explored and we hereby invite you to participate.

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expand care

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What is the process of the study?

The study is being conducted in 11 nursing homes in Lübeck and Hamburg. Per nursing home, 15 residents can participate. The nursing homes are **randomly assigned to** two different groups. One group of nursing homes will receive further training, i.e. one of the facility's nursing staff will receive additional training and will apply what they have learned to nursing care and, for example, conduct structured personal conversations with residents. The other group of nursing homes receives care as usual (this means for you everything remains as before). The group allocation is random, which means you yourself, the nursing home and the study staff have no influence on which group the nursing home where you live is allocated to.

If you agree to participate in the study, study staff will collect information of interest from your resident record. In addition, you and a (specialist) caregiver responsible for you at your nursing home will be interviewed by a study staff member on various health-related topics using a questionnaire. This information will be collected at regular intervals at three points in time: at the beginning of the study, after three months and after six months. Your participation is expected to last a total of six months, after which the study will end. We will coordinate all appointments with you and the nursing staff of your institution. You will not incur any financial expenses during the entire study. Participation in the study will require about 30 minutes of your time twice for the interviews. This time expenditure cannot be compensated within this study.

What data is collected from me?

We would like to collect the following information from your resident file and from you as part of the survey:

- Your personal data (age, sex, marital status, degree of care, care aids, and whether you have powers of attorney or a living will).
- Information about your physical and mental health,
- Information from the documentation of the nursing home (e.g. medical diagnoses, medication and medical care, number of falls, hospitalisations, pressure ulcers).

Do I have to give my consent? What happens if I withdraw my consent?

Participation in this study is voluntary. You therefore do not have to participate. Even after you have given your consent, you can terminate your participation in the study at any time without giving reasons and without incurring any disadvantages.

If you would like to withdraw from participation at a later date, please contact the principal investigator Prof. Dr. Katrin Balzer. If you withdraw from the study, data that has already been collected from you can be deleted if you wish, provided that the data has not yet been completely anonymised (see section on data protection). In this case, a connection to your person is no longer given and deletion is therefore no longer possible.

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What are the possible risks and benefits of participation?

Participation in the study is not associated with any risks for you. The applicable hygiene rules (e.g. personal protection equipment) will be observed during personal meetings. Participation in the study can have a direct benefit for you and for other residents of your nursing home, e.g. increased nursing care. In addition, the results of the study may help other residents in nursing homes in the future.

However, it is possible that you will not directly benefit from your participation.

What happens to the results of the study?

The findings will shed light on whether the integration of nursing professionals with expanded competencies in nursing homes leads to better care and quality of life for residents and should be introduced in the future. The results of the study will be presented anonymously to the general public and the professional public, e.g. in scientific journals and at congresses.

Who reviewed the study?

The ethics committee of the University of Lübeck has approved the study protocol (vote of: 11.05.2022; file number: 22-162).

Data protection information

In this study, Prof. Dr. Katrin Balzer, Nursing Research Unit, Institute for Social Medicine and Epidemiology, University of Lübeck, Ratzeburger Allee 160, 23562 Lübeck, Tel.: 0451 500-52162, e-mail: Katrin.Balzer@uksh.de is responsible for data processing. The legal basis for processing your data is your personal consent (Art. 6 para. 1a, Art. 9 para. 2a DSGVO). The data will be treated confidentially at all times.

Your data will only be collected for the purpose of this study and will only be used in the context of this study.
The data also includes personal identifying data such as name, address and date of birth. All data directly related to your person will be replaced by a letter-digit combination (pseudonymised). This largely excludes the possibility of your person being identified by unauthorised persons. Your data is stored and evaluated without reference to your name, i.e. your name is not mentioned anywhere.

Your data is stored in the Nursing research unit on the server of the Science Network of the University Hospital Schleswig-Holstein, Lübeck Campus and in the Institute and Polyclinic for General Medicine on the server of the University Hospital Hamburg-Eppendorf. Paper-based data is stored in lockable and protected cabinets. Only members of the study team have access to your data. These persons are obliged to maintain confidentiality. The data is protected against unauthorised access. All data is stored for 10 years in accordance with legal regulations and deleted after this period has expired.

Monitoring of the study implementation

For the purpose of reviewing the conduct of the study, competent employees of the initiator of the study or study partners commissioned by the initiator for the purpose of reviewing the quality of the

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conduct of the study may inspect the study documents available at the study centre. This can also be done after all relevant data have already been submitted. The reviewers may be, for example, monitors or auditors. For this measure, you release the members of the study team from their duty of confidentiality.

The provisions of the General Data Protection Regulation (DSGV) are complied with. Consent to the processing of your data is voluntary, you can revoke your consent at any time without giving reasons and without disadvantages for you. You have the right to receive information about the data concerning you, also in the form of a free copy. Furthermore, you can request the correction or deletion of your data. To do so, please contact the principal investigator: Prof. Dr. Katrin Balzer (see above for contact details). Anonymously collected or anonymised data cannot be deleted in the event of revocation, however, as it is not possible to trace the data back to individuals.

If you have any queries or complaints regarding data protection, please contact the data protection officer at the University of Lübeck: x-tention Informationstechnologie GmbH, Karl- Drais-Str. 4e, 86167 Augsburg, e-mail: datenschutz@uni-luebeck.de

In the event of a complaint, you can also contact the responsible data protection supervisory authority: Independent Centre for Data Protection Schleswig-Holstein, Holstenstraße 98, 24103 Kiel, e-mail: mail@datenschutzzentrum.de.

Please do not hesitate to contact us if you have any questions!

Thank you for your interest and best regards,

Prof. Dr Katrin Balzer

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Tel.: 0451 500-51261
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Informed consent for participation in the study

" Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)"

I have received, read and understood the written study information for the above-mentioned study. I was informed in detail - verbally and in writing - about the aim and the course of the study, the risks and benefits of participation, my rights and obligations and the voluntary nature of participation.
I had the opportunity to ask all my questions. These were answered satisfactorily and completely.

Surname, first name resident

Date of birth

I was informed about the study by the following person:

Surname, first name study team member

Telephone number

I hereby declare my participation in the above study. I have been informed that my participation is voluntary and that I have the right to terminate it at any time without giving reasons and without incurring any disadvantages.

I agree to the collection and storage of the data mentioned in the study information, especially the personal data. I have been informed about the possibilities of the right to information and the right to object.

I have received the study information and a copy of this consent.

Place, date

Signature Resident

Place, date

Signature study team member

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Information on the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)"

(Translation based on Version 1.3, 08.07.2022)

Dear Ladies and Gentlemen,

We would like to invite the resident(s) you care for to participate in the study "Expand-Care". The study is being conducted by the Nursing research unit at the University of Lübeck and the Institute for General Practice at the University Medical Centre Hamburg Eppendorf. The study is funded by the German Federal Ministry of Education and Research (BMBF).

The study was reviewed by an independent ethics committee. This committee did not raise any objections to the conduct of this study.

The resident's participation in the study is voluntary. If the resident does not wish to participate or if you later withdraw your consent, you and the resident under your care will not suffer any disadvantages as a result.

Please read this information carefully. If you have any further questions regarding the study, please contact us, the study team:

Prof. Dr Katrin Balzer
Principle investigator
Katrin.Balzer@uksh.de
Tel.: 0451 500-52162

Katharina Silies
Research assistant
Katharina.Silies@uksh.de
Tel.: 0451 500-52161

What is the aim of this study?

The aim of this study is to find out whether nursing professionals with special additional qualifications should take on additional tasks in the care of residents in nursing homes. The aim is to improve the nursing care and health of the residents and to adapt it to their needs. The employment of nursing professionals with additional qualifications in nursing homes is now to be explored and we hereby invite the resident(s) you care for to participate.

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Who can participate in the study?

We invite residents in nursing homes to participate in the study.

In addition, they should have a care degree 3 or higher **or** have a care degree 2 and **additionally** fulfil one of the following points:

OR

- several long-lasting conditions at the same time (e.g. diabetes, high blood pressure and Alzheimer's disease).
- unplanned hospitalisation or emergency medical treatment in the last 8 weeks

What is the process of the study?

The study is being conducted in 11 nursing homes in Lübeck and Hamburg. Per nursing home, 15 residents can participate. The nursing homes are **randomly assigned to** two different groups. One group of nursing homes will receive further training, i.e. one of the facility's nursing staff will receive further training and will apply what they have learned in their nursing care and, for example, conduct structured personal conversations with residents. The other group of nursing homes receives care as usual (i.e. everything remains as before). The groups are randomly assigned, i.e. you, the nursing home and the study staff have no influence on which group the nursing home in which the resident you care for lives will be assigned to.

If you consent to participate in the study on behalf of the resident you care for, study staff will collect information of interest from the resident's file. In addition, the resident him/herself, if possible, and a caregiver of the nursing home responsible for him/her will be interviewed by a study worker on various health-related topics using a questionnaire.

This information is collected at regular intervals at a total of three points in time: at the beginning of the study, after three months and after six months. Participation in the study is expected to last a total of six months, after which the study will end. We will coordinate all appointments with the resident and the nursing staff of the facility. There will be no financial costs for you or the resident during the entire study. Participation in the study will take about 30 minutes twice for the resident. This time expenditure cannot be compensated within this study.

What data is collected from the resident?

We would like to collect the following information from the resident's file and during the survey:

- Personal data (age, sex, marital status, degree of care, care devices and whether powers of attorney or a living will are available),
- Information on physical and mental health,
- Information from the documentation of the nursing home (e.g. medical diagnoses, medication and medical care, number of falls, hospitalisations, pressure ulcers).

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Do I have to give my consent? What happens if I withdraw my consent?

Participation in this study is voluntary. The resident does not have to participate. Even after consent has been given, you can terminate the participation of the resident in the study at any time without giving reasons and without any disadvantages for you or the resident you are looking after.

Furthermore, the interview will only be carried out if the resident himself/herself has given at least verbal consent. If the resident refuses, the interview will not be conducted or will be terminated.

If you would like to withdraw your participation at a later date, please contact the principal investigator Prof. Dr. Katrin Balzer (Katrin.Balzer@uksh.de). In the event of withdrawal from the study, data already collected from the resident can be deleted if desired, provided that the data have not yet been completely anonymised (see section on data protection). In this case, a connection to the person no longer exists and deletion is therefore no longer possible.

What are the possible risks and benefits of participation?

Participation in the study is not associated with any risks for you and the resident. The applicable hygiene rules will be observed during the personal meetings. Participation in the study may have a direct benefit for the resident and for other residents of the nursing home, e.g. increased nursing care. In addition, the results of the study may help other residents in nursing homes in the future.

However, it is possible that the resident you care for will not directly benefit from participation.

What happens to the results of the study?

The findings will provide information on whether the integration of nursing professionals with expanded competencies in nursing homes leads to better care and health of the residents and should be introduced in the future. The results of the study will be presented anonymously to the general public and the professional public, e.g. in scientific journals and at congresses.

Who reviewed the study?

The ethics committee of the University of Lübeck has approved the study protocol (vote of: 11.05.22; file number: 22-162).

Data protection information

In this study, Prof. Dr. Katrin Balzer, Section for Research and Teaching in Nursing, Institute for Social Medicine and Epidemiology, University of Lübeck, Ratzeburger Allee 160, 23562 Lübeck, Tel.: 0451 500-52162, e-mail: Katrin.Balzer@uksh.de responsible for data processing. The legal basis for processing the data is personal consent (Art. 6 para. 1a, Art. 9 para. 2a DSGVO). The data will be treated confidentially at all times. The data will be collected exclusively for the purpose of this study and will only be used within the scope of this study. The data also includes personal identifying data such as name, address and date of birth. All data directly related to the person will be replaced by a letter-digit combination (pseudonymised). This largely excludes identification of the person by unauthorised persons. The data is stored and evaluated without reference to the name, i.e. the name of the resident is not mentioned anywhere.

All data are stored in the Nursing research unit on the server of the Science Network of the University Hospital Schleswig-Holstein, Lübeck Campus and in the Institute and Polyclinic for General Medicine on the server of the University Hospital Hamburg-Eppendorf. Paper-based data is stored in lockable and protected cabinets. Only members of the study team have access to the data. These persons are obliged to maintain confidentiality. The data is protected against unauthorised access. All data is kept for 10 years and deleted after this period.

Monitoring of the study implementation

For the purpose of reviewing the conduct of the study, competent employees of the initiator of the study or study partners commissioned by the initiator for the purpose of reviewing the quality of the conduct of the study may inspect the study documents available at the study centre. This can also be done after all relevant data have already been submitted. The reviewers may be, for example, monitors or auditors. For this measure, you release the members of the study team from their duty of confidentiality.

The provisions of the General Data Protection Regulation (DSGV) are complied with. Consent to the processing of data is voluntary; you can revoke your consent at any time without giving reasons and without disadvantages for yourself or the resident. You have the right to receive information about the relevant data of the resident(s) looked after by you, also in the form of a free copy. Furthermore, you can request the correction or deletion of the data. To do so, please contact the head of the study: Prof. Dr. Katrin Balzer (see above for contact details). Anonymously collected or anonymised data cannot be deleted in the event of revocation, however, as it is not possible to trace the data back to individual persons.

If you have any queries or complaints regarding data protection, please contact the data protection officer at the University of Lübeck: x-tention Informationstechnologie GmbH, Karl- Drais-Str. 4e, 86167 Augsburg, e-mail: datenschutz@uni-luebeck.de. In the event of a complaint, you can also contact the competent data protection supervisory authority: Independent Centre for Data Protection Schleswig-Holstein, Holstenstraße 98, 24103 Kiel, e-mail: mail@datenschutzzentrum.de.

Please do not hesitate to contact us if you have any questions!

Thank you for your interest and best regards,

Prof. Dr Katrin Balzer

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Informed consent for participation in the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)".

I have received, read and understood the written study information for the above-mentioned study. I was informed in detail - verbally and in writing - about the aim and the course of the study, the risks and benefits of participation, my rights and obligations and the voluntary nature of participation. I had the opportunity to ask all my questions. These were answered satisfactorily and completely.

Surname, first name guardian/ Authorised representative

Date of birth

I was informed about the study by the following person:

Surname, first name study team member

Telephone number

I hereby declare the participation of the resident(s) in my care:

Surname, first name resident

Date of birth

in the above-mentioned study. I have been informed that participation is voluntary and that I have the right to terminate it at any time without giving reasons and without any disadvantage to me or the resident.

I agree to the collection and storage of the data mentioned in the study information, especially the personal data. I have been informed about the possibilities of the right to information and the right to object.

I have received the study information and a copy of this consent.

Place, date

Signature of guardian/ Authorised representative

Place, date

Signature study team member

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Reported on page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract
	2b	All items from the World Health Organization Trial Registration Data Set	✓
Protocol version	3	Date and version identifier	Abstract
Funding	4	Sources and types of financial, material, and other support	21
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, 21
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	21
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	22

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	5,6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6,7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n.a.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8,9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n.a.

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9,11,12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	9,10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			10
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	10

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	10
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	10-14
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14,15
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	16

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n.a.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	16
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n.a.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	17
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n.a.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	21
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17,18

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	21
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplement
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol for an exploratory cluster-randomised trial

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Primary Subject Heading:	Nursing
Secondary Subject Heading:	Evidence based practice, Health services research, Medical education and training
Keywords:	Aged, Health Services for the Aged, Patient-Centered Care, Quality of Life

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol for an exploratory cluster-randomised trial

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ABSTRACT

Introduction

Older age is associated with multi-morbidity, chronic diseases and acute deteriorations and leads to complex care needs. Nursing home residents are more often unnecessarily transferred to emergency departments or hospitals than community dwellers - largely due to a lack of qualified staff and diffusion of responsibility in the institutions. In Germany, only few academically trained nurses work in nursing homes, and their potential roles are unclear. Therefore, we aim to explore feasibility and potential effects of a newly defined role profile for nurses with Bachelors' degree or equivalent qualification in nursing homes.

Methods and analysis

A pilot study (Expand-Care) with a cluster-randomised controlled design will be conducted in 11 nursing homes (cluster) in Germany, with an allocation ratio of 5:6 to the intervention or control group, aiming to include 15 residents per cluster (165 participants in total). Nurses in the intervention group will receive training to perform role-related tasks such as case reviews and complex geriatric assessments. We will collect data at three timepoints (t0 baseline, t1 three months and t2 six months after randomisation). We will measure on residents' level: hospital admissions, further health services use and quality of life; clinical outcomes (e.g. symptom burden), physical functioning and delivery of care; mortality, adverse clinical incidents and changes in care level. On nurses' level we will measure perception of the new role profile, competencies, and implementation of role-related tasks as part of the process evaluation (mixed methods). An economic evaluation will explore resource use on residents' (health care utilisation) and on nurses' level (costs and time expenditure).

Ethics and dissemination

The ethics committees of the University of Lübeck (Nr. 22-162) and the University Clinic Hamburg-Eppendorf (Nr. 2022-200452-BO-bet) approved the Expand-Care study. Informed consent is a prerequisite for participation. Study results will be published in open access, peer reviewed journals, and reported at conferences and in local healthcare providers' networks.

Trial registration

German Registry for Clinical Trials, DRKS00028708 (registered May 25, 2022). Manuscript based on protocol version V1.3 (Sept 25, 2022).

Strengths and limitations of this study

- The intervention was developed systematically based on a root cause analysis of unplanned hospital admissions or emergency service utilisation and participatory workshops with patient representatives and other stakeholders.
- A logic model including assumed causal mechanisms, distinct distal and proximal (mediating) outcomes and potentially relevant moderators (context factors) guides the evaluation, including a comprehensive process evaluation.
- Outcomes will be assessed at patient and staff levels and include patient-reported outcome and experience measures as well as objective measures such as hospital admissions.
- A potential limitation is the risk of early drop out of whole clusters (nursing homes) due

to nursing staff shortages in the German elderly long-term care sector.

- This pilot study will be exploratory in nature as we will rely on a small sample size and a short follow-up of three months after completion of implementation.

