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Strengthening geriatric expertise in Swiss nursing homes: INTERCARE implementation study protocol

Running title: INTERCARE implementation study protocol

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ABSTRACT

Background / Objectives: Nursing home (NH) residents with complex care needs ask for attentive monitoring of changes and appropriate in-house decision making. However, access to geriatric expertise is often limited with a lack of geriatricians, general practitioners and/or nurses with advanced clinical skills, leading to potentially avoidable hospitalizations. This calls for the development, implementation and evaluation of innovative, contextually adapted, nurse-led care models that support NHs in improving their quality of care and reducing hospitalizations by investing in effective clinical leadership, geriatric expertise and care coordination.

Design: An effectiveness-implementation hybrid type II design to assess clinical outcomes of a nurse-led care model and a mixed-method approach to evaluate implementation outcomes will be applied. The model development, tailoring and implementation are based on the Consolidated Framework for Implementation Research (CFIR).

Setting: NHs in the German-speaking region of Switzerland.

Participants: Eleven NHs are recruited. The sample size was estimated assuming an average of 0.8 unplanned hospitalizations/1,000 resident days and a reduction of 25% in NHs with the nurseled care model.

Intervention: The multilevel, complex, context-adapted intervention consists of six core elements, e.g. specifically trained INTERCARE nurses or evidence-based tools like ISBAR. Multilevel implementation strategies include leadership and INTERCARE nurse training and support.

Measurements: The primary outcome are unplanned hospitalizations /1000 care days. Secondary outcomes include unplanned emergency department visits, quality indicators (e.g. physical restraint use) and costs. Implementation outcomes include e.g. fidelity to the model's core elements.

Conclusion: The INTERCARE study will provide evidence about the effectiveness of a nurseled care model in the real-world setting and accompanying implementation strategies.

Key words: nursing home, hospitalization, nurse expert, interprofessional models of care, clinical leadership, implementation science, quality of care

INTRODUCTION

Nursing home (NH) residents show increasingly complex care needs due to multimorbidity or dementia, demanding higher levels of geriatric expertise from care staff. In Switzerland, 44.7% of residents enter a nursing home after a hospital stay. While 80% of NH residents receive longterm care and stay for 2.5 years, about one third return home and transitional care is increasing [1]. The gap between demand and supply of both registered nurses and general practitioners (GPs) is widening worldwide. Direct care in NHs is increasingly provided by care workers with minimal or no professional education [2, 3]. With NH admissions of frail residents in later stages of chronic conditions, care workers' capacity for early detection and reaction to changes in health conditions is critical to avoid adverse health outcomes [4]. However, signs and symptoms in older persons are often atypical and the lack of geriatric expertise, interprofessional communication skills and clinical leadership in NHs jeopardizes the quality of care and quality of life of this frail high-risk population. One quality issue are avoidable hospitalizations, associated with potential negative outcomes for residents, such as increased mortality, delirium or falls, and excess costs [5, 6]. Between 19% and 67% of hospitalizations from NHs might be avoidable [7], i.e. the condition for which the resident was admitted could have been prevented with adequate chronic disease management.

Interprofessional, nurse-led health care teams effectively support NH care quality by improving the management of chronic conditions and residents' quality of life and reducing clinical outcomes such as falls, hospitalizations, and overall costs [8-11]. Many models are led by advanced practice nurses (APNs) with a Master's level education, who drive residents' needs assessment, care coordination and transitions between settings, while providing geriatric clinical leadership and supporting quality improvement [12]. Some models have proven efficient with registered nurses (RNs) with specific education taking up clinical leadership roles [13]. Despite this evidence, the scalability of these types of care models is hindered by characteristics of the local context (e.g. absence of trained RNs or APNs). The challenge remains to implement a model that is contextually adapted and to test its effectiveness while simultaneously using and evaluating effective implementation strategies.

The INTERCARE study

Experts call for the evaluation of the implementation as well as clinical and economic outcomes when introducing nurse-led models in a new context [12]. Lessons learned from these measures will guide future implementation in diverse real-world settings and fuel scalability. Accordingly,

the main purpose of the INTERCARE (Nurse-led model in Swiss nursing homes: improving INTERprofessional CARE for better resident outcomes) implementation science study is to develop, to implement and to evaluate a Swiss model (cf. Figure 1). In phase A of INTERCARE (2017 - 2018), a state-of-the-art nurse-led care model adapted to the local Swiss context was developed. In phase B (2018 - 2020), we will implement the model and evaluate its clinical effectiveness with the main outcome of unplanned hospitalizations, costs, and implementation outcomes (e.g. feasibility, acceptability). This protocol focuses on the model's implementation and evaluation in Phase B.

