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.

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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

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

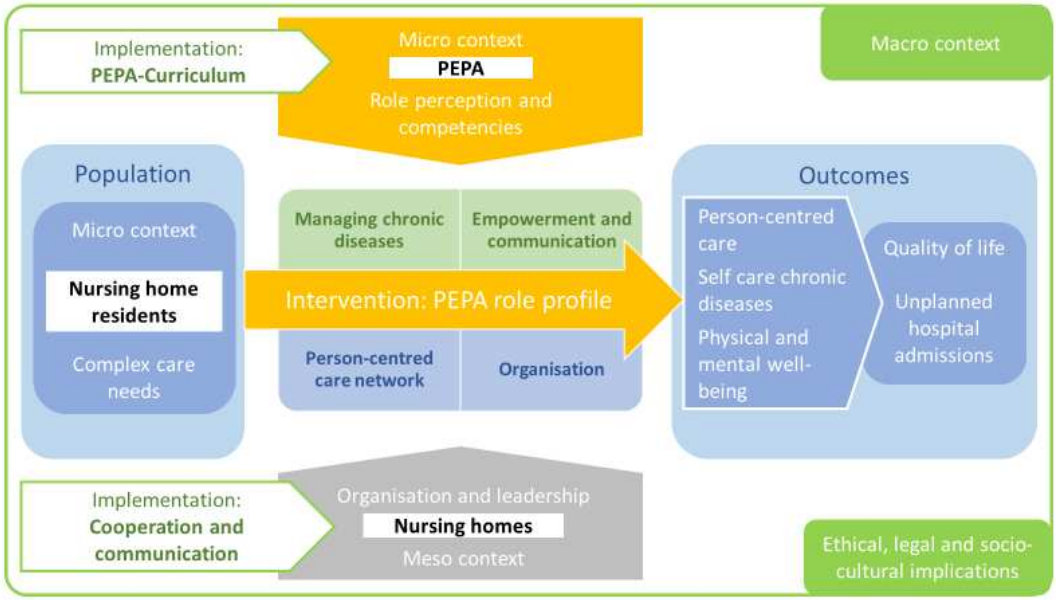

Figure 1: Logic model of the Expand-Care intervention

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.

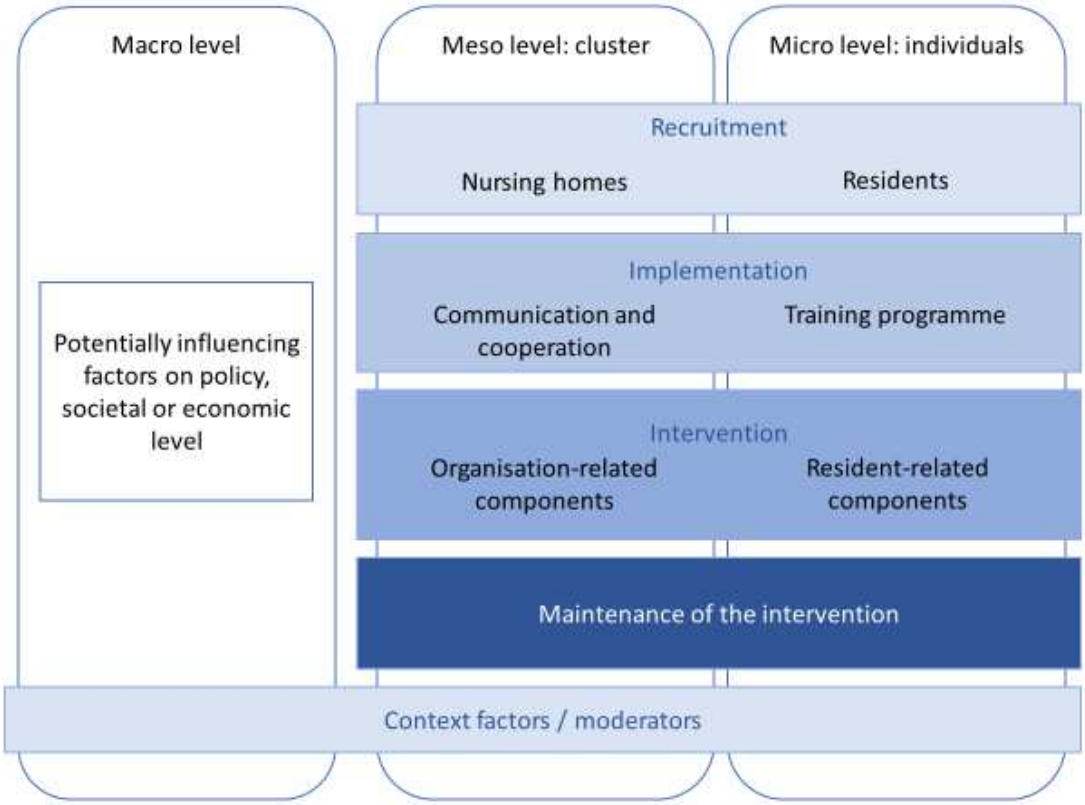

Figure 1: Process evaluation within the framework of cluster-randomised studies. Own representation based on Grant et al., 2013, p. 4.

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.

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

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