Keywords: nursing homes, complex care needs, graduate nursing education, pilot project, cluster-randomised trial

INTRODUCTION

Background and rationale

Older age and aging processes are associated with multi-morbidity, including both acute and chronic diseases. Symptom control in long-term illnesses, cognitive impairment, an overall high degree of dependency or need for end of life care lead to increasingly complex care needs.[1,2] Nursing professionals in nursing homes (NH) are often the first to decide whether the use of emergency medical services is necessary when residents' health status deteriorates. These decisions are influenced by diverse contextual factors, among them unclear expectations of responsibilities of the NH regarding primary care, limited availability of qualified staff and the fear of exceeding one's scope of responsibilities. Inadequate access to multidisciplinary outpatient care, as well as poor communication with other decision-makers or families exerting pressure may also contribute to hospital admissions although in principle they might be avoidable.[3] Consequently, NH residents are significantly more often transferred to hospitals than community-dwellers. 90% of these hospital transfers are unplanned, and between 4% and 55% are considered avoidable.[4] For these residents, skills of academically qualified nurses could create a meaningful benefit.[5] Academic training enables nurses to combine their clinical expertise with scientific evidence to provide care according to patient's or resident's preferences (evidence-based nursing).[6] Care that is guided by individuals' values and preferences is referred to as person-centred care and can improve patient experiences and outcomes, and enhance the efficiency of healthcare delivery.[7,8]

With the introduction of the new Nursing Professions Act (PflBG) 2020, academic nursing education is now implemented as a regular primary nursing qualification in Germany. Work areas of Bachelor graduates are predominantly in direct patient care, but include taking over process responsibility in complex or unclear patient situations.[9] However, surveys show that Bachelor graduates rarely find satisfyingly suitable job profiles.[10] Especially in the long-term care setting, defined work areas and competency-oriented differentiation of tasks and responsibilities for Bachelor-qualified nurses are lacking.

In the Expand-Care project, we developed a role profile for academically trained nurses in a participatory research process:[11] PEPA (German acronym for nurse specialists with expanded competencies for person-centred elderly care, [Pflegefachperson mit erweiterten Handlungskompetenzen für personenzentrierte Pflege in der Altenpflege]). The PEPA covers competence areas with a focus on residents' needs regarding management of chronic and geriatric diseases, and empowerment and communication. Comprehensive implementation strategies target educational, supervisory and organisational levels.

Trial objectives

The objective of this trial is to explore feasibility, safety and resident-relevant benefits of the Expand-Care intervention programme promoting person-centred care in NH residents.

To assess safety and potential patient-relevant benefits, we will examine:

(1) What are potential effects of the programme on

a. patient-relevant indicators of quality of care (distal outcomes) like hospital admissions, emergency service utilisation, residents' out-of-hour physician contacts, and quality of life within 6 months of follow-up?

b. intermediate (proximal) outcomes regarding residents' clinical wellbeing and functioning and the delivery of care?

(2) What is the risk of adverse effects of the programme on residents' health, e.g. with regard to mortality?

To assess programme feasibility, we will conduct a process evaluation addressing a) nurses' ability to acquire, maintain and apply the desired competencies for expanded care tasks; b) implementation (reach and dose); c) nurses' perception of feasibility and fidelity of the intervention; d) adaptations to intervention care tasks; e) changes to care processes induced by the intervention; and f) changes to subjective professional roles, self-concept and self-efficacy of nurses.

With an economic analysis we will assess implementation costs of the programme and consequences for health care resource utilisation.

METHODS AND ANALYSIS

Trial design

The Expand-Care trial is an exploratory bicentric cluster-randomised trial (cRCT). Nursing homes (clusters) will be randomly assigned either to the implementation of the Expand-Care intervention programme (intervention group) or to usual care (control group). Follow-up measurements take place 3 (t1) and 6 months (t2) post randomised allocation. For the process evaluation, the trial includes a parallel mixed methods study which is described in detail in Supplement 1.

Study setting and participants

The trial will take place in 11 NH in Northern Germany. Eligible residents living in the participating NH will be invited to participate. Each NH has to nominate a qualified nurse specialist who will perform the intervention if randomised to this group (Table 1, eligibility criteria).

Table 1. Eligibility criteria for nursing homes, residents and nurse specialists

Participants	**Eligibility criteria**
Nursing homes	*All of the following conditions apply:* – provides in-patient long-term care services – provides a minimum of 50 beds

	– does not participate in other research projects on prevention of hospital admissions and emergency service utilization
Residents	*One of the following conditions applies:* – receives care services at the care level 3 or higher – receives care services at the care level 2 *and* fulfils at least one of the following conditions: … *multimorbidity confirmed by suffering from three or more co-existing chronic diseases (DEGAM 2017)[9]* … *hospital admission or utilisation of out-of-hour physician contacts or emergency services within the previous eight weeks.*
Nurse specialists	*One of the following conditions applies:* – academic qualification (Bachelor degree) and at least one year of job practice after professional licensing – 3 years vocational training and additional qualification in geriatric, gerontopsychiatric or palliative care after professional licensing – 3 years vocational training and additional qualification (300 h cumulative in the last 2 years) after professional licensing – 3 years vocational training and above average performance, assessed by head nurses based on pre-specified criteria (e.g. knowledge and skills, open-mindedness for innovation and improvement of nursing practice, and personal competencies)[12]

DEGAM: Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin e.V. (German association for primary care);[13] German care levels (range from 0 to 5) are assessed by expert raters of the German statutory health care insurance and can be described as low (0/1/2), medium (3/4), high (5).

Interventions

Control group residents will receive optimised usual care: we will offer a 1.5 h workshop on principles of person-centred care to control group NH.

Intervention group residents will receive person-centred care through the implementation of a new role profile for nurses with expanded competencies (PEPA). The role profile addresses four competence areas: 1) managing chronic diseases; 2) empowerment and communication; 3) person-centred care network; 4) organisation (Figure 1, logic model).

In practice, PEPAs will perform specific intervention components (PEPA activities) which are defined as core (obligatory) and optional activities on direct care (resident-related) and organisational levels (Table 2).

Table 2. Intervention components

Core activities	Optional activities
Direct care level	
– Implementation of a structured care plan – Structured conversations with residents and relatives – Case conferences – Joint visits with physicians – Hospital visits – Geriatric assessments – Pain management	– Short checklist for external care providers (residents' essential information)
Organisational level	
– Introduction of ISBAR for handovers and communication with general practitioners – Nurse led staff training on ISBAR – Monitoring of residents' advance care planning status	– Nursing research activities – Supervision and consultation for colleagues

ISBAR: Structure for interprofessional communication consisting of Identification, Situation, Background, Assessment, Recommendation.

Parallel to the intervention development, we have designed implementation strategies targeting areas of *education*, *supervision/evaluation* and *organisation*. [14,15] Detailed information on rationale, target groups, mode of delivery and materials for each intervention component and implementation strategy is described according to the TIDieR template (Supplement 2).[16]

The main *educational strategy* is a 300-hour training for participating nurses (PEPA training programme) led by lecturers of the University of Lübeck. This education will be delivered based on a detailed curriculum containing two modules: 1) enhanced roles and competencies for nurses, and 2) person-centred nursing and care for people with chronic diseases. Module 1) targets topics such as interprofessional communication, coaching and consulting, evidence-based practice, role development, and legal aspects. Example topics of module 2) are pathology of chronic diseases, geriatric and nursing assessments, exacerbation of symptoms, pharmacological therapy, models of self-care, person-centred care, and advanced care planning. Training methods comprise classroom and online teaching, training on the job and self-study time (about 100 hours each). Training will start immediately after randomisation and last for three months. *Supervision and evaluation strategies* will be performed by members of the research team via on-site or online mentoring sessions. By target agreement talks with PEPAs and nurse managers, a shared goal for the implementation will be established. Supervisors will review and give feedback on PEPAs' performance of the implementation of intervention components in practice.

Organisational strategies aim to strengthen NHs' commitment to the study: formal cooperation agreements between the university and participating NH comprise responsibilities regarding recruitment of residents and granted worktime for PEPAs. NH are allowed to adapt the intervention locally to their needs to a defined degree (optional activities, Table 2). A detailed description of the intervention development and the PEPA training programme will be published elsewhere.

Outcomes

Trial outcomes are based on the programme's logic model (Figure 1) and comprise distal and proximal outcomes. Distal outcomes include patient-important indicators of the quality of care that are assumed to be influenced by the Expand-Care intervention and are highly critical to residents' wellbeing (e.g. hospital admissions, need for emergency services, and health-related quality of life). Proximal outcomes are variables targeted by the intervention and deemed to mediate its effects on distal outcomes. They include clinical outcomes (e.g. falls and fall-related injuries, pressure ulcers category ≥2 and patient-reported symptom burden), outcomes on physical functioning (self-care and/or health behaviour and management), and outcomes on delivery of care in terms of patient-reported experiences and use of potentially inappropriate medication. For the assessment of safety, we consider mortality of residents, other adverse events not captured by distal or proximal outcomes, and increased care needs of residents (care level). Outcomes will be followed-up until 6 months post randomisation (Figure 2).

Sample size

Sample size is calculated for the purpose of planning a confirmatory trial rather than any confirmatory efficacy analyses (Supplement 3, statistical study plan). We expect to achieve a cluster size of 15 residents per nursing home based on an average nursing home size of 50 residents, eligibility rate of 60 % and participation rate of 50 %.[17-20] Considering an intra-cluster correlation coefficient of 0.021 [21, 22] this mean cluster size results in a design factor (inflation factor) of 1.294. Based on empirical results on the annual incidence of hospital admissions among nursing home residents,[18] it is assumed that the proportion of residents with at least one hospital admission in the control group will be 25% (i.e. 0.25 rate of hospital admissions) for the six-month observation period in this study. Furthermore, it is assumed that the Expand-Care programme to be tested in the intervention group can realistically lead to a reduction in the incidence by a maximum of 10% to 15% (= 0.152 rate of hospital admissions) within the six-month observation period. The planned sample sizes allow these rates to be estimated with a confidence interval of +/- 0.119 in the control group and +/- 0.0985 in the intervention group. This is considered to be sufficient for a precise calculation of the required sample size for subsequent randomised controlled trials.

Initially, 12 NH had consented to participate. One NH declined participation before recruitment of residents had started and we revised the sample size calculation. Now, in total, 11 NH shall be included with at least 15 participating inhabitants for a total of 75 (5x15) and 90 (6x15)

individual participants per study arm (165 participants in total). We will not replace institutions or residents lost to follow-up.

Recruitment

We will apply two recruitment strategies for NH: 1) eligible facilities already collaborating with the study centres (Universities) will be invited to participate and 2) public lists of NH in the target regions will be screened and eligible facilities (Table 1) invited to participate. Invitations will comprise written material (per post and email) and follow up phone calls by the research team.

Recruitment of residents will start after NH directors' written confirmation of participation. Ward nurses will screen residents' eligibility following the given eligibility criteria. If residents (or their legal guardians, if applicable) have confirmed their willingness to participate, research staff will check eligibility based on information from residents' charts.

Allocation

NH (unit of randomisation) will be randomised with an allocation ratio of 5:6 to the intervention or control group. Investigators in charge of the respective NH will initiate randomised allocation after completion of baseline assessment (t0). The random sequence will be generated by permutation with validated software.

Registration and randomisation of NH are carried out centrally at the Institut für Medizinische Biometrie und Statistik of the Universitätsklinikum Schleswig-Holstein, Campus Lübeck, at the Universität zu Lübeck. This ensures the concealment of allocation until the intervention commences (Supplement 3, statistical study plan).

Blinding

Due to the intervention's nature, blinding of residents and nursing staff against the allocated intervention will not be feasible. Information provided to participants contains no specific hypotheses about possible directions of effects in measured outcomes. Study assistants blinded to allocation will collect distal outcome data (hospitalisation). The trial statistician will be unaware of assignments until after blinded review and data base closure (Supplement 3, statistical study plan).

Data collection methods

Baseline assessment

At resident level, we will extract data on age, sex, date of moving into the NH (length of stay), current medical diagnoses and treatment, nomination of legal guardians and existence of agreements for advance care planning from residents' records.

Additionally, NH directors will provide baseline information about NH characteristics (e.g. sponsorship, number of care places, wards, residents, nursing staff capacity, medico-technical infrastructure, and mode of collaboration with external health care providers) in a written standardised questionnaire.

Potential benefits and safety outcomes

We will extract data from residents' record using instruments which have been successfully applied in other studies.[22,23] To collect self-reported data, we will conduct standardised interviews with residents and/or proxies (Table 3, outcomes and data sources).

Table 3. Outcomes, measurements and metrics for the evaluation of potential benefits and safety of the Expand-Care intervention

Outcome	Specific measurement	Specific metric	Time point		
			t0	t1	t2
Distal outcomes (extracted from residents' record)					
Hospital admissions (primary outcome)	Number of admissions	Within 3 months	X	X	X
	Number of hospital days	Within 3 months	X	X	X
	Reason for admission, initiator, discharge diagnosis	Within 3 months	X	X	X
Out-of-hour physician contacts	Number of contacts	Within 3 months	X	X	X
	Number of contacts	Within 3 months	X	X	X
	Kind of contacts: telephone, visit to nursing home	Within 3 months	X	X	X
	Reason for admission, initiator	Within 3 months	X	X	X
Emergency service use	Number of service utilizations	Within 3 months	X	X	X
	Kind of services used: (emergency) ambulance, emergency control centre, emergency room	Within 3 months	X	X	X
Distal outcomes (self-reported by resident or proxy assessment by nursing staff)					
Health-related quality of life	EuroQol-5 Dimension-5 Level (EQ-5D-5L)	At the day of data collection	X		X
Proximal outcomes (data extracted from residents' records)					
Falls and fall-related injuries	Number of falls and fall-related injuries	Within 3 months	X	X	X
Pressure ulcer category ≥2	Number or newly developed pressure ulcers per category	Within 3 months	X	X	X
Incontinence-associated dermatitis (IAD)	Number or newly developed IAD	Within 3 months	X	X	X
Potentially inappropriate medication	Prescribed medication and dosage, evaluated according to PRISCUS criteria	Current medication	X	X	X
Contacts with GP	Kind of contact (remote via fax, phone or other electronic form, visit in nursing home or GP office)	Within 3 months	X	X	X

	Reason for contact, initiator	Within 3 months	X	X	X
	Planned vs unplanned	Within 3 months	X	X	X
Proximal outcomes (self-reported by resident)					
Symptom burden	Four-dimensional Symptom Questionnaire (4DSQ) Dimensions: distress, depression, anxiety, somatisation	Within the last seven days	X		X
Self-care/ health behaviour and management	LTCQ-8, German version	Within the last 4 weeks	X		X
Person-centredness of care	PCQ-P-G, Dimensions: safety climate and everyday living climate		X		X
Safety outcomes (harms) (data extracted from residents' records)					
All-cause mortality	Death (date, reasons)	Within 3 months		X	X
Level of care	Current level of care based on the Nursing Care Insurance Act (Sozialgesetzbuch XI)	Current level	X	X	X
Resource use (data extracted from residents' records)					
Other health care utilisation	FIMA categories of resource use (e.g. medical specialists, physiotherapy, occupational therapy, speech therapy, rehabilitation)	Within 3 months	X	X	X

4DSQ: Four-dimensional Symptom Questionnaire; EQ-5D-5L: EuroQol-5 Dimension-5 Level; FIMA: [Fragebogen zur Inanspruchnahme medizinischer und nicht-medizinischer Versorgungsleistungen im Alter] Questionnaire for Health-Related Resource Use in an Elderly; GP: General practitioner; IAD: incontinence associated dermatitis; LTCQ-8: Long-term conditions questionnaire short form; PRISCUS: List of potentially inadequate medication for elderly people.

Distal outcomes

Hospital admissions as primary outcome is defined according to Müller et al.[23] For each hospital admission, we will collect information about the kind (elective versus unplanned), initiator, reason, length of stay, and discharge diagnoses, similarly for each episode of general practitioner, medical specialists, out-of-hour physician or emergency services utilisation.

Health-related quality of life will be measured using the EQ-5D-5L (EuroQol Group).[24] The EQ-5D-5L measures health-related quality of life on five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. It uses 5-point-ordinal scales ranging from

1 (no problems) to 5 (unable to/extreme problems). Dimensions are combined into a 5-digit code that represents the unique health state. This code can be transformed into an index value between 0 and 1 using standard value sets. The EQ-5D-5L contains a visual analogue scale (EQ VAS) ranging from 0 to 100 (worst to best possible health status).[25-27] We will apply German versions of the EQ-5D-5L for self-reported quality of life to all residents with a Dementia Screening Score <4, else, we will perform the EQ-5D-5L proxy instrument with nurses in charge of residents at data collection.[22,28]

Proximal outcomes

Residents' records will provide data on falls, fall-related injuries and care activities responding to falls, pressure ulcers and IAD. Reported fall-related injuries will be categorised as: no injuries, minor injuries, moderate injury, major injuries, death or unclear/not reported.[29] For pressure ulcers, we will extract categories at first observation and at data collection as well as successive medical treatments (hospital admission, outpatient surgical treatment) from residents' records. All record entries classifying observed skin damages as IAD or describing perianal/perigenital skin damages associated with urinary or faecal incontinence and information about progression or healing since first observed will be extracted.