We adhere to active principles of *Public Patient Involvement* (PPI) throughout the study [14, 15]. The research group consults with a broad stakeholder group with representatives from policy, education, insurance companies, professional groups, patient groups, and health care providers in the design of the intervention, data interpretation, and dissemination of results.

Three theoretical frameworks support the context analysis and the development and implementation of the nurse-led care model: the PEPPA (participatory, evidence-based patient-centred process for APN role development, implementation, and evaluation), PEPPA+ frameworks [16, 17] and the Consolidated Framework For Implementation Research (CFIR) [18].

Preliminary work in preparation of the intervention study

For effective implementation, contextual adaptation and assessment of possible barriers and facilitators are of paramount importance during the development of the model. Accordingly, phase A used a mixed-method design and stakeholder input to develop the contextually adapted nurse-led care model. In a first step, we collected evidence from a) a literature review of the international evidence, and b) 17 case studies of both evaluated and non-evaluated international and local Swiss NH models. These explored barriers and facilitators for model implementation, as well as a scope of practice, competencies and expected outcomes of nurses in expert roles. For data collection we used a questionnaire survey of nurse experts and interviews with NH leadership, nurse experts, and the medical director or GP related to the NH. In our analysis, we identified facilitators such as strong leadership support, and barriers such as lack of clarity about the nurse expert's role and scope of practice, unclear task distribution between care workers and the nurse expert, and lack of resources (time and finances).

In a second step, stakeholder involvement was guaranteed by asking the stakeholder group about the appropriateness of the nurse experts' competencies and the expected outcomes we found in the case studies for the Swiss context with an adapted form of the RAND-/UCLA

Appropriateness Method, a modified Delphi study [19]. Their ratings supported us in focusing the INTERCARE nurses' training on core competencies for the main study outcomes and distinguishing clearly between their role and the RNs' role. Last, we gained feedback from seven residents and eleven relatives in three workshops performed in three NHs working with expert nurses. We assessed their values and preferences concerning care in acute situations, mainly finding that residents and relatives feel a lack of support in their decision-making. As a result of phase A, we gained an understanding of the social, financial, policy and organizational variations of nurse-led care models in Switzerland, as well as of implementation barriers and facilitators. We defined core elements of a nurse-led model as a multilevel intervention and planned implementation strategies to address barriers and facilitators and support the uptake of the model.

Aims of the intervention study

Phase B aims to assess the clinical effectiveness of the new model, its economic and its implementation outcomes. Clinical outcomes are unplanned hospitalizations as primary outcome, i.e. unexpected admissions to a hospital, hypothesizing a significant reduction. Secondary outcomes at resident level are avoidable hospitalizations, unplanned and avoidable ED visits, national quality indicators (physical restraints, pain, weight loss, polypharmacy), while at staff level we assess job satisfaction, satisfaction with care quality, interprofessional collaboration and self-efficacy in clinical situations. For economic outcomes, we will calculate the implementation costs of INTERCARE and the incremental cost-effectiveness ratio for hospital days for unplanned hospitalizations. Finally, we assess implementation outcomes including the adoption, acceptability and feasibility of the model and the fidelity to its core elements. The effectiveness of the implementation strategies supporting the uptake of the model will be explored through regular meetings with INTERCARE nurses, leadership and by mean of questionnaire surveys.

METHODS

Design

For phase B, running from June 2018 to February 2020, INTERCARE uses an effectiveness-implementation hybrid type II design [14] combining the assessment of the clinical effectiveness of the newly built care model on unplanned hospitalizations, costs and implementation outcomes. For the clinical effectiveness and cost part, a non-randomized quasi-experimental stepped wedge design (21 months) will be used [20] (cf. supplementary figure S1). This unidirectional crossover design allows each NH to be first a control, then an intervention site. For the evaluation of

implementation outcomes, a concurrent mixed-method design will be used. INTERCARE has been registered at clinicaltrials.gov (Protocol Record NCT03590470).