We will document current medication prescriptions (permanent and on-demand) and classify them as potentially inadequate according to the PRISCUS list relevant for the German healthcare system.[30]

The Four-Dimensional Symptom Questionnaire (4DSQ) is a 50-item self-report questionnaire designed to measure common expressions of psychological problems in primary care patients. Items are distributed over four scales: distress, depression, anxiety and somatization. With a reference period of the last 7 days it offers a 5-point Likert scale (scored 0 (no); 1 (sometimes), and 2 (regularly, often, and very often or constantly)). Corresponding item scores are summed up for scale scores.[31,32] Each dimension is interpreted in itself. We will use the cross-culturally validated German version of this instrument.[32]

We will use the long-term conditions questionnaire short-form (LTCQ-8) to measure self-care comprising health behaviour and management. The LTCQ-8 is an 8-item questionnaire assessing the impact of long-term health conditions on people's lives and their support needs.[33,34] A long-term condition is defined as any health issue that has lasted, or will last, for at least 12 months. It uses a 5-point Likert-scale (never – rarely – sometimes – often – always). Each question is scored with values ranging from 0 to 4 or 4 to 0 (depending on the question's meaning) to a single composite measure. A higher score indicates a higher health-related quality of life. We will generate a German version of this instrument prior to this trial following the translation and evaluation protocol of the original scale's authors.

With the German Person-centred Climate Questionnaire – Patient version (PCQ-P-G) we will assess residents' perception of person-centredness of experienced care delivery.[35,36] PCQ-P-G is a 14-item self-report questionnaire measuring person-centredness of care in the dimensions: a climate of safety, a climate of everydayness and a climate of community. It uses a 6-point Likert scale ranging from 1 (no, I totally disagree) to 6 (yes, I totally agree). Items are

summated to an overall score and one sub score for each dimension. For the present study, we will use only dimension-wise summated items on a climate on safety and a climate of everydayness, as the climate of community is not addressed by the intervention.

Safety outcomes

We will extract residents' current need of nursing care (care level) based on external assessment of residents' care needs according to criteria laid down in the Nursing Care Insurance Acts (Sozialgesetzbuch XI). Criteria cover functional impairments (e.g. regarding mobility, communication and cognitive abilities), behavioural and psychological wellbeing, self-care (e.g. eating and drinking, personal hygiene, elimination), coping with illnesses and treatment requirements, and social participation. Care levels range from one to five, higher levels indicating larger need of (professional) care support.

NH continuously record residents' mortality. In case of death, we will extract information about date, place and reasons of death from residents' records.

Resource use

We will use the FIMA questionnaire (FIMA: Questionnaire for Health-Related Resource Use in an Elderly) to measure health care utilisation (monetary value by standard unit costs).[37,38] The FIMA is adapted to the German health care system and specialised for elderly populations. It measures utilisation of health care providers (e.g. hospital stays, outpatient visits to physicians and non-physicians, use of pharmaceuticals or out-of-hour care).

Data management

All resident-related data will be documented with patient identifiers. (Sub-)investigators will keep patient identification lists and NH identifiers under lock at the respective study centre, separated from resident data, and data will be archived for ten years.

Worksheets used for data collection in NH are defined as source data. Source data will be transferred to an eCRF (electronic case report form), which the (sub-)investigator will check and sign digitally.

We will manage data with the study management tool secuTrial®. The database programmer will in cooperation with the responsible biometrician and the documentarists check the study database for errors before use and afterwards release it for use. Data of the worksheets are entered into the secuTrial®-database via input masks. Data will be analysed using SAS 9.3 or higher. We will implement editing checks in the electronic data capture system (EDC) and use SAS 9.3 or higher for manual programming.

A daily complete backup of all data will take place. Correctness of data is checked by further range, validity and consistency checks. Implausible or missing data are queried at the test centre (query management) and corrected or supplemented if necessary. We will document any changes to the data, e.g. due to the incorporation of answered queries, in the database via automatic change tracking system (audit trail). A hierarchical access concept based on

roles makes unauthorised access to patient data impossible. Anonymity of data within the scope of evaluations is ensured.

We will use the Medical Dictionary for Regulatory Affairs (MedDRA) to code database entries on prior diseases, co-morbidities, and diagnoses and the anatomical, chemical and therapeutic classification (ATC) for drugs to code medication. Minimal objective is the first level of those hierarchical classifications.

After final analyses the data base will be closed and data handed over to the study management for archiving.

Statistical methods

To prepare a confirmatory clinical trial that will be adequately powered, this pilot study will yield two-sided 95%-confidence intervals for the 6-months incidence of hospitalisation that extend <10% in either direction. All participants will be analysed by intention to treat. Absorbing endpoints like death are considered as competing risk or worst possible assessment, so that other missing observations may be considered missing at random. The hospitalisation rates in treatment groups are estimated by mixed logistic regression from the occurrence of hospitalisation within 6 months on treatment and occurrence of hospitalisation within 3 months prior to the trial (both fixed factors with two levels) and institution (random effects). The primary treatment effect estimator is the marginal odds ratio in that model fit. The hazard ratio from Cox regression and the marginal rate ratio from Poisson regression serve as sensitivity analyses. Proof of mechanism is tested at multiple significance level 0.05 in a Bonferroni-Holm procedure for sixteen endpoints of the nine variables of formal process evaluation (proximal endpoints describing changes in care). All other analyses are adjusted for the respective baseline measurement in mixed models without imputation. Safety, exploratory and sub-group analyses are pre-specified in the statistical study plan (Supplement 3). The true allocation list will be used only after all analyses will have been coded and the code tested.

Process evaluation

We will conduct an embedded parallel mixed methods study to examine processes at the cluster level (nursing facilities) and at the individual level (nursing staff, residents) in the participating NH. Data will be evaluated in terms of recruitment, implementation, intervention and maintenance, and context factors.[39] Target groups are NH managers, PEPAs, other NH nursing staff, residents and relatives. Written informed consent is a prerequisite for participation in the study. Qualitative methods of data collection are guideline-based semi-structured interviews, focus groups and observation or recording of practice supervision, conducted by trained members of the research team at the NH or via telephone (relatives). We will evaluate these data by qualitative content analysis.[40] Quantitative methods of data collection are questionnaires, which we will analyse using descriptive statistics. We will triangulate data at the analysis stage on the level of results using joint displays. The process evaluation study design and procedures are outlined in Supplement 1.

Health economic analyses

The economic evaluation covers two aspects: 1) Analysis of implementation costs, and 2) Analysis and modelling of incurred health care expenditures.

Analysis of implementation costs

Economic analysis will focus on the main implementation strategy, the PEPA training programme. This comprises time expenditures and costs for the programme (e.g. lecturer and expert fees), employers' expenses for time off (release of human capital), and time spent on PEPA training including self-study time. Considering potential government support and funding opportunities, we will develop a preliminary cost figure to estimate implementation costs in case of a positive evaluation of the intervention.

Analysis and modelling of incurred health care expenditures

Health care expenditure and savings comprise 1) avoidance of empty journeys during ambulance service missions, and 2) billable inpatient stays.

We will analyse occurring rescue service interventions (ambulance, emergency ambulance, control centre, transport to the emergency room) regarding projected costs incurred by the service, including initiators, reason for initiation and empty runs.

Reasons for inpatient stays will be derived from patients' diagnosis and discharge letters. We will therefore rate data on usage of medical services monetarily with standardised cost unit rates.

Data monitoring

A qualified Clinical Research Associate (CRA) of the ZKS (centre for clinical studies Lübeck) will conduct risk-based monitoring according to ICH GCP and written SOPs to ensure patients' rights and safety as well as reliability of trial results. Initiation visits and two regular on-site visits per study centre are planned. Recruitment of residents requires centre initiation by a CRA. Closeout visits will be conducted by telephone. Details of the monitoring, such as key data, will be defined and documented in a monitoring manual. The principal investigator will receive a monitoring report after each visit.

Harms

We will collect comprehensive data on potential harms throughout the trial to allow valid assessment of the intervention's safety. The research team will continuously supervise and follow-up implementation of the Expand-Care programme to strengthen fidelity. We will discuss any concerns due to unintended changes to care procedures or care outcomes observed and report to the Ethics Committee with a suggestion for amendments to the trial plan, if required.

Patient and public involvement

Representatives of the senior citizens advisory council and of NH resident boards participated in the intervention development. We will capture perspectives of residents, their family/ surrogates and NH staff on acceptability and feasibility of the intervention through process evaluation. Results will be presented and discussed at conferences with local health care providers and relevant stakeholders. The project's advisory board comprises representatives for patient and public, nursing science and education, nursing practice and medical law.

ETHICS AND DISSEMINATION

Research ethics approval

This trial adheres to the Declaration of Helsinki in the current version. The ethics committees of the University of Lübeck (Nr. 22-162) and the University Clinic Hamburg-Eppendorf (Nr. 2022-200452-BO-bet) approved the study protocol.

Protocol amendments

Principal investigators and the affected collaborators will consent to any amendments to this protocol before submission to ethics review. Protocol deviations are documented in writing and filed with the coordinating investigator and the trial biostatistician together with the rationale.

Consent or assent

Eligible residents and/or their authorised surrogates will receive written information about objectives and scope of the study from ward nurses. If residents are interested in further information, researchers of the study centres will provide further oral and written information (Supplement 4).

Residents will only be enrolled in the trial if they or their authorised surrogates have provided written informed consent. Residents can end participation at any time either orally or in writing, regardless of written confirmation by the surrogate. NH directors will inform the facility's residents' board, NH staff and employee representation about the objectives of the trial.

Confidentiality

For this study, we developed a comprehensive data protection concept in collaboration with the data protection official of the University of Lübeck. The concept comprises study information including information on data protection, forms for written informed consent for participants, descriptions of all data processing processes, and measures to protect data and participants rights according to the General Data Protection Regulation (Datenschutzgrundverordnung).

Access to data

The Sponsor (UKSH, Universitätsklinikum Schleswig-Holstein, nursing research unit) will retain records until 10 years after the publication of the article on the primary endpoint.

Anonymised individual patient data used for all analyses reported in the article on the primary endpoint will be made available on reasonable request for medical research purposes in easily machine-readable format.

Dissemination policy

We will publish study results following the CONSORT statement in open access, peer reviewed journals, and at conferences. A stakeholder advisory board including patient representatives discusses study procedures regularly. Furthermore, we will present results in local networks of relevant healthcare providers.

Trial status

At submission of this manuscript (17th of February, 2023) the recruitment of residents had been completed, while data collection was ongoing.

First patient in: July 26th, 2022.

Last patient out: April 13th, 2023.

CONTRIBUTORS

Roles and responsibilities

Trial sponsor: University hospital Schleswig-Holstein, Katrin Balzer; principal investigator: Katrin Balzer (KB); sub-investigators: Katharina Silies (KS), Janna Sill (JS), Tilman Huckle (TH), Simone Inkrot (SI); collaborating partners and sub-investigators: Nadine Pohontsch (NP), Dagmar Lühmann (DL), Martin Scherer (MS); health economics: Fabian Frielitz (FF); biostatistics: Reinhard Vonthein (RV), Inke König (IK); monitoring: Denise Olbrich (DO); data management: Maren Vens (MV).

Contributions

KB, SI, RV, IK, MS and DL developed the study design; RV and IK designed the statistical analysis plan for the study. FF and KB designed the economic evaluation. KS, KB, JS, NP and DL designed the process evaluation plan. KB, KS, TH, NP and DL developed the intervention. RV and MV developed the database and pilot-tested it. KS, JS, TH, NP, MV and DO were responsible for data collection, -entry and controls. Analysis and interpretation of data will be performed by RV, IK, KB, KS, NP, and DL. KS, RV and KB drafted the manuscript, all authors contributed to the writing of the report and read, provided important revisions and approved the final version of the manuscript.

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COMPETING INTERESTS

The authors declare that there are no conflicts of interests.

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Supplemental material

Supplement 1. Process evaluation

Supplement 2. Description of the intervention's components and implementation strategies

Supplement 3. Statistical analysis plan

Supplement 4. Informed consent materials

Abbreviations

CRA	Clinical Research Associate
cRCT	Cluster randomised controlled trial
DEGAM	[Deutsche Gesellschaft für Allgemeinmedizin und Familienmedizin e.V.] German association for primary care
DM	Data management

eCRF	Electronic case report form
EDC	Electronic data capture
4DSQ	Four-Dimensional Symptom Questionnaire
EQ VAS	Visual analogue scale developed by the EuroQol Group
EQ-5D-5L	Tool to measure health-related quality of life developed by the EuroQol Group
FIMA	Questionnaire for Health-Related Resource Use in an Elderly population
HH	City of Hamburg
HL	City of Lübeck
IAD	Incontinence associated dermatitis
ICH GCP	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – Good Clinical Practice
ISBAR	Introduction, Situation, Background, Assessment, Recommendation
LTCQ-8	Long-term conditions questionnaire short-form
NH	Nursing home
PCC	Person-centred care
PCQ-P-G	German Person-centred Climate Questionnaire – Patient version
PEPA	[Pflegefachperson mit erweiterten Handlungskompetenzen für personenzentrierte Pflege in der Altenpflege] Nurse specialists with expanded competencies for person-centred elderly care
PflBG	[Pflegeberufegesetz] Nursing professions law
PREM	Patient-reported experiences measures
PROM	Patient reported outcomes measures
SAP	Statistical analysis plan
SIS®	Strukturierte Informationssammlung
SOP	Standard operating procedure
TIDieR	Template for Intervention Description and Replication
UKSH	[Universitätsklinikum Schleswig-Holstein] University hospital Schleswig-Holstein

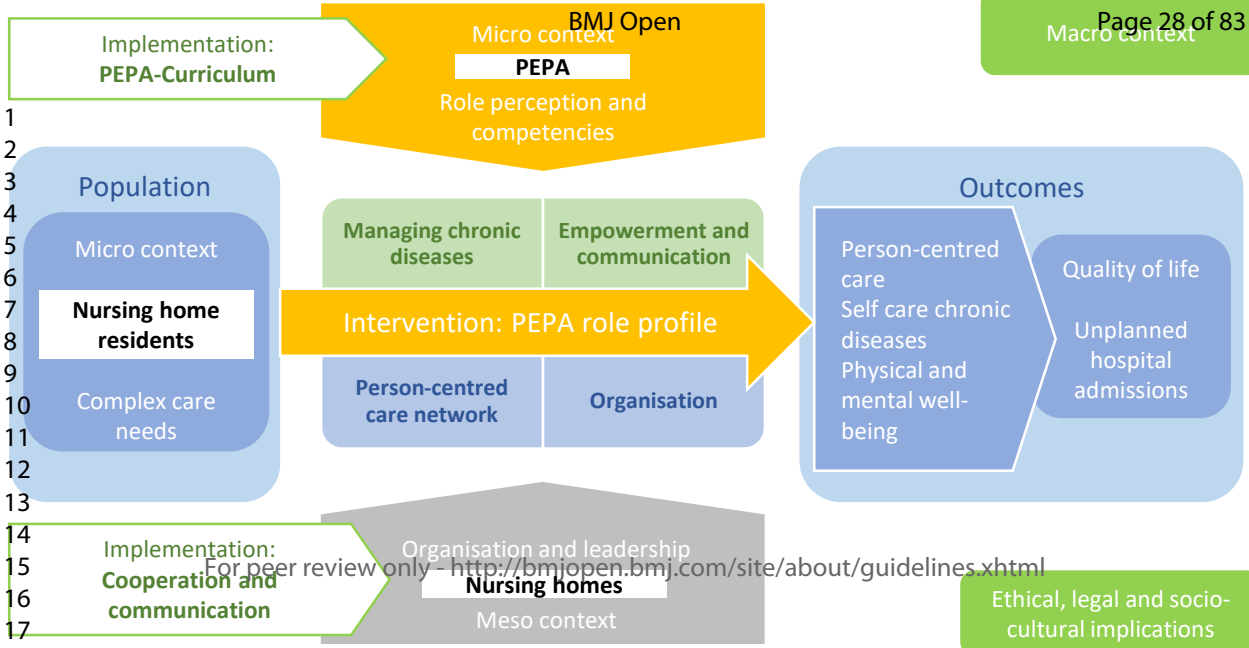
ZKS	[Zentrum für klinische Studien] Centre for clinical studies

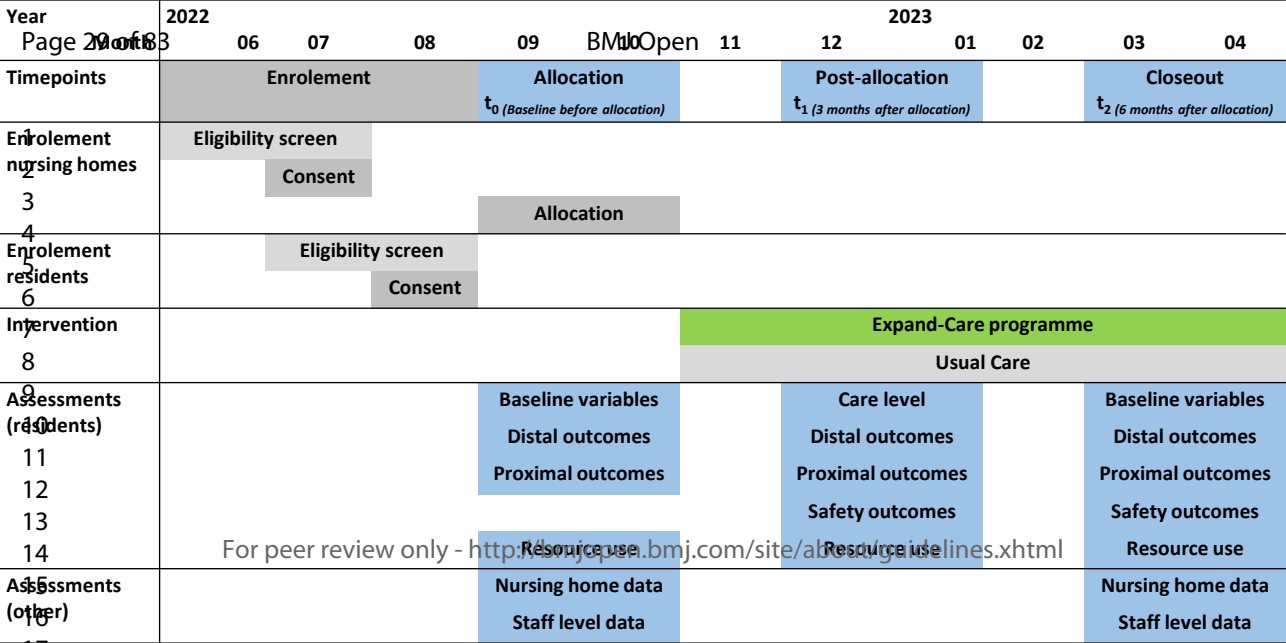
FIGURE TITLES AND LEGENDS

Figure 1. Logic model of the Expand-Care intervention and implementation strategies

PEPA: German acronym for nurse specialists with expanded competencies for person-centred elderly care.

Figure 2. Participant timeline





Supplement 1 to

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol of an exploratory cluster-randomised trial

Expanded nursing competencies to improve person-centred care for residents with complex care needs (Expand-Care): **study protocol for the process evaluation** of an exploratory cluster-randomised trial

Based on the process evaluation study protocol version: 1.0, August 12th, 2022

Synopsis

Study title	Expanded care competencies to improve person-centred care for nursing home residents with complex care needs (Expand-Care): **process evaluation**
Short title of the study	Expand-Care
Study no.	DRKS00028708
Ethical approval	Approval of the main study: 22-162, decision on 05/05/22 Approval of the process evaluation amendment: decision on 22/08/22
Study design	Mixed methods study for the process evaluation (main study: cluster-randomised, parallel, bicentre, national, open, controlled)
Indication	Nursing home residents with complex care needs
Aim	Exploration of feasibility, related to the implementation of the intervention and implementation of the study procedures, as well as evaluation of the intervention, mechanisms of action and contextual factors.
Sponsor	University Medical center Schleswig-Holstein
Principal investigator	Prof. Dr Katrin Balzer Section for Research and Teaching in Nursing, Institute for Social Medicine and Epidemiology, University of Lübeck
Inclusion criteria for care facilities	Hamburg or Lübeck region, >50 resident places, long-term care according to §43 SGB XI
Inclusion criteria for residents	Care level 3 or Care level 2 and either >2 chronic conditions or care level 2 and one unplanned acute medical care event within the last 8 weeks.
Intervention	Role profile for nursing professionals with expanded competencies. Intervention components are the planning and evaluation of residents' care based on the structured information collection (SIS) and tasks individually adapted to participants needs, e.g. structured conversations, participation in general practitioners' visits, case conferences and geriatric assessments. To support implementation, nursing professionals participate in a comprehensive training programme (300 hours in three learning formats: Contact hours, self-study, training on the job).
Observation period	6 months
Process evaluation outcomes at cluster level	Recruitment of institutions and nurses, implementation and learning outcomes of the training programme (Kirkpatrick model), contextual factors of nurses and organisations.
Process evaluation outcomes at resident level	Recruitment of residents, acceptance of intervention components and contextual factors among residents and relatives.
Sample	11 facilities from two regions (Hamburg and Lübeck area). In total approx. 12 residents, 6 care managers, 6 PEPAs ("Pflegefachperson mit erweiterten Kompetenzen für personenzentrierte Pflege in der Altenpflege"), 42 members of nursing staff (focus group), 120 members of nursing staff (questionnaire), 12 relatives, 6-8 lecturers.
Start & Duration	Total project duration: 01/04/21 to 31/03/24, inclusion of first participants in the cluster-randomised trial: August 2022
Funding agency	Federal Ministry of Education and Research FKZ: 01GY2003A (UzL/UKSH); 01GY2003B (UKE)

Content

Abstract

Background

Older people with complex care needs living in nursing homes (NH) are more likely to receive unplanned emergency or acute inpatient care than those living at home. The frequency of these care needs can be reduced through the employment of nurses with expanded competencies. In the Expand-Care study, a newly developed nursing role profile comprising expanded competence areas and tasks (intervention components) is tested in an exploratory cluster-randomised trial (DRKS00028708). Outcomes at residents' level are quality of life and unplanned acute medical care. The intervention is implemented by nursing professionals with above-average qualification profiles (German level DQR 6, equivalent to Bachelor's degree). To support implementation, these nurse specialists will receive a specifically developed training programme.

The intervention is complex, as it contains several components, targets micro and meso level and addresses several target groups. Following the UK-MRC framework for the development and evaluation of complex interventions in health, this warrants a comprehensive process evaluation.

Aim

Through the process evaluation, the implementation of the new role profile (intervention), its mechanisms of impact and relevant contextual factors will be investigated. Thus, insights into the feasibility as well as specific barriers and facilitating factors for the implementation in long-term care will be gained.

Methods

Parallel triangulation design embedded into the main trial: Processes at the cluster level (nursing facilities) and at the individual level (nursing staff, residents) in the participating nursing facilities of the Expand Care study will be examined. Target groups are nursing home managers, nurse specialists, other nursing staff of participating facilities, residents and relatives. Written informed consent is a prerequisite for participation in the study. Qualitative methods of data collection are guideline-based semi-structured interviews, focus groups and observation or recording of practice supervision, which are evaluated by qualitative content analysis. Quantitative methods of data collection are questionnaires, which are analysed using descriptive statistics. For the parallel mixed methods design, data is triangulated at the analysis stage using joint displays.

Expected results

The results of the process evaluation provide an important basis for interpreting the feasibility and effectiveness of the newly developed role profile for nurses with expanded competencies. They will be the basis for the development of study design and methods of a future effectiveness study.

Abbreviations

DQR	German Qualifications Framework
EL	Head of nursing home
IG	Intervention group
CG	Control group
GP	General practitioner
LTCQ	Long Term Conditions Questionnaire
LZP	Nursing home
PCQ	Person-centred Climate Questionnaire
PDL	Nurse manager
PEPA	PEPA: nurse with expanded competencies in person-centred care for the elderly
SHURP	Swiss Nursing Homes Human Resources Project (questionnaire)
UK-MRC	United Kingdom Medical Research Council

1. Background

1.1. Introduction

Older age is associated with increasing multimorbidity, which can include both chronic and acute illnesses and leads to increased care needs. Symptom control to prevent exacerbation of chronic diseases, cognitive impairment, frailty and high levels of care dependency increase the complexity of care needed for this population (Chadborn et al. 2019, Kiljunen et al. 2017). To meet these demands, a need for more highly qualified care professionals has been identified. Academic training for nurses has been established in Germany since 2003/2004. So far, only few academically trained nurses work in nursing homes, and role profiles are unclear. The aim of the Expand-Care research project is to develop a clear role profile for academically trained nursing professionals in nursing homes as an intervention and to test its possible effects and feasibility.

1.2. Expand-Care Intervention

The intervention is addresses two target groups: Residents with complex care needs in long-term care and nursing professionals with a qualification level equivalent to level 6 of the German Qualifications Framework (DQR, Deutscher Qualifikationsrahmen). The intervention is defined as a role profile of a nursing professional with extended competencies: PEPA (German acronym for nurse specialist with extended competences for person-centred care in long-term care). It focuses on four competence areas: 1) dealing with chronic and geriatric diseases, 2) empowerment and communication with residents, 3) building and maintaining a person-centred care network, and 4) organisation/institution. These areas comprise fields of action and goals. In order to implement these, various intervention components (see Table 1) were developed on resident related level as well as on organisational level. For the implementation of the intervention in nursing homes (NH), a distinction is made between core components and optional components (Tab. 1). The optional components include activities that are to be prioritised and adapted within the facility depending on their specific needs.

Table 1: Intervention components

	Core components of the intervention	Optional components
Resident related	• Planning and evaluating care • Structured conversation with residents • Structured conversation with relatives/ surrogates • Geriatric assessments • Joint visits with physician • Case conference • Hospital visit • Pain management	• Short form resident information
Organisation related	• Handover according to ISBAR • Structured fax communication according to ISBAR • Nurse-led staff training • Monitoring of Advance Care Planning	• Nursing research • Supervision • Collegial counselling

Various implementation strategies were developed to support the introduction of the intervention. These are measures to enable the implementation of the intervention or to overcome barriers to implementation. These strategies include a comprehensive additional training programme for the nursing professionals (PEPA training), monitoring and evaluation of the intervention by means of a PEPA manual and target agreement meetings, as well as measures on the organisational level, for

example a cooperation agreement with the LZP and possibilities to adapt the intervention (Figure 1, logic model).

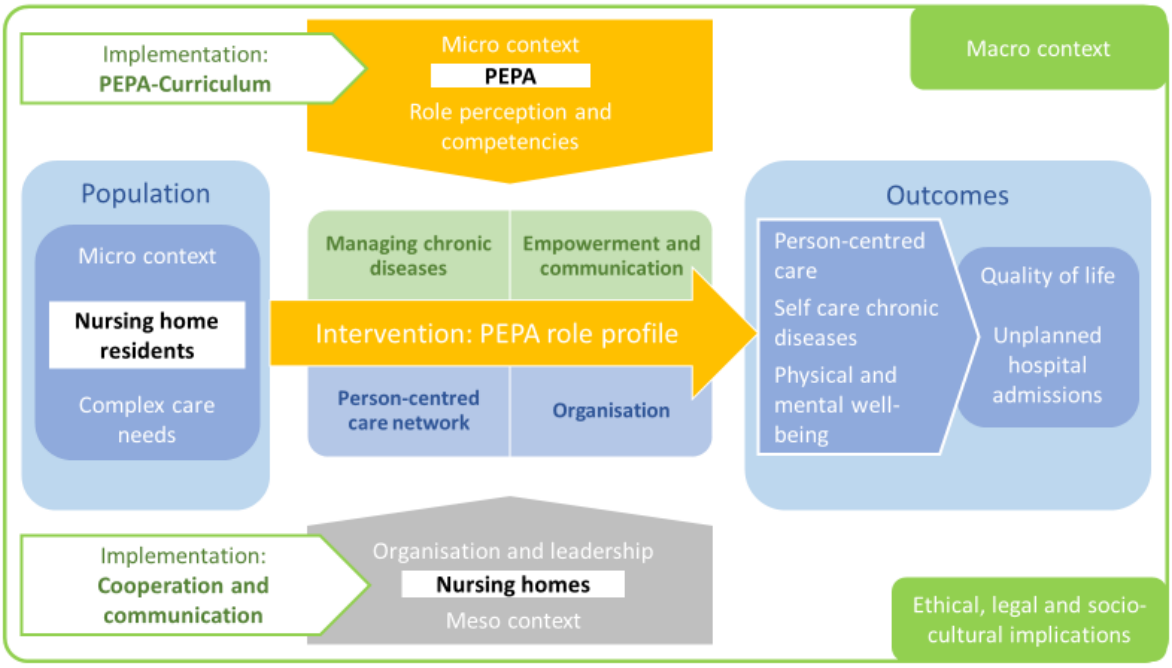


Figure 1: Logic model of the Expand-Care intervention

1.3. Expand-Care pilot study

A pilot study with a cluster-randomised controlled design will be conducted in 11 care facilities with the aim of including 15 residents and one caregiver per facility. Data collection will take place at three time points: t0 (baseline, September 2022), t1 will take place three months (+92 days) and t2 six months (+184 days) after randomisation. Key outcome domains at residents' level are utilisation of care, such as hospitalisation and emergency services, and quality of life (distal outcomes). Proximal outcome domains are clinical outcome parameters (e.g. symptom burden), physical functioning (e.g. self-care and health behaviours and management) and care delivery (person-centredness of care). Safety-related outcome measures at the resident level are mortality, adverse events and changes in level of care. The intervention is to be defined as complex, as it contains several components, starts at several levels and addresses several target groups.

In order to explain change mechanisms of complex interventions and to appropriately interpret the effects on patient-relevant outcomes, a comprehensive process evaluation is required in addition to the evaluation of these effects. Therefore, the process evaluation described here will be carried out embedded in the main trial, based on established, scientific frameworks for the development and evaluation of complex health interventions (Moore et al. 2015, Grant et al. 2013). The aim of the process evaluation is to evaluate the actual implementation of the trial/intervention, the implementation strategies and the intervention as well as their mechanisms of change in the specific context of the Expand Care trial. Thus, conclusions can be drawn regarding the feasibility of the intervention and the study procedures in order to subsequently prepare an effectiveness study. In addition, the process evaluation helps to understand how interventions can be transferred from research to practice and into other settings.

2. Methods

2.1. Process evaluation of complex interventions

In the context of process evaluation, processes are distinguished at the cluster level and the individual level. Furthermore, the context, the maintenance of the intervention, possible effects on the main target variables and unexpected events are observed (Grant et al. 2013, Fig. 1). In the Expand Care study, nursing homes are defined as clusters. The individual level in the Expand Care study refers to residents and nursing professionals (PEPAs). Contextual factors are considered at these levels (micro level) as well as at facilities' level (meso level) and at a supra-organisational level (macro level). After implementation (PEPA qualification phase), the intervention, its maintenance and overarching changes that influence the distal targets at the resident level are monitored.

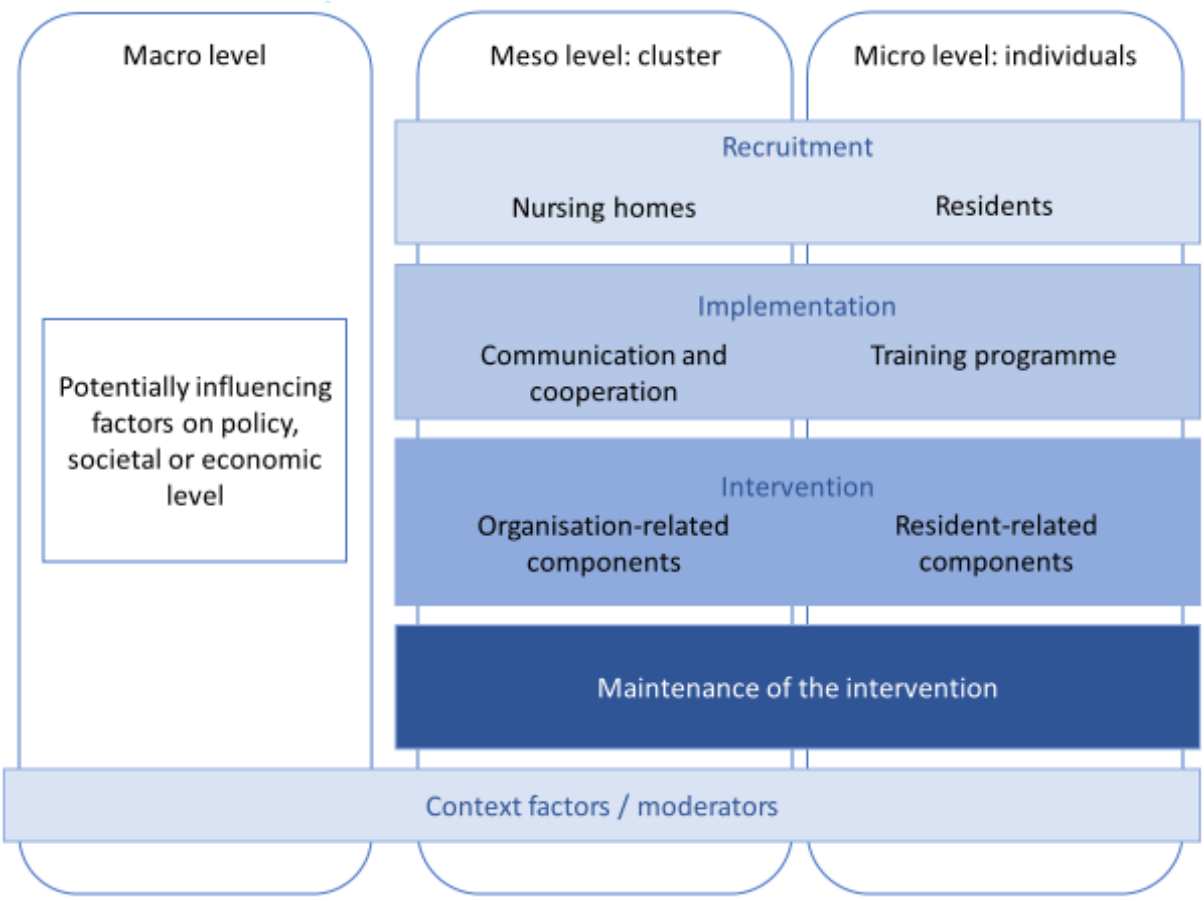


Figure 1: Process evaluation within the framework of cluster-randomised studies. Own representation based on Grant et al., 2013, p. 4.

2.2. Mixed Methods

The process evaluation is conducted in a parallel triangulation design ("convergence model", Creswell & Plano Clark, 2007). Integration of data obtained by means of qualitative and quantitative survey methods takes place at the outcome level using a mixed methods matrix/joint display (O'Cathain et al. 2010).

2.3. Outcomes of the process evaluation

Process evaluation outcomes are organised according to the given structure (Figure 1 and Tables 2 a-2d). The methods listed are used to collect data on several outcomes (for an overview of data collection methods for specific target groups, see Table 4 in Chapter 2.4.2 Sampling). The focus of the process

evaluation is on qualitative methods (interviews, focus groups). Quantitative data, for example characteristics that can be assigned to the context of the residents, such as care level and socio-demographic information, are already partially included in the data collection of the main study. The process evaluation data are collected at different points in time during the preparation of the study (recruitment of facilities and residents, t-1) and during the entire course of the study (tables 2a-2d).

Table 2a: Outcomes, methods and measurement times of the process evaluation - recruitment

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
Recruitment of nursing homes	Procedure Recruitment success Reasons for non-participation	**Study teams:** documentation of contacts and conversations	X				/
	Motivation for participation	**PDL:** Guided semi-structured interviews				X	IG
Recruitment of residents	Procedure Recruitment success Reasons for non-participation	**Contact person for Expand-Care Study:** Documentation of recruitment	X				IG, CG
	Characteristics of the target group	**Residents:** Quantitative: Data collection main study		X	X	X	IG, CG

Shaded grey: Part of the main study. CG: Control group; IG: intervention group; PDL: nurse manager.