Setting and Sample

We purposefully selected 11 highly motivated NHs with the willingness to change their current care model. NHs were included if they: 1) have ≥60 long-term care beds, 2) have ≥0.8 hospitalization per 1.000 resident days, 3) are in the German speaking part of Switzerland, 4) collect RAI-NH data for each resident (Resident Assessment Instrument − Nursing Home version), 5) have a NH physician(s) agreeing to work collaboratively with the INTERCARE nurses, if the physician is hired by the NH, 6) show willingness to provide for the INTERCARE nurse's salary, and 7) show willingness and high commitment of NH leadership to participate. For the primary outcome of unplanned hospitalizations, all long-term care residents in the NHs are included if informed consent is provided. Further inclusion and exclusion criteria at the resident, staff, and GP level can be consulted in the supplementary material (table S1).

Intervention

The INTERCARE model includes both 'core', i.e. binding intervention components, and 'peripheral', i.e. locally adaptable intervention components [18]. Based on our preliminary work, we defined six core elements for this multilevel, complex intervention: a) An interprofessional care team, b) INTERCARE nurse, c) comprehensive geriatric assessment, d) advance care planning, e) evidence-based instruments (e.g. ISBAR), and f) data-driven quality improvement (cf. supplementary table S2 for a detailed description). A basic prerequisite was that the NH leadership was engaged in promoting INTERCARE. For the nursing homes with responsible physicians, they were fully involved in the project and in on-site training of the INTERCARE nurse(s). For the NHs working with community-based GPs, they were informed about the project and further involved if willing to be. The minimal requirements for each core element were made definite once the corresponding teaching module for the INTERCARE nurses was finished (February 2019).

Implementation strategies

Specifically tailored strategies help to address the barriers for model implementation. Based on the conceptualization provided by Powell at al. in the Expert Recommendations for Implementing Change (ERIC) [21], we use implementation strategies on the levels of planning, education, and quality management (cf. supplementary table S3 for further information). We assist the participating NHs in planning the implementation of core and peripheral components, supporting

them in the local tailoring for high acceptability and buy-in from co-workers, clearly working out the content of the new role and its added value for RNs. This was done in preparatory leadership meetings of one full day and two half days, with phone support on demand and two-monthly visits. INTERCARE nurses follow a blended learning curriculum of approximately 140 hours preparing them for their role. They receive continuous support during the implementation with two-weekly phone calls and two-monthly meetings with the leadership and research team. The implementation strategies were flexible at roll-out and locked once the last NH has finished the one-month run-in period (February 2019). Finally, we provide quarterly performance feedback about the resident outcomes.

Intervention outcomes

Primary outcome of the study will be unplanned hospitalizations [22] (s. Table 1), where unplanned refers to unexpected hospitalisations where the resident needs attention for his condition at the earliest possible time. Potentially avoidable hospitalizations will be assessed by a subset of specific ambulatory care specific diagnoses or conditions (ACSC). It is assumed that conditions such as congestive heart failure or pneumonia could be treated without hospitalization given early identification of deterioration and adequate symptom management. Such NH-specific ACSC will be defined based on the current state-of-the-art [22-24]. However, since diagnoses alone cannot account for the necessity of hospitalizations, additional process measures will be used [22]: From baseline to the end of the intervention, INTERCARE nurses assess each hospitalization with the INTERACT Quality Improvement Tool for Review of Acute Care Transfers (cf. http://www.pathway-interact.com/tools/), adapted to the Swiss context. This allows to integrate contextual and clinical factors in the evaluation whether a hospitalization would have been avoidable. The operationalization of further effectiveness outcomes are described in Table 1 and supplementary table S4.

Economic outcomes

Economic outcomes will be assessed at the NH level. We will assess the implementation cost of INTERCARE for NHs (staff costs: salary and training INTERCARE nurse, staff-related expenses to implement program; material cost: e.g. new devices) (see supplementary Table S5). On the other hand, we will assess the incremental cost-effectiveness ratio for hospital days for unplanned hospitalizations. This ratio will be measured as increase in staff costs during the intervention phase (after run-in period of one month) divided by decrease of days of unplanned

hospitalizations (days of stay after run-in period of 1 month minus days of stay during control phase).