Table 2b: Outcomes, methods and measurement points of the process evaluation - implementation

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
Implementation at facility level: cooperation and communication	Perceived support in the implementation of the intervention	**PEPA:** semi-structured qualitative interviews				X	IG
PEPA training	Implementation of the training programme	**Lecturer:** Documentation Contact hours, practice supervision **PEPA:** Documentation PEPA Manual			X	X	IG
PEPA training	Experiences with the training programme	**Lecturer:** Focus group (online)			X		IG
PEPA training	Perception of implementation: Kirkpatrick Level 1	**PEPA:** Semi-structured qualitative interviews				X	IG
		Focus group			X		IG

	Learning Success: Kirkpatrick Level 2 and 3	**PEPA:** Learning success checks, practical support, focus group, reflection discussion			X		IG
PEPA training	(Change) in professional self-image, understanding of roles: Kirkpatrick Level 4	**PEPA:** Semi-structured qualitative interviews				X	IG
		Quantitative: Questionnaire Role Understanding: (SHURP)			X	X	IG
		Focus group, reflection meetings			X		IG

SHURP: Swiss Nursing Homes Human Resources Project (Schwendimann et al, 2014; https://shurp.unibas.ch/). ***PCQ: person-centred climate questionnaire; PEPA: nurse with expanded competencies in person-centred care for the elderly; PDL: nurse manager.***

Table 2c: Outcomes, methods and measurement times of the process evaluation - intervention

Domain	Outcomes	Target group/method	Timepoint t-1	t0	t1	t2	Group
Implementation of the intervention: resident related and organisation-related components	Implementation of intervention components: Kirkpatrick Level 3	**Lecturer:** Focus group				X	IG
		Practical support, observation			X		IG
		PEPA: Focus group				X	IG
		Reflection talks, PEPA manual			X	X	IG
		Nursing staff: Focus group				X	IG
Implementation of the intervention as quality indicators: resident related and organisation-related components	Quality indicators: structured handover and fax communication, joint physician visits, case conferences, geriatric assessments, hospital visit, awareness of the study	**Nursing staff:** Quantitative: Questionnaire quality indicators		X		X	IG, CG
	Perception of the intervention and of changes	**Residents, relatives, nursing staff:** Semi-structured qualitative interviews/focus group				X	IG

Domain	Outcomes	Target group/method	Timepoint				Group
			t-1	t0	t1	t2	
	Perceived person-centred care climate, Self-Care Participation, empowerment	**Residents** Quantitative: Data collection form (PCQ, LTCQ-8 (main study)		X		X	IG, CG
		Semi-structured qualitative interviews				X	IG
	person-centred care climate	**Nursing staff:** Quantitative: Questionnaire (PCQ-Staff)		X		X	IG, CG
Implementation of the intervention	Maintaining implementation after the end of implementation / qualification	**PEPA, PDL:** Semi-structured qualitative **interviews**				X	IG
Course of studies	Perception of the study process as a whole	**PDL and PEPA:** Guided semi-structured interviews				X	IG

Shaded grey: Part of the main study. PCQ: person-centred climate questionnaire; PEPA: nurse with expanded competencies in person-centred care for the elderly; PDL: nurse manager.

Table 2d: Outcomes, methods and timepoints of the process evaluation - contextual factors

Domain	Outcomes	Target group/method	timepoints				Group
			t-1	t0	t1	t2	
Micro level / PEPA	Characteristics of PEPA (qualification, experience)	**PEPA:** Quantitative: Questionnaire			X	X	IG
	Motivation for participation	**PEPA:** Semi-structured qualitative interviews				X	IG
		Quantitative: Questionnaire			X	X	IG
Micro level / residents	Characteristics of residents (e.g. sociodemographics, care level	**Residents** Quantitative: Data collection form (main study)		X		X	IG, CG
	Attitudes, expectations	**Residents** Guided semi-structured interviews				X	IG
Meso level / organisation	Characteristics of the facility (skill mix, staffing ratio, size of the facility, sponsorship, care level	**PDL/EL:** Quantitative: Data collection form nursing facility (main study)		X		X	IG

Domain	Outcomes	Target group/method	timepoints				Group
			t-1	t0	t1	t2	
	of residents, special care services)						
	Willingness and ability of team members to participate in implementation	**PEPA:** Guided semi-structured interviews				X	IG
Macro level / political, legal, ethical	ELSI as perceived problems or barriers	**PDL and PEPA:** Guided semi-structured interviews				X	IG
Macro level / other events	Overarching factors / changes that may have had an influence on the intervention	**PDL and PEPA:** Guided semi-structured interviews				X	IG

Shaded grey: Part of the main study. ELSI: Ethical, legal and social implications; LTCQ-8: Long-term conditions questionnaire short form; PCQ: person-centred climate questionnaire; PEPA: nurse with expanded competencies in person-centred care for the elderly; PDL: nurse manager.

2.4. Target groups

2.4.1. Inclusion criteria

Participants will be recruited from the main study's sample. Inclusion criteria for participants in the process evaluation therefore are the same as the criteria for participation in the main study. All persons entrusted with nursing tasks and permanently employed in the facility can participate as members of the nursing team. In this study, relatives/surrogates are persons who consider themselves to be related to a participating resident (Table 3). Participation in the process evaluation means an additional burden, especially for residents. It is therefore voluntary with an additional declaration of consent and targets only residents who are able to consent to participation independently.

Table 3: Inclusion and exclusion criteria for participation in the process evaluation

Target group	Inclusion	Exclusion
Relatives	Person close to or associated with a study participant (named as primary caregiver by resident or on file)	/
Residents	Participants of the main study	Dementia Screening Scale Score > 3, residents who are unable to give their own consent
Nursing staff	Staff members of the facility who are involved in direct care	Worktime less than 50% of fulltime
Nurse/ PEPA*	Nurse who has been designated as a potential participant or is a PEPA after randomisation.	/
Nurse manager	Person who assumes the function of care manager.	/

**PEPA: nurse with expanded competencies for person-centred care for the elderly*

2.4.2. Sampling

The selection and number of participants will be determined according to the research question and respective methods (Table 4, Sample size, methods and timepoint of measurement). For the description of the clusters (facilities, n=11) and for qualitative and quantitative questions directed at the PEPAs (n=6), a 100% sample is aimed.

At the level of the residents, the sample will be selected according to the criteria of care facility affiliation and gender. One male and one female resident from each of the care facilities participating in the intervention group will be included (n=10-12). Only persons who can independently consent to the additional qualitative survey will be included (Kelle & Kluge, 2010).

Relatives are selected independently of the residents participating in the process evaluation. The aim is to include two relatives per cluster (IG): one relative of a resident without cognitive impairment (able to give consent him/herself) and one of a resident with cognitive impairment (not able to give consent him/herself), in order to generate a heterogeneous sample (purposive sampling).

The review and evaluation of the qualitative data already takes place during the data collection process, so that recruitment of representatives of additional target groups can be considered, for example general practitioners or specialists (purposive sampling).

Table 4: Sample size, methods and timepoint of measurement

Target group	Method	N t-1	N t0	N t1	N t2	Group
Residents	semi-structured qualitative interviews				12	IG
	Data collection sheet: context, intervention		75-90		90	IG, CG
	Data collection sheet: Notes on the survey		75-90		90	IG, CG
Nursing management	semi-structured qualitative interviews				6	IG
	Data collection form Institution: Recruitment		10-12			IG, CG
	Documentation sheet for recruitment of residents	10-12				IG, CG
Nurse / PEPA	Semi-structured qualitative interviews				6	IG
	Focus group			6		IG
	PEPA Manual*				6	IG
	Decision support / planning*				6	IG
	Reflection talk (protocol)*			6		IG
	Learning success checks*					
	Questionnaire			6	6	IG
Nursing staff	Focus group[1]				~ 42	IG

Target group	Method	N t-1	N t0	N t1	N t2	Group
	Questionnaire		120		120	IG, CG
Relatives	Guided semi-structured interviews				12	IG
Lecturer	Focus group (online) Documentation Contact hours*, Practice supervision*, Observation*.			6-8		-
Family doctors	Guided semi-structured interviews (optional)				6	IG
Medical specialists	Guided semi-structured interviews (optional)				6	IG

[1]One focus group per cluster (á n= 6-8 carers)

BW: resident:in; IG: intervention group; CG: control group; PCQ: person-centred climate questionnaire; PEPA: nurse with advanced competencies in person-centred care for the elderly; PDL: nurse manager. Blue shading: Audio recording/transcript. Grey shading: Part of the main study.

Marked with an asterisk: Work tools that are used as part of the training programme and are only evaluated in aggregated and anonymous form.

2.5. Data collection

Individual interviews will be conducted with residents, relatives, nursing staff, PEPAs and care managers (Table 4). PEPAs will be interviewed in a focus group at the end of the training programme. One focus group will be conducted with nursing staff and one with lecturers (online). If necessary, general practitioners (GPs) and other specialists will be additionally interviewed, either in the facility or by (video) telephone.

Residents will be visited in the care facility for data collection. Relatives, nursing staff, PEPAs and nursing service managers will be visited according to their preference or, if necessary, interviewed (by video) telephone. Video-telephonic interviews will be conducted via Cisco Webex (licence of the University of Lübeck). The focus group with PEPAs will be conducted at the end of the training programme, on the premises of the University of Lübeck.

The written survey will be conducted by means of paper-based questionnaires. Nursing staff will be invited to participate in writing. The completed (anonymous) questionnaires will be collected centrally by the nursing home and then handed over to the university.

All interviews and focus groups will be conducted by experienced study staff specifically trained for data collection for the Expand Care study. The conduct of the interviews and focus groups will be supported by a semi-structured guide (Helfferich, 2011, table 5).

Table 5: Overview of topic guides for qualitative interviews and focus groups

A) PEPA /head of nursing homes/nursing managers (T2, interviews)	***B) Focus group with teaching staff (T1)***
1. Motivation for participation 2. Overall impression of the study 3. Changes due to study participation regarding a. professional role perception b. care processes c. communication with residents and relatives d. interprofessional collaboration e. team work 4. Implementation barriers, facilitators, hindering factors 5. Perception of support 6. Perspective of maintenance 7. Adverse events 8. Other aspects 9. Implications for further research	1. Overall impression of the teaching programme 2. Satisfaction a. of participants b. own satisfaction 3. Hindering and facilitating factors 4. Impression of participants: a. Fit of participants' qualification with performance requirements of the educational programme b. Usefulness of the training programme's content for participants c. Participants' performance during supervision visits in the facility d. Maintenance of the intervention 5. Overall impression of the training programme 6. Need for adjustments for future implementation of the training programme 7. Other aspects
C) Residents (T2, interviews)	***D) Relatives (T2, interviews)***
1. Introduction ("tell me something about yourself") 2. Motivation for participation 3. Changes due to study participation regarding a. Relationship with nurse b. Care processes c. Contact with general practitioner d. Contact with other health care professionals e. Contact with relatives 4. Other aspects/ negative experiences with care	1. Introduction ("tell me something about yourself and your relationship with [resident]") 2. Motivation for participation (proxies who consented in participation as surrogates) 3. Perception of the study in the nursing home 4. Changes due to study participation regarding a. Care processes b. Contact with nurses c. Contact with general practitioners d. Contact with other health care professionals e. Negative changes 5. Other aspects

Table 5, continued

E) Focus group nursing staff (T2)	*F) Focus group PEPAs (T1)*
5. Overall impression/knowledge of the study	Satisfaction
6. Impact on training courses and (team) meetings	Transfer of knowledge
7. Changes in own everyday working life	Effort-benefit-ratio
8. Changes in everyday working life of the PEPA	a. individual
9. Changes in care processes	b. in general
10. Changes in the team	other aspects
11. Positive/negative consequences	

2.6. Data management

Interviews and focus groups will be audio recorded. Audio recordings will be transcribed by study assistants and checked by research assistants. Transcripts will be stored and analysed pseudonymously under a personal ID (letter-digit combination). During transcription, all names or places mentioned in the interview will be deleted and replaced by an anonymous description of the function (e.g. [facility management], [clinic]). Audio recordings will be deleted after the study is completed.

Questionnaire data will be collected, stored and evaluated anonymously. The assignment of the questionnaires to the cluster (institution) is maintained by marking them with a cluster ID (letter-digit combination) on the questionnaire.

The programmes MAXQDA (Verbi Software) and Microsoft Office applications will be used to process the data.

The processes described in the study protocol of the main study and the associated appendices apply to the storage and backup of data.

2.7. Data analysis

The transcripts of the qualitative surveys (interviews, focus groups) will be analysed according to the principles of qualitative content analysis by Kuckartz (Kuckartz, 2012). Both deductive categories, derived from the research questions, and inductive categories, emerging from the material, will be formed. The primary analysis is carried out by a team of two researchers. The results are also discussed (anonymously) in an interdisciplinary working group in order to ensure the intersubjective comprehensibility of the evaluation. The software MAXQDA will be employed for processing and analysing qualitative data. Quantitative data will be analysed descriptively (frequencies, means, range, median). Triangulation of data will be performed on the level of results.

2.8. Information and consent

Information and consent will be based on processes described in the study protocol of the main study. Participation in the process evaluation is voluntary. Written informed consent is a prerequisite for participation from nursing staff. For participation in the written survey of the nursing staff, submission of the questionnaire is considered as written informed consent.

For participation in focus groups and/or an interview, participants receive an expense allowance of 20€.

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Supplement 2 to

Expanded nursing competencies to improve person-centred care for nursing home residents with complex health needs (Expand-Care): study protocol of an exploratory cluster-randomised trial

Description of the Expand-care intervention components and implementation strategies based on the TIDieR template (Template for Intervention Description and Replication, Hoffmann et al. 2014[1])

In the following, the Expand Care intervention is presented in terms of the rationale, the target group, the way of implementation and the materials used. The intervention is defined as a new role profile for nurses with expanded competencies for person-centred care. This role is specified by intervention components (activities) at a resident-related and an organisation related level, which are additionally differentiated as core and optional elements (Fig. 1, Table 1).

Additionally, strategies to ensure the implementation of the intervention are presented according to the same scheme (Table 2).

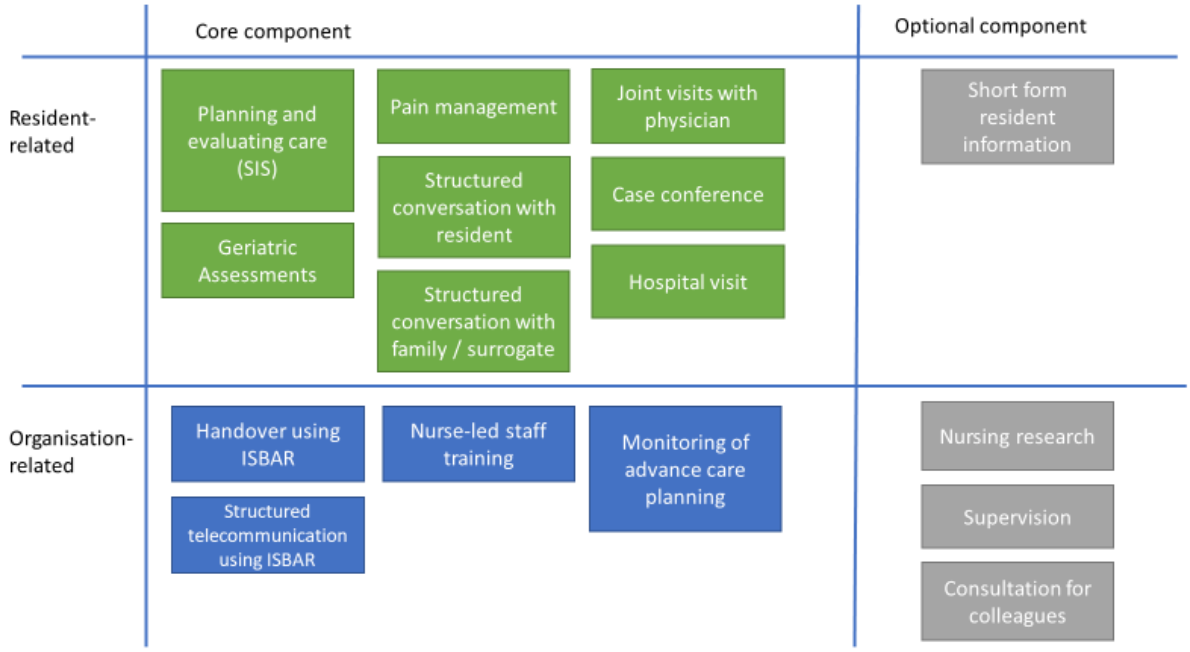

Figure 1: Core and optional components of the Expand-Care intervention. SIS: Structured Information Collection®.

[1] Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687.

Table 1: Intervention components

Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
Resident-related activities						
Planning and evaluating care	Residents Place: nursing home (NH)	Through targeted planning that considers the long-term course of defined events, changes in the condition are better perceived and activities/services can be derived in advance and initiated or adapted in a timely manner. The planning and evaluation of the care situation is the central element for deciding on the use and linkage of different intervention components. Structured according to the SIS® [strukturierte Informationssammlung] (structured assessment plan), all elements of a complex nursing assessment are mapped and the component is linked to the existing system of care planning so that integration is supported.	PEPA	PEPA carries out planning and evaluation of care by means of a decision algorithm. Based on the results, nursing measures (as well as intervention components such as assessments or structured conversations) are implemented or medical measures are initiated. Guiding points for the decision algorithm are key events that are defined on the basis of the resident's transition through the course of care in the care facility (e.g. moving in, settling in, increase in care needs, health deterioration, hospitalisation).	Defined by (key) events related to the individual situation of the residents (e.g. moving in, settling in, increase in care needs, health deterioration, hospital stay).	SIS-based decision algorithm: planning and evaluation tool
Structured conversation with resident	Residents Setting: NH (residents' room or counselling room)	Structured discussions ensure that residents have the opportunity to reflect and express their needs and that these are considered in their care. Residents perceive that their right to make decisions is taken seriously.	PEPA	Personal structured conversation with residents in an undisturbed setting. Topics are life in the facility; self-care, chronic illnesses; nursing care; communication with	At regular intervals and at key events defined in the SIS-based decision algorithm (e.g. moving in, deterioration in health, hospitalisation).	Interview guide for structured conversation with residents (linked to the SIS).