Implementation outcomes

We will assess the acceptability and feasibility of the model via questionnaire surveys of NH staff and INTERCARE nurses at baseline and 6 and 12 months after implementation with the Acceptability of Implementation Measure (AIM) and Feasibility of Intervention Measure (FIM) [25] (see supplementary table S6). Concurrently, qualitative data about both implementation outcomes will be explored in discussions in leadership meetings, in individual interviews with INTERCARE nurses and GPs, and focus groups with NH staff. Fidelity will be measured quantitatively, e.g. in quarterly reports about the number of residents with clarified do-not-resuscitate order for the core element advance care planning. Additionally, the two-monthly meetings with NH leadership and INTERCARE nurses mentioned previously will be used to assess the model's adoption. As for the implementation strategies, we will evaluate each module of the INTERCARE nurse curriculum in a participant survey and explore the acceptability and usefulness of the bi-monthly meetings and bi-weekly phone calls 12 and 18 months after the intervention start in group discussions with NH leadership and INTERCARE nurses (see supplementary table S7).

Data collection

As shown in supplementary figure S1, each NH will start with a 3-month baseline phase prior to the implementation of the nurse-led care model. The first NH started with the implementation of the model in September 2018 and the others sequentially begin every month thereafter. A run-in period of 1 month was planned to address possible timing problems with the model start. Data collection points are shown in supplementary figure S1, and include quantitative questionnaire surveys of NH leadership, NH staff, and INTERCARE nurses at baseline and 6, resp. 12 month after implementation. Qualitative data collection points at months 6 and 12 include interviews with INTERCARE nurses and GPs, and focus groups with NH staff. NHs will provide 3-monthly exports of quality indicators per institution and collect continuous data on unplanned hospitalizations and related secondary outcomes, captured with CASTOR EDC®. They both will be used to measure resident outcomes and as part of the core element data-driven quality improvement to allow internal quality monitoring and benchmarking. Ethical approval has been granted from all ethic committees responsible for the eleven participating NHs (EKNZ 2018-00501).

Sample size

The non-probabilistic sample size for the primary outcome was estimated with a simulation of the proposed stepped wedge design assuming an average of 0.8 unplanned hospitalizations/1,000 resident days and a reduction of 25% in NHs with the nurse-led care model [4, 10]. Eleven NHs will allow to detect a 25% reduction of unplanned hospitalization with a power of 80% using a significance level alpha = 5%. The sample size for the mixed-method design is guided by including the full sample (INTERCARE nurses, NH leadership, quantitative resident data) or by reaching data saturation (interviews with GPs, nursing staff) [26].

Data analysis

Resident outcomes will be analysed using the R statistical programming language (R version 3.X). To assess the effectiveness of the nurse-led care model for unplanned hospitalizations, a generalized linear mixed effects model with binomial error distribution and logistic link function will be applied, with the NH identifier as random effect and the intervention as fixed effect. In a stepped-wedge design, the distribution of the results for unexposed periods is compared with that of exposed periods [20]. A sensitivity analysis will be performed adding time as fixed factor to the model. We will perform intention-to-treat analyses and include sensitivity analyses based on whether the intervention was actually in place.

Implementation outcomes are assessed in a concurrent mixed-method design: quantitative data from questionnaire surveys or document analysis will be described according to their distribution. All interviews will be analysed deductively using the framework method, identifying and refining descriptive coding categories to reduce the amount of data [27]. The analysis is divided into five phases: Familiarization with the data, identifying a thematic framework, indexing parts of the text, charting the indexed text and mapping and interpretation. Data management will be supported by the software MAXQDA. Data will be mixed at the level of the discussion.

DISCUSSION

Expected impact / Significance

The INTERCARE implementation science study fuels the uptake of a stakeholder-supported and contextually adapted model in the real world of Swiss NHs. On a pragmatic-explanatory continuum, it is a highly pragmatic trial [28] (see supplementary table S8). The combination of 1) intervention development based on evidence and context analysis and 2) the intervention's multilevel implementation supported by locally adapted implementation strategies improves the

likelihood of successful implementation. Moreover, active stakeholder involvement insures the model has a broad acceptance and prepares for its scalability. This overall approach can serve as an example for other countries facing similar challenges.

The new nurse-led, interprofessional NH care model is expected to address quality of care issues in NHs by remediating the current shortage of geriatric expertise in NHs, advancing interprofessional communication and care coordination and improving the allocation of health care resources, therewith also addressing residents' quality of life. The study results will support evidence-based decision making at the policy level and management level of individual NHs concerning the use of nurse-led care models. They will also address economic implications and reimbursement issues for the model to be economically sustainable. Due to its complexity, the model's generalizability will be limited to nursing homes with high leadership involvement.

Limitations

Implementation research provides the possibility to evaluate programs in the real-life settings by taking into