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
		Guiding questions ensure that all relevant topics are considered. The component is linked to the SIS and thus to the existing system of care planning, so that integration is supported.		doctors, therapists, relatives; advance care planning (status).		
Structured conversation with relatives	Relatives / surrogates Setting: NH (residents' room or counselling room)	Structured discussions ensure that the perspective of relatives and important information from them are considered in care. The organisation of medical care and social support can thus be coordinated with the relatives. The conversation's structure is based on the structure of the conversation with residents, so that it is possible to link results with the documentation.	PEPA	Personal structured conversation with relatives, if necessary together with the resident.	At regular intervals and at key events defined in SIS-based decision algorithm (e.g. moving in, deterioration in health, hospitalisation).	Interview guide for structured conversations with relatives (linked to the SIS).
Joint visit with General practitioner (GP)	General practitioners and specialists Residents Relatives Setting: NH	By accompanying physicians' ward rounds, current observations, questions and needs of the residents can be clarified directly and more efficient communication (differentiated use of ward rounds, fax and telephone calls) can be promoted. The ISBAR scheme promotes the complete and focused transfer of information. The continuous and structured approach promotes regular evaluation and adjustment of the care situation. The	PEPA (or nurse in charge)	Time for joint visits is scheduled in the PEPA's or supervising professional's duties for visits that are scheduled in advance or regularly. Beforehand, the accompanying person compiles information based on the ISBAR scheme.	Depending on on-site visits by the supervising physicians	Template for structured transfer of information in handovers (ISBAR scheme, Identification, situation, background, assessment, recommendation).

Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
		involvement of residents (and relatives) promotes regular communication between the parties involved. In addition to joint visits, the organisation, coordination and evaluation of the visit with GPs within the NH is beneficial for interprofessional collaboration.				
Case conference	Residents Relatives General practitioners and specialists Other parties involved in residents' medical care and nursing Setting: NH or virtual conference	Through direct communication of all those involved in resident's care, needs and care can be directly coordinated and timely and needs-based care can be ensured. Participation of residents and relatives supports the person-centred perspective of care. Residents perceive that their right to decide is taken seriously and that care measures address their own wishes. The care situation is evaluated and adapted interprofessionally. By taking a longitudinal view, undesirable events can be anticipated and preventive measures can be taken. The joint holistic and comprehensive view promotes the professional and personal competence of those involved.	PEPA	PEPA organises appointment and carries out preparatory care planning, collects information in advance if necessary, including current or long-term issues.	One case meeting per 6 months	Guideline for case conferences If applicable, video conferencing system and hardware
Hospital visit	Residents Acute care ward team	By visiting residents during inpatient treatment, questions that arise due to acute	PEPA or nurse in charge	Visit the clinic, obtain authorisation in advance to obtain	For hospital stays lasting longer than 3 days.	

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
	Setting: Hospital	changes in care after the hospital stay can be clarified and prepared in advance. The acute care ward team can be supported in dealing with residents' special needs.		information about the resident's care.		
Pain management	Residents Setting: NH	Residents' quality of life is promoted through the individual support of the pain therapy.	PEPA	Procedure and instruments according to the recommendations of the S3 guideline "Pain assessment in older people in full inpatient care for the elderly" (German Pain Society & German Centre for Neurodegenerative Diseases 2017)	According to the needs of the resident(s)	Templates for instruments according to the S3 guideline "Pain assessment in older people in full inpatient care for the elderly".
Geriatric assessments	Inhabitants:in Setting: NH	Through geriatric and nursing assessments, changes in residents' condition are recognised and documented at an early stage, can be adequately communicated and used to support the initiation and evaluation of individual measures.	PEPA or trained professional	Depending on the assessment method	Regularly depending on the assessment and on an ad hoc basis (according to the result of SIS-based decision algorithm)	Assessment tools, for example: • Mobility • Fall • Cognition • Delir • Nutritional status • Pain • Skin condition • Continence • Change in medication
Organisation-related activities						
Care handover according to ISBAR	Nursing team General practitioners and specialists	The ISBAR structure ensures complete and efficient communication about the current care needs of the	PEPA, professionals	The handover of care is structured using the ISBAR scheme.	At every care handover	ISBAR scheme and information materials explaining the application

Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
	Other parties involved in residents' medical care and nursing Setting: NH	residents. Important information is prioritised.				
Structured (fax) communication	General practitioners and specialists Other parties involved in residents' medical care and nursing Setting: NH	Structured communication ensures that information is passed on in full and that there is an adequate basis for decision-making for GPs and physician specialists, so that decisions can be made more quickly.	PEPA, professionals	A pre-structured fax form is used for the transmission of information or enquiries to general practitioners and specialists.	For all fax communications with general practitioners and specialists.	Fax form with ISBAR scheme
Training (on ISBAR)	Nursing team Setting: NH	Through the training, the nursing staff members are introduced to the structured handover and the implementation is practised so that it can be adopted in the handovers without guidance.	PEPA	PEPA organises the training for nursing staff on ISBAR. The training includes information and exercise modules as well as supporting information materials	Once in the study period on the topic of ISBAR	ISBAR scheme and information materials explaining the application Training concept prepared by PEPA as part of the PEPA curriculum.
Monitoring of Advance Care Planning	Nursing team General practitioners and specialists Setting: NH	The monitoring of ACP should ensure that existing plans are documented and known. This will improve the conditions for implementing the wishes of the residents.	PEPA	The PEPA checks whether advance care planning or health care planning exists and is documented. PEPA checks the consistency of entries on ACP in the analogue and digital documentation. In case of discrepancies, their PEPA	Regularly and on an ad hoc basis, e.g. after a stay in hospital or health deterioration	Existing documentation of information on ACP in the facility (digital and analogue).

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
				initiates clarification, e.g. in cooperation with the ACP facilitator of the nursing home.		
Peripheral elements (optional)						
Participation in evidence-based practice development	Organisation / Facility Setting: NH	Through specified impulses from practice for research, questions relevant to the institution can be worked on in cooperation with nursing scientists. Thus, further development of nursing practice in an evidence-based manner can be supported and quality of care care can be improved.	PEPA	PEPA identifies needs for quality development or research and initiates cooperation with quality management or the University.	On demand.	
Supervision	Nursing team Setting: NH	The targeted discussion of cases from practice that are experienced as difficult on the one hand promotes learning from experience. On the other hand, situations experienced as stressful can be worked through in the team to enhance mutual support and reduce stress.	PEPA	PEPA offers supervision in the form of structured case discussions of about 1 hour. Cases that are experienced as difficult or stressful are selected.	On demand	Background information given as part of the curriculum. Guiding questions for structuring a supervision session.
Collegial counselling	Nursing team Setting: NH	Through the possibility of an individual conversation, topics can be addressed that are not suitable for supervision. In particular, professional uncertainties or one's own mistakes can be discussed and thus learnt from experience.	PEPA	PEPA is available for one-to-one meetings on an ad hoc basis with a focus on professional discussion.	On demand	Background information given as part of the curriculum.

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Intervention component	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
Short info sheet	Care team, external health care providers Setting: when care is provided outside the NH, e.g. clinic	Important information about the resident is briefly summarised on an information sheet so that care outside the nursing home can be tailored to residents' individual needs.	Nursing team	The PEPA creates and presents the information sheet and makes sure that the nursing staff implement it.	Initially with all residents [of the study], then event-related (as part of the planning and evaluation of the care situation).	Information Sheet Template

GP: General practitioner; ISBAR: Information, situation, background, assessment, recommendation, template to ensure structured and complete information transfer in handovers; NH: Nursing home; PEPA: German acronym for nurse specialist with expanded competencies for person-centred care; PDL: nurse manager; SIS®: [Strukturierte Informationssammlung] structured plan for the professional assessment of residents' care needs, containing a broad question (What is important to you at the moment?) and six assessment topics (1. Cognitive and communicative abilities; 2. Mobility and agility; 3. Health related requirements and burden; 4. Self-care; 5. Living in social relationships; 6. Living environment) as well as a matrix for the assessment of nursing-sensitive risks within the assessment topics.

Table 2: Implementation strategies

Implementation strategy	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
Education						
PEPA Curriculum (training programme)	PEPA Setting: University of Lübeck, online, NH	The training programme ensures the PEPAs' knowledge of person-centred care. They are supported in developing their understanding of their role and develop competences for transferring the knowledge into care. The learning objectives and learning target checks are documented in the curriculum.	Lecturers from the participating universities, learning in working groups, supervision by the university.	Different learning formats according to the curriculum.	A total of 300 hours of teaching (10 ETC), consisting of contact time, self-study and on-the-job training. The qualification takes place in the first three months after randomisation.	Learning materials and tools according to the curriculum. Manual for documenting learning objectives, presentations, digital learning platform (Moodle), assignment descriptions, materials individually designed by lecturers.
Monitoring / Evaluation						
PEPA Handbook	PEPA Setting: University of Lübeck, NH	A detailed manual for documenting participation in courses and other learning activities, as well as for documenting learning objectives, increases the commitment to implementation and shows PEPAs their learning progress.	Study centres	The study centres introduce the handbook during contact time and provide a print version. Attendance is documented in the courses. PEPA maintains the handbook and collects the documentation.	According to curriculum. The handbook is kept during the three months of the training programme (implementation).	Print version of the manual.
Target agreement talks	PEPA Nurse manager (PDL) Setting: NH	The aim of the conversation is to talk about a shared idea of good care and how the intervention (role of PEPA) can support this. This will involve the PDL more in the project and thus support the implementation of the intervention components. Hindering and supporting factors	PEPA PDL If applicable, researchers from the university	PEPA and PDL meet to discuss study participation and implementation and document the outcome of the discussion in writing.	Meetings of 45-60 min, time points: 1. After randomisation, before the start of the training programme. 2. 4 weeks after randomisation.	Interview guide and protocol template.

Implementation strategy	Target group Setting	Why?	Who implements?	How?	When and how much?	Materials
		are discussed and solutions are sought if necessary.				
Organisation						
Cooperation agreement with the NH	NH Universities Setting: University, NH	A formal declaration of commitment increases the binding nature of the respective tasks of the partners (nursing homes and universities) in the project and thus supports compliance with the project plan, in particular the recruitment of participants, granting PEPAs worktime to perform Expand-Care tasks and the implementation of the curriculum.	Study centres and NH	Study centres hold a cooperation agreement, authorised representatives of the university and the NH sign the agreement.	Before the recruitment of residents begins.	Draft contract for the cooperation agreement.
Adaptability of the intervention	NH, PEPA Setting: NH	The PEPA intervention comprises several sub-components, some of which can be implemented optionally, others are mandatory. The possibility to adapt the intervention to the individual circumstances and needs of the NH promotes identification with the intervention and subsequently implementation.	PEPA PDL Researchers at the university.	At the beginning of the implementation, it is determined which components the intervention should include in the respective NH (discussion with PEPA, PDL and university).	After randomisation. If necessary, further discussion during the study if it becomes apparent that there are deviations from the original planning.	Interview guide and protocol template.

GP: General practitioner; ISBAR: Information, situation, background, assessment, recommendation, template to ensure structured and complete information transfer in handovers; NH: Nursing home; PEPA: German acronym for nurse specialist with expanded competencies for person-centred care; PDL: nurse manager; SIS®: [Strukturierte Informationssammlung] structured plan for the assessment of residents' care needs, containing a broad question (What is important to you at the moment?) and six assessment topics (1. Cognitive and communicative abilities; 2. Mobility and agility; 3. Health related requirements and burdens; 4. Self-care; 5. Living in social relationships; 6. Living environment) and a matrix for risk assessment and care needs.

Statistical study plan for the study Expand-Care

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(Director: Univ.-Prof. Dr. Inke R. König)

Date: *23.09.2022*
Version: *2.0*

This document is valid for the study protocol (version: *V 1.3)* of the study mentioned above.

Confidential

Condition for the services of the IMBS described in this statistical study plan is a cost-covering funding from the sponsor of the study (third-party funds) on the basis of a budget plan to be made by the IMBS.

Table of content

This statistical study plan is part of the study plan.

1. General

All statistical analyses except for the health economics evaluations and process evaluation are carried out by the Institut für Medizinische Biometrie und Statistik (IMBS) at the Universität zu Lübeck. All analyses are described in detail in the statistical analysis plan (SAP), which will be finalised before the registration of the last patient in the study.

2. Purpose, objectives and hypotheses of the study

Purpose of the study is to prepare a confirmatory clinical trial that will be adequately powered. The objective is the necessary precision of estimates of variation. As a consequence, a confidence interval of predefined width replaces hypotheses.

2.1 Purpose

Purpose of the study is to prepare a confirmatory clinical trial that will be adequately powered, smoothly conductible, and may be augmented by the evidence generated in the pilot study.

2.2 Objectives

Objective of the study is a narrow confidence interval for both, the population summary measure and the standard deviation of the outcome variable. The 6-months rate of hospital admissions in each group shall be estimated with a two-sided 95%-confidence interval that extends no more than 10 percentage points in either direction, as this would effectively restrict the range of possible sample sizes of the subsequent confirmation study. The 6-months incidence of hospitalisation of nursing home residents is thought to be 25% (Leutgeb et al., 2019). Using a rate of 30% or 20% in the control group as a basis for planning, sample size of the subsequent confirmatory study to detect a difference of 15 percentage points would change by 50%. If that rate was 25%, but the risk difference to be detected was 15% or 10%, one possible sample size would be 250% of the other, so that an interim analysis of the subsequent confirmatory trial could be justified or not.

2.3 Hypotheses

This pilot study will be used to define the hypotheses of the subsequent confirmatory study. They will have the form: There is no difference in the 6-months hospitalisation rates of nursing home residents cared for according to current standards or with the Expand-Care programme versus the risk difference is P1 % with P1 to be determined by the pilot study to be a number of perhaps 10 or 15.
Sample size planning of the pilot study could be thought of as being for a test of the hypotheses that 6-months hospitalization rates of nursing home residents cared for according to current standards is 25% versus 15% and with the Expand-Care programme 15% versus 25%.

3. Design of the study

3.1 General

The study will be national, bicentric, cluster-randomised, open, in parallel groups

3.2 Randomisation, blinding, confounding

Randomisation will be central to ensure concealment of allocation and will be stratified by time to balance any seasonal effects. Blinding is not possible in this complex intervention, but will be observed during statistical analysis and data review.

3.2.1 Registration and randomisation

The randomised allocation will be initiated after completion of the baseline assessment (t0) in participating nursing home residents by the investigators responsible for the respective nursing

homes. Participating nursing homes (unit of randomisation) will be randomised with an allocation ratio of 5:6 to the intervention or the control group. The random sequence will be generated by the IMBS by permutation with validated software once two nursing homes have faxed their readiness. So, date has to be stated on the fax asking for randomisation.
The trial statistician will write and test SAS code like

```
/* randomisation.sas
Reinhard Vonthein 18.03.2022 nach
Kundu & Roy auf lexjansen.com/pharmsug/2007/ad/AD07.pdf
Per stratum 3 blocks of size 2 */

data _null_;
 x=round(ranuni(0)*10000000);
 call symput ('seed', x);
run;

title1 "Seed number = &seed.";
title2 " Blocks are times of randomization,";
title3 "subject means nursing homes within a block in the temporal
order of their registration for randomization";

proc plan seed=&seed.;
 factors block=6 ordered subject=2 ordered/noprint;
 treatments treatment=2 random;
 output out=out
treatment cvals=('Expand-Care' 'Usual care');
run;

proc print data=out noobs;
 var block subject treatment;
 format subject z3.;
run;
```

for the generation of the randomisation sequence by permutation within time – the latter is called a block in the code. The effective randomisation sequence is generated, tested for balance (5:6 in total), and kept confidential by another person. Assignment of an institution is disclosed to just the designated investigator and only after registration, i.e. written assurance that all baseline assessments detailed in the protocol and other necessary preparations have been completed.
Registration and randomisation will be done via fax (++ 49 (0) 451 500-50614) from Monday to Friday from 08:00 to 14:00. Exceptions in which no randomisation is carried out are holidays and the period from 27.12. until 31.12. every year. The randomisation procedure is based on IMBS internal standard operating procedures.
The statistical analysis is prepared using place-holders assuming alternating assignments, so that results may not be guessed. True assignments are inserted into the code only after blinded review and data base closure.

3.2.2 Blinding

Due to the nature of the Expand-Care intervention, blinding of the nursing home residents and the nursing staff against the allocated intervention will be not feasible. However, in the information provided to the nursing home residents no specific hypotheses about possible directions of effects in measured outcomes will be described. The distal outcome data on hospital admissions, out-of-hour physician contacts and emergency service utilisation in the nursing home residents will be collected by study assistants blinded to the allocated intervention. For the assessment of all distal outcome (i.e hospital admissions, out-of-hour physician contacts, emergency service use and HRQoL) and resource use data in the nursing home residents, standardised instruments and

procedures will be used which have been proven feasible and reliable in previous trials of the authors (Müller et al. 2019, Richter et al. 2019). The trial statistician will be unaware of the assignments until after blinded review and data base closure. To this end, tests of the program code for analysis use an alternating assignment instead of the true allocation. The randomisation list will be merged to the data as a last step. A test of that step will use the list with alternating assignments.

3.2.3 Confounding

The primary endpoint is an event within 6 months, and the individual baseline measurement for this is the occurrence of the same event in the 3 months prior to randomisation. This will be observed retrospectively for adjustment in statistical analysis.
All analyses need to consider institution or one of its features as a moderator. This is usually done in the form of random effects/frailty to adequately model correlations. One exemption to this rule are the median differences and Hodges-Lehman confidence intervals, that take care of the problem by the resampling-like mode of their computation.

3.3 Endpoints

The hospitalisation rate measures a relevant burden to nursing home residents and from a payer perspective. Other measurements of resource use are complemented by residents' reports on quality of life, and safety outcomes. Morbidity endpoints will be used to describe the mechanism behind treatment effects.

3.3.1 Primary endpoints and hypotheses

The endpoint used in sample size calculation is the binary variable, whether a resident is hospitalised at least once during the six months following randomisation of the nursing home. All hospitalisations qualify irrespective of urgency, reason, duration, and initiator.
The primary estimand directly linked with sample size calculation is the difference of the proportion of such residents.
The endpoint for the first sensitivity analysis is the individual mean time between hospitalisations. All episodes between randomisation and hospitalisation or censoring and between discharge and re-hospitalisation or censoring are entered in a recurrent event analysis.
The endpoint for the second sensitivity analysis is the individual rate of hospitalisations (number divided by days in institution) within 6 months. This is analysed by Poisson regression with number of days in institution defining the offset.

3.3.2 Secondary endpoints

The list of endpoints is a subset of clinical investigation plan Tables 1, 2, 4.
(P) Occurrence of hospital admission within last 3 months at 3 and 6 months
(C) Number of hospital admission within last 3 months at 3 and 6 months
(C) Number of hospital days within last 3 months at 3 and 6 months
(P) Occurrence of out-of-hours physician contact within last 3 months at 3 and 6 months
(C) Number of out-of-hours physician contacts within last 3 months at 3 and 6 months
(P) Occurrence of emergency service use within last 3 months at 3 and 6 months
(C) Number of emergency service uses within last 3 months at 3 and 6 months
(M) EQ5D subscales and summary at 6 months
(M) 4DSQ subscales at 6 months
(P) Occurrence of falls within last 3 months at 3 and 6 months
(C) Number of falls within last 3 months at 3 and 6 months
(P) Occurrence of fall related injury within last 3 months at 3 and 6 months
(C) Number of fall related injuries within last 3 months at 3 and 6 months
(P) Occurrence of pressure ulcer of degree 2+ within last 3 months at 3 and 6 months
(P) Occurrence of pressure ulcer of degree 2 within last 3 months at 3 and 6 months

(P) Occurrence of pressure ulcer of degree 3 within last 3 months at 3 and 6 months
(P) Occurrence of pressure ulcer of degree 4 within last 3 months at 3 and 6 months
(P) Occurrence of incontinence associated dermatitis within 3 months at 3 and 6 months
(P) Occurrence of potentially inadequate medication within 3 months at 3 and 6 months
(M) Self-care subscales at 6 months
(M) Person-centredness subscales at 6 months
(T) Mortality within 6 months
(P) Occurrence of general practitioner visit within 3 months at 3 and 6 months
(C) Number of general practitioner visits within 3 months at 3 and 6 months
(P) Occurrence of specialist visit within 3 months at 3 and 6 months
(C) Number of specialist visits within 3 months at 3 and 6 months
(P) Occurrence of physiotherapy visit within 3 months at 3 and 6 months
(C) Number of physiotherapy visits within 3 months at 3 and 6 months
(P) Occurrence of occupational therapy visit within 3 months at 3 and 6 months
(C) Number of occupational therapy visits within 3 months at 3 and 6 months
(P) Occurrence of speech therapy visit within 3 months at 3 and 6 months
(C) Number of speech therapy visits within 3 months at 3 and 6 months
(P) Occurrence of rehabilitation visit within 3 months at 3 and 6 months
(C) Number of rehabilitation visits within 3 months at 3 and 6 months

(M) Time for PEPA training at 3 and 6 months
(M) Costs of PEPA training at 3 and 6 months
(M) 5 PEPA quality indicators at 6 months
(M) Time for other training at 6 months
(M) Costs of other training at 6 months
(M) Time for PEPA training per institution at 3 and 6 months
(M) Costs of PEPA training per institution at 3 and 6 months
(M) Time for other training per institution at 6 months
(M) Costs of other training per institution at 6 months
(M) Costs of medical devices and apps per institution at 6 months

3.4 Analysis timing

The statistical analysis will be prepared during the follow-up period and performed after monitoring, blinded review, and data base lock. No interim analyses are planned, not even for safety data.

4. Statistical analysis

4.1 Analysis population

The primary analysis population is defined by the intention to treat for all analyses including safety data, as the intervention is empowerment of carers rather than the actual application of the resulting methods of care.

4.2 Intercurrent events

Discontinuation of the Expand-Care intervention or adoption of a policy meant to reverse consequences of the Expand-Care intervention would affect whole institutions. Failure at PEPA training in single carers or at policy implementation are possibilities. Implementation of different policies is another possible intercurrent event.
Intercurrent events that may affect the individual participants are absorbing endpoints (permanent hospitalisation, death).

4.2.1 Analysis strategy

The default analysis strategy is the treatment policy strategy, i.e. intercurrent events are irrelevant as a rule. Absorbing endpoints are considered as competing risks or worst possible assessment by the composite strategy.

4.2.2 Estimands

The primary estimand of the marginal rates in treatment groups is estimated by mixed logistic regression from the occurrence of hospitalisation within 6 months on treatment and occurrence of hospitalization within 3 months prior to the trial (both fixed factors with two levels) and institution (random effects). All participants in all institutions are analysed by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation.
For the treatment effect:
The primary estimand is the marginal odds ratio of occurrence of hospitalisation within 6 months after randomisation adjusted for the presence of hospitalisation within the 3 months prior to the trial among all participants in all institutions by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation.
First sensitivity estimand is the hazard ratio of a Cox regression of recurrent events with shared frailty from times to hospitalisation on treatment and occurrence of hospitalisation within 3 months prior to the trial among all participants in all institutions by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation instead of as a competing risk.
Second sensitivity estimand is the marginal rate ratio of hospitalisation within 6 months in a mixed Poisson regression on treatment and occurrence of hospitalisation within 3 months prior to the trial among all participants in all institutions by the assigned intervention irrespective of intercurrent events like incomplete policy enforcement. Death in the institution is counted as hospitalisation.
All estimands above should be complemented by additional sensitivity estimands that employ GEE for GLM instead of random effects.

4.3 Descriptive statistics

The type of descriptive statistics used in this study are described in the following:

- Type C (count): Absolute frequencies of counts without adjustments and estimated marginal rates and 95% confidence interval for the marginal rate ratio from a mixed Poisson regression on allocated treatment with random institution effects (proc `genmod; ln log(n) model … / dist = poisson link = log offset = ln; repeated subject = institution / type = exch`).
- Type M (measurement): Median and range with 95% confidence Hodges-Lehmann intervals for the difference of medians.
- Type N (normal): Marginal means and total standard deviations (SD) for each treatment group and 95% confidence interval for the difference of marginal means all estimated using the mixed model with fixed treatment effect and random institution effects (proc `mixed; random`).
- Type LN (log-normal): Type N statistics are computed for logarithms and converted back to geometric means, ratio of geometric means and coefficients of variation.
- Type O (ordinal): Absolute frequencies without adjustments and estimated marginal probabilities and 95% confidence Wald interval for the odds ratio from a mixed ordinal logistic regression on allocated treatment with random institution effects (proc `glimmix; random intercept / subject = institution`).
- Type P (proportion): Absolute frequencies without adjustments and estimated marginal probabilities together with 95% confidence score interval for the difference of marginal proportions using a mixed logistic regression (proc `glimmix; random intercept / subject = institution`)..

Type T (time to event): Unadjusted Kaplan-Meier-curves, marginal cause specific hazard ratio (HR) with 95% confidence interval estimated from Cox-regression with shared frailty (proc `phreg; random`), and cumulative incidence functions for competing risks where needed.

The disposition of patients will be described by a CONSORT flow chart.

4.4 Overall methods of analysis

4.4.1 Testing strategy

The primary estimands, proportions in treatment groups, will be estimated into 95%-confidence intervals. Their odds ratio will be estimated into a 95%-confidence interval, too. Additionally, to adjust for multiplicity, (1 – 0.05/2) = 97.5%-confidence for the three will be calculated, as the third is fixed, if two are known. These are the results needed to plan a confirmatory study with the full confidence. They will be superseeded subsequently, so that they are not part of the second testing strategy.

This pilot study is not meant to confirm any claims, but may confirm some, nevertheless. In contrast to the subsequent confirmatory study, this pilot study will not primarily aim at the distal endpoints relevant to the patient, but rather confirm the mechanism of action by tests of the proximal endpoints describing changes in care. No interim analysis is planned with the aim of terminating the study early for efficacy or futility. This formal process evaluation will employ the Bonferroni-Holm procedure for the sixteen endpoints of the nine variables without adjustments, as most moderators will be measured after randomisation. The multiple significance level is set at 0.05, the first local significance level is set at 0.05/16, both for two-sided alternatives. As there was no power calculation directed at these tests, results have to be interpreted as tests of significance rather than tests between alternatives.

Conclusions other than those formulated above cannot be statistically ascertained. Confidence limits may, however, indicate what reasonable expectations are.

4.4.2 Methods of analysis

All analyses are described in detail in the statistical analysis plan (SAP), which will be finalised before the registration of the last patient in the study. The analyses specified therein will be translated into computer code. The results of that code applied to the closed data base are the basis for the statistical study report, on which the clinical study report will be based.

Analyses like the ones in 4.3 will be adjusted for baseline measures of the same, if measured, or by age in the case of mortality. The mapping of endpoints to analysis type is indicated in the list 3.3.2 above by abbreviations of types in parentheses.

4.5 Sample size calculation

A total of 11 nursing homes are to be included, with an average of 15 participating residents. These will be randomised with chance 5:6 to the intervention group and to the control group, resulting in 75 and 90 study participants per study arm. With an assumed drop-out rate of max. 20% (Richter et al., 2019, Saal et al., 2019), data of 60 and 72 residents for each study arm are expected.

The sample size calculation is based on the following assumptions: With an average of 50 residents per nursing home (Statistisches Amt für Hamburg und Schleswig-Holstein, 2020) and an assumed rate of approx. 60% residents meeting eligibility criteria (clinical estimate based on epidemiological data on the incidence of hospital admissions (Leutgeb et al., 2019) and emergency room visits (Brucksch et al., 2018)), it is assumed that on average 60%, i.e. 30 residents, are potentially eligible for participation. Assuming a participation rate of 50% among these residents (Saal et al., 2019), an achievable mean cluster size of 15 residents is assumed. Considering an intra-cluster correlation coefficient of 0.021 (Adams et al., 2004, Richter et al., 2019), this mean cluster size results in a design factor (inflation factor) of 1.294, i.e. the assumed number of 60 and 72 residents with analysable

outcome data corresponds to an effective analysable sample of 46 and 55 residents per treatment group.
The aim of the present study is to estimate as precisely as possible the proportion of residents with at least one hospital admission during the six-month observation period in each of the two treatment groups. Based on empirical results on the annual incidence of hospital admissions among nursing home residents (Leutgeb et al., 2019), it is assumed that the proportion of residents with at least one hospital admission in the control group will be 25% (i.e. 0.25 rate of hospital admissions) for the six-month observation period in this study. Furthermore, it is assumed that the Expand-Care programme to be tested in the intervention group can realistically lead to a reduction in the incidence by a maximum of 10% to 15% (= 0.152 rate of hospital admissions) within the six-month observation period. The planned sample sizes allow these rates to be estimated with a confidence interval of +/- 0.115 or +/- 0.119 in the control group and +/- 0.095 or +/- 0.0985 in the intervention group. This is considered to be sufficient for a precise calculation of the required sample size for subsequent explanatory randomised controlled trials.

4.6 Interim analyses and design adaptions

4.6.1 Interim analyses

No interim analysis is planned, so that any interim analysis would be preceded by an amendment to the trial protocol.

4.6.2 Design adaptions

No design adaption is planned, so that any design adaption would be preceded by an amendment to the trial protocol.

4.7 Adjustment and stratification

The analyses of endpoints will be adjusted for the respective baseline observations and will correct for correlated observations within institutions by random effects models and by GEE as sensitivity analyses.

4.8 Subgroup analysis

The primary analysis will be complemented by subgroup analyses that are exploratory in nature. The results will be displayed as a forest plot of confidence intervals for odds ratios within subgroups, absolute frequencies, and descriptive P values of the statistical tests for interaction between the grouping variable and the treatment. Subgroups will be defined by the baseline values of binary outcome variables and some plausible predictors, if subgroup sizes reach at least 20:
Occurrence of hospital admission within last 3 months
Level of care needed (Pflegegrad) at baseline (care level 2 versus 3 or higher)
Number of comorbidities in classes of at least 20 participants
Dementia Screening Score </=4 versus >4 at baseline
Two classes of maximum number of persons cared for at the institutions
Degree of implementation of Expand-Care programme as quantified in the process evaluation pooled to groups of at least 3 institutions
Occurrence of out-of-hours physician contact within last 3 months
Occurrence of emergency service use within last 3 months
Occurrence of falls within last 3 months
Occurrence of fall related injury within last 3 months, if at least 20 participants
Occurrence of pressure ulcer within last 3 months
Occurrence of incontinence associated dermatitis within 3 months
Occurrence of potentially inadequate medication within 3 months
Occurrence of specialist visit within 3 months
Occurrence of physiotherapy visit within 3 months
Occurrence of occupational therapy visit within 3 months

Occurrence of speech therapy visit within 3 months
Occurrence of rehabilitation visit within 3 months
Sex
Region (HL or HH).
Interpretation of implementation groups would be even more tentative than the rest of the hypothesis generating subgroup analyses, as this happens after randomisation and groups are formed so as to be extreme. An exploratory mediator analysis should be tried instead.

4.9 Missing data

Missing observations in random effects analyses are not imputed. The only exception are "worst case" imputations of hospitalisations in case of death in the institution, when death is not a competing risk. That is a conservative assumption to prevent death from being a favourable outcome. Subjective assessments that were collected earlier than 77 days after randomisation or later than 207 days after randomisation will be set to missing, as the former could severely bias the treatment effect in case of a missing assessment at t2 and the latter would not capture the effect of the intervention that is considered discontinued by then.

4.10 Safety analyses

Medical treatments will be reported. Their frequency will be tabulated by treatment and kind rather than system organ class. The extraction from the eCRF is complex, as the information is scattered. Types are:

- Emergency service, if ambulance or emergency physician, but not just a phone call
- Contact with general practitioner,
- Unplanned visit of general practitioner,
- Visit at the general practitioner's,
- Contact with specialist,
- Physiotherapy,
- Ergotherapy,
- Logopaedic therapy,
- Osteopathy.
- others

Complications:

- Falls,
- Pressure ulcer,
- Dermatitis caused by incontinence
- Deterioration of care level

will be tabulated by randomised treatment and degree or damage. Duration of pressure ulcers and dermatitis will be described by treatment group.
Hospitalisations that are not planned will be tabulated by category (rather than system organ class), duration, outcome, and treatment. Mortality will be tabulated by treatment and cause of death.
Hospitalisations that could have a causal association with the intervention will be listed with all available data and additional information on mitigating treatment.

4.11 Health services research

Medical treatments and requests for these will tabulated by function of the person that initiated the contact, whether the need newly arose, whether the requested treatment was delivered, and the means used.

Complications:

Falls,
Pressure ulcer,
Dermatitis caused by incontinence,
Deterioration of care level
will be tabulated by randomised treatment and requested treatment of the complication.

4.12 Exploratory and sensitivity analyses

The effect of missing data on occurrences is explored by sensitivity analyses of individual incidence rates (Poisson Regression) and event times (Cox regression). This applies to the endpoints that may occur more than once:
Times to or number of out-of-hours physician contact within 6 months
Times to or number of emergency service use within 6 months
Times to or number of falls within 6 months
Times to or number of fall related injury within 6 months
Times to or number of pressure ulcer of category 2+ within 6 months
Times to or number of pressure ulcer of category 2 within 6 months
Times to or number of pressure ulcer of category 3 within 6 months
Times to or number of pressure ulcer of category 4 within 6 months
Times to or number of incontinence associated dermatitis within 6 months
Times to or number of potentially inadequate medication within 6 months
Times to or number of AE within 6 months
Times to or number of SAE within 6 months
Times to or number of general practitioner visit within 6 months
Times to or number of specialist visit within 6 months
Times to or number of physiotherapy visit within 6 months
Times to or number of occupational therapy visit within 6 months
Times to or number of speech therapy visit within 6 months
Times to or number of rehabilitation visit within 6 months

Further adjusted and mediation analyses should explore the need for more or less data in any subsequent trial.

5. Reporting and publication

Reporting will adhere to the CONSORT statement.
Results from the study will only be published after the database has been closed with the only exceptions being publications concerning the design of the study. Before, for methodological-statistical reasons, it must only be reported in general form without results, e.g. recruitment status or demographic characteristics of study participants (within the meaning of Table 1 of a study). There will be no publications or conference contributions on outcomes prior to the first publication on the primary outcome that encompasses the results from all participating institutions.
Any publication shall be consented among the authors and the coordinating investigator. All reports and publications concerning the study are agreed with the responsible biostatistician of the IMBS in order to avoid misinterpretations of statistical results. Conclusions or recommendations formulated in the publications for which a statistical assurance is claimed require the consent of the statistical co-authors. Conclusions or recommendations for which no statistical coverage is claimed are expressly designated as such at the request of the statistical co-authors (see, for example: Grundsätze für die ordnungsgemäße Durchführung der klinischen Prüfung von Arzneimitteln. 9.12.1987. Bundesminister für Jugend, Familie, Frauen und Gesundheit, Bundesanzeiger Nr. 243 vom 30.12.1987, S. 16167, Punkte 4.2. und 4.2.5, and International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, ICH-Efficacy Topic 3, Structure and Contents of Clinical Study Reports, Annex VIII, point A d) (ii)).

A study-assisting member of the IMBS or the ZKS is second on the authors list and the senior author of the IMBS or ZKS second to last in the authors list. Further co-authorships of the IMBS and ZKS are based on the Good Scientific Practice Guideline of the DFG and the four rules of the ICMJE.
The data from the respective centre will be made available to investigators upon request at the end of the study. Publication of this study data from individual centres is only possible after publication of the overall study results.

6. Literature

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Information on the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)".

(Translation based on Version 1.3, 09.07.2022)

Dear Ladies and Gentlemen,

we would like to invite you to participate in the study "Expand-Care". The study is being conducted by the Nursing Research Unit at the University of Lübeck and the Institute for General Practice at the University Medical Center Hamburg Eppendorf. The study is funded by the Federal Ministry of Education and Research (BMBF).

The study was reviewed by an independent ethics committee. This committee did not raise any objections to the conduct of this study.

Your participation in the study is voluntary. If you do not wish to participate or if you later withdraw your consent, you will not suffer any disadvantages as a result.

Please read this information carefully. If you have any further questions regarding the study, please contact us, the study team:

Prof. Dr Katrin Balzer
Principal investigator
Katrin.Balzer@uksh.de
Tel.: 0451 500-52162

Katharina Silies
Research assistant
Katharina.Silies@uksh.de
Tel.: 0451 500-52161

What is the aim of this study?

The aim of this study is to find out whether nursing professionals with special additional qualifications should take on additional tasks in the care of residents in nursing homes. The aim is to improve nursing care and health of residents and to adapt care to their needs. The employment of nursing professionals with additional qualifications in nursing homes is now to be explored and we hereby invite you to participate.

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What is the process of the study?

The study is being conducted in 11 nursing homes in Lübeck and Hamburg. Per nursing home, 15 residents can participate. The nursing homes are **randomly assigned to** two different groups. One group of nursing homes will receive further training, i.e. one of the facility's nursing staff will receive additional training and will apply what they have learned to nursing care and, for example, conduct structured personal conversations with residents. The other group of nursing homes receives care as usual (this means for you everything remains as before). The group allocation is random, which means you yourself, the nursing home and the study staff have no influence on which group the nursing home where you live is allocated to.

If you agree to participate in the study, study staff will collect information of interest from your resident record. In addition, you and a (specialist) caregiver responsible for you at your nursing home will be interviewed by a study staff member on various health-related topics using a questionnaire. This information will be collected at regular intervals at three points in time: at the beginning of the study, after three months and after six months. Your participation is expected to last a total of six months, after which the study will end. We will coordinate all appointments with you and the nursing staff of your institution. You will not incur any financial expenses during the entire study. Participation in the study will require about 30 minutes of your time twice for the interviews. This time expenditure cannot be compensated within this study.

What data is collected from me?

We would like to collect the following information from your resident file and from you as part of the survey:

- Your personal data (age, sex, marital status, degree of care, care aids, and whether you have powers of attorney or a living will).
- Information about your physical and mental health,
- Information from the documentation of the nursing home (e.g. medical diagnoses, medication and medical care, number of falls, hospitalisations, pressure ulcers).

Do I have to give my consent? What happens if I withdraw my consent?

Participation in this study is voluntary. You therefore do not have to participate. Even after you have given your consent, you can terminate your participation in the study at any time without giving reasons and without incurring any disadvantages.

If you would like to withdraw from participation at a later date, please contact the principal investigator Prof. Dr. Katrin Balzer. If you withdraw from the study, data that has already been collected from you can be deleted if you wish, provided that the data has not yet been completely anonymised (see section on data protection). In this case, a connection to your person is no longer given and deletion is therefore no longer possible.

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What are the possible risks and benefits of participation?

Participation in the study is not associated with any risks for you. The applicable hygiene rules (e.g. personal protection equipment) will be observed during personal meetings. Participation in the study can have a direct benefit for you and for other residents of your nursing home, e.g. increased nursing care. In addition, the results of the study may help other residents in nursing homes in the future.

However, it is possible that you will not directly benefit from your participation.

What happens to the results of the study?

The findings will shed light on whether the integration of nursing professionals with expanded competencies in nursing homes leads to better care and quality of life for residents and should be introduced in the future. The results of the study will be presented anonymously to the general public and the professional public, e.g. in scientific journals and at congresses.

Who reviewed the study?

The ethics committee of the University of Lübeck has approved the study protocol (vote of: 11.05.2022; file number: 22-162).

Data protection information

In this study, Prof. Dr. Katrin Balzer, Nursing Research Unit, Institute for Social Medicine and Epidemiology, University of Lübeck, Ratzeburger Allee 160, 23562 Lübeck, Tel.: 0451 500-52162, e-mail: Katrin.Balzer@uksh.de is responsible for data processing. The legal basis for processing your data is your personal consent (Art. 6 para. 1a, Art. 9 para. 2a DSGVO). The data will be treated confidentially at all times.

Your data will only be collected for the purpose of this study and will only be used in the context of this study.
The data also includes personal identifying data such as name, address and date of birth. All data directly related to your person will be replaced by a letter-digit combination (pseudonymised). This largely excludes the possibility of your person being identified by unauthorised persons. Your data is stored and evaluated without reference to your name, i.e. your name is not mentioned anywhere.

Your data is stored in the Nursing research unit on the server of the Science Network of the University Hospital Schleswig-Holstein, Lübeck Campus and in the Institute and Polyclinic for General Medicine on the server of the University Hospital Hamburg-Eppendorf. Paper-based data is stored in lockable and protected cabinets. Only members of the study team have access to your data. These persons are obliged to maintain confidentiality. The data is protected against unauthorised access. All data is stored for 10 years in accordance with legal regulations and deleted after this period has expired.

Monitoring of the study implementation

For the purpose of reviewing the conduct of the study, competent employees of the initiator of the study or study partners commissioned by the initiator for the purpose of reviewing the quality of the

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conduct of the study may inspect the study documents available at the study centre. This can also be done after all relevant data have already been submitted. The reviewers may be, for example, monitors or auditors. For this measure, you release the members of the study team from their duty of confidentiality.

The provisions of the General Data Protection Regulation (DSGV) are complied with. Consent to the processing of your data is voluntary, you can revoke your consent at any time without giving reasons and without disadvantages for you. You have the right to receive information about the data concerning you, also in the form of a free copy. Furthermore, you can request the correction or deletion of your data. To do so, please contact the principal investigator: Prof. Dr. Katrin Balzer (see above for contact details). Anonymously collected or anonymised data cannot be deleted in the event of revocation, however, as it is not possible to trace the data back to individuals.

If you have any queries or complaints regarding data protection, please contact the data protection officer at the University of Lübeck: x-tention Informationstechnologie GmbH, Karl- Drais-Str. 4e, 86167 Augsburg, e-mail: datenschutz@uni-luebeck.de

In the event of a complaint, you can also contact the responsible data protection supervisory authority: Independent Centre for Data Protection Schleswig-Holstein, Holstenstraße 98, 24103 Kiel, e-mail: mail@datenschutzzentrum.de.

Please do not hesitate to contact us if you have any questions!

Thank you for your interest and best regards,

Prof. Dr Katrin Balzer

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University of Lübeck
Nursing research unit
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Ratzeburger Allee 160, 23562 Lübeck

Prof. Dr Katrin Balzer
Secretariat: Elena Teisch
Tel.: 0451 500-51261
Fax: 0451 500-51264

Informed consent for participation in the study

" Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)"

I have received, read and understood the written study information for the above-mentioned study. I was informed in detail - verbally and in writing - about the aim and the course of the study, the risks and benefits of participation, my rights and obligations and the voluntary nature of participation.
I had the opportunity to ask all my questions. These were answered satisfactorily and completely.

Surname, first name resident

Date of birth

I was informed about the study by the following person:

Surname, first name study team member

Telephone number

I hereby declare my participation in the above study. I have been informed that my participation is voluntary and that I have the right to terminate it at any time without giving reasons and without incurring any disadvantages.

I agree to the collection and storage of the data mentioned in the study information, especially the personal data. I have been informed about the possibilities of the right to information and the right to object.

I have received the study information and a copy of this consent.

Place, date

Signature Resident

Place, date

Signature study team member

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University of Lübeck
Nursing research unit
Institute for Social Medicine and Epidemiology
Ratzeburger Allee 160, 23562 Lübeck

Prof. Dr Katrin Balzer
Secretariat: Elena Teisch
Tel.: 0451 500-51261
Fax: 0451 500-51264

Information on the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)"

(Translation based on Version 1.3, 08.07.2022)

Dear Ladies and Gentlemen,

We would like to invite the resident(s) you care for to participate in the study "Expand-Care". The study is being conducted by the Nursing research unit at the University of Lübeck and the Institute for General Practice at the University Medical Centre Hamburg Eppendorf. The study is funded by the German Federal Ministry of Education and Research (BMBF).

The study was reviewed by an independent ethics committee. This committee did not raise any objections to the conduct of this study.

The resident's participation in the study is voluntary. If the resident does not wish to participate or if you later withdraw your consent, you and the resident under your care will not suffer any disadvantages as a result.

Please read this information carefully. If you have any further questions regarding the study, please contact us, the study team:

Prof. Dr Katrin Balzer
Principle investigator
Katrin.Balzer@uksh.de
Tel.: 0451 500-52162

Katharina Silies
Research assistant
Katharina.Silies@uksh.de
Tel.: 0451 500-52161

What is the aim of this study?

The aim of this study is to find out whether nursing professionals with special additional qualifications should take on additional tasks in the care of residents in nursing homes. The aim is to improve the nursing care and health of the residents and to adapt it to their needs. The employment of nursing professionals with additional qualifications in nursing homes is now to be explored and we hereby invite the resident(s) you care for to participate.

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Who can participate in the study?

We invite residents in nursing homes to participate in the study.

In addition, they should have a care degree 3 or higher **or** have a care degree 2 and **additionally** fulfil one of the following points:

OR

- several long-lasting conditions at the same time (e.g. diabetes, high blood pressure and Alzheimer's disease).
- unplanned hospitalisation or emergency medical treatment in the last 8 weeks

What is the process of the study?

The study is being conducted in 11 nursing homes in Lübeck and Hamburg. Per nursing home, 15 residents can participate. The nursing homes are **randomly assigned to** two different groups. One group of nursing homes will receive further training, i.e. one of the facility's nursing staff will receive further training and will apply what they have learned in their nursing care and, for example, conduct structured personal conversations with residents. The other group of nursing homes receives care as usual (i.e. everything remains as before). The groups are randomly assigned, i.e. you, the nursing home and the study staff have no influence on which group the nursing home in which the resident you care for lives will be assigned to.

If you consent to participate in the study on behalf of the resident you care for, study staff will collect information of interest from the resident's file. In addition, the resident him/herself, if possible, and a caregiver of the nursing home responsible for him/her will be interviewed by a study worker on various health-related topics using a questionnaire.

This information is collected at regular intervals at a total of three points in time: at the beginning of the study, after three months and after six months. Participation in the study is expected to last a total of six months, after which the study will end. We will coordinate all appointments with the resident and the nursing staff of the facility. There will be no financial costs for you or the resident during the entire study. Participation in the study will take about 30 minutes twice for the resident. This time expenditure cannot be compensated within this study.

What data is collected from the resident?

We would like to collect the following information from the resident's file and during the survey:

- Personal data (age, sex, marital status, degree of care, care devices and whether powers of attorney or a living will are available),
- Information on physical and mental health,
- Information from the documentation of the nursing home (e.g. medical diagnoses, medication and medical care, number of falls, hospitalisations, pressure ulcers).

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Do I have to give my consent? What happens if I withdraw my consent?

Participation in this study is voluntary. The resident does not have to participate. Even after consent has been given, you can terminate the participation of the resident in the study at any time without giving reasons and without any disadvantages for you or the resident you are looking after.

Furthermore, the interview will only be carried out if the resident himself/herself has given at least verbal consent. If the resident refuses, the interview will not be conducted or will be terminated.

If you would like to withdraw your participation at a later date, please contact the principal investigator Prof. Dr. Katrin Balzer (Katrin.Balzer@uksh.de). In the event of withdrawal from the study, data already collected from the resident can be deleted if desired, provided that the data have not yet been completely anonymised (see section on data protection). In this case, a connection to the person no longer exists and deletion is therefore no longer possible.

What are the possible risks and benefits of participation?

Participation in the study is not associated with any risks for you and the resident. The applicable hygiene rules will be observed during the personal meetings. Participation in the study may have a direct benefit for the resident and for other residents of the nursing home, e.g. increased nursing care. In addition, the results of the study may help other residents in nursing homes in the future.

However, it is possible that the resident you care for will not directly benefit from participation.

What happens to the results of the study?

The findings will provide information on whether the integration of nursing professionals with expanded competencies in nursing homes leads to better care and health of the residents and should be introduced in the future. The results of the study will be presented anonymously to the general public and the professional public, e.g. in scientific journals and at congresses.

Who reviewed the study?

The ethics committee of the University of Lübeck has approved the study protocol (vote of: 11.05.22; file number: 22-162).

Data protection information

In this study, Prof. Dr. Katrin Balzer, Section for Research and Teaching in Nursing, Institute for Social Medicine and Epidemiology, University of Lübeck, Ratzeburger Allee 160, 23562 Lübeck, Tel.: 0451 500-52162, e-mail: Katrin.Balzer@uksh.de responsible for data processing. The legal basis for processing the data is personal consent (Art. 6 para. 1a, Art. 9 para. 2a DSGVO). The data will be treated confidentially at all times. The data will be collected exclusively for the purpose of this study and will only be used within the scope of this study. The data also includes personal identifying data such as name, address and date of birth. All data directly related to the person will be replaced by a letter-digit combination (pseudonymised). This largely excludes identification of the person by unauthorised persons. The data is stored and evaluated without reference to the name, i.e. the name of the resident is not mentioned anywhere.

All data are stored in the Nursing research unit on the server of the Science Network of the University Hospital Schleswig-Holstein, Lübeck Campus and in the Institute and Polyclinic for General Medicine on the server of the University Hospital Hamburg-Eppendorf. Paper-based data is stored in lockable and protected cabinets. Only members of the study team have access to the data. These persons are obliged to maintain confidentiality. The data is protected against unauthorised access. All data is kept for 10 years and deleted after this period.

Monitoring of the study implementation

For the purpose of reviewing the conduct of the study, competent employees of the initiator of the study or study partners commissioned by the initiator for the purpose of reviewing the quality of the conduct of the study may inspect the study documents available at the study centre. This can also be done after all relevant data have already been submitted. The reviewers may be, for example, monitors or auditors. For this measure, you release the members of the study team from their duty of confidentiality.

The provisions of the General Data Protection Regulation (DSGV) are complied with. Consent to the processing of data is voluntary; you can revoke your consent at any time without giving reasons and without disadvantages for yourself or the resident. You have the right to receive information about the relevant data of the resident(s) looked after by you, also in the form of a free copy. Furthermore, you can request the correction or deletion of the data. To do so, please contact the head of the study: Prof. Dr. Katrin Balzer (see above for contact details). Anonymously collected or anonymised data cannot be deleted in the event of revocation, however, as it is not possible to trace the data back to individual persons.

If you have any queries or complaints regarding data protection, please contact the data protection officer at the University of Lübeck: x-tention Informationstechnologie GmbH, Karl- Drais-Str. 4e, 86167 Augsburg, e-mail: datenschutz@uni-luebeck.de. In the event of a complaint, you can also contact the competent data protection supervisory authority: Independent Centre for Data Protection Schleswig-Holstein, Holstenstraße 98, 24103 Kiel, e-mail: mail@datenschutzzentrum.de.

Please do not hesitate to contact us if you have any questions!

Thank you for your interest and best regards,

Prof. Dr Katrin Balzer

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Informed consent for participation in the study

"Expanded nursing competencies to improve person-centred care for residents in nursing homes (Expand-Care)".

I have received, read and understood the written study information for the above-mentioned study. I was informed in detail - verbally and in writing - about the aim and the course of the study, the risks and benefits of participation, my rights and obligations and the voluntary nature of participation. I had the opportunity to ask all my questions. These were answered satisfactorily and completely.

Surname, first name guardian/ Authorised representative

Date of birth

I was informed about the study by the following person:

Surname, first name study team member

Telephone number

I hereby declare the participation of the resident(s) in my care:

Surname, first name resident

Date of birth

in the above-mentioned study. I have been informed that participation is voluntary and that I have the right to terminate it at any time without giving reasons and without any disadvantage to me or the resident.

I agree to the collection and storage of the data mentioned in the study information, especially the personal data. I have been informed about the possibilities of the right to information and the right to object.

I have received the study information and a copy of this consent.

Place, date

Signature of guardian/ Authorised representative

Place, date

Signature study team member

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Reported on page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	Title page
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	Abstract
	2b	All items from the World Health Organization Trial Registration Data Set	✓
Protocol version	3	Date and version identifier	Abstract
Funding	4	Sources and types of financial, material, and other support	2~~3~~1
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	Title page, 2~~2~~1
	5b	Name and contact information for the trial sponsor	Title page
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2~~3~~1
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	2~~3~~2

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5
	6b	Explanation for choice of comparators	
Objectives	7	Specific objectives or hypotheses	5,6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6,7
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n.a.
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	8,9
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n.a.

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	9,12-14~~1,12~~
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10~~9~~
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	~~9,~~10
Methods: Assignment of interventions (for controlled trials)			
Allocation:			1~~1~~0
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	1~~1~~0
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	1~~0~~1
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	1~~1~~0
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	1~~1~~0

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	1~~0~~
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	1~~0~~-1~~5~~4
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	1~~4~~4
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	~~14,~~15,16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	1~~6~~5
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	1~~6~~5
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	1~~6~~5
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	1~~7~~6

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n.a.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	17~~6~~
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n.a.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18~~7~~
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	18~~7~~
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	18~~7~~
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n.a.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	18~~7~~
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	23~~1~~
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	~~17,~~18,19

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	198
	31b	Authorship eligibility guidelines and any intended use of professional writers	231
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	197
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplement
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	Not applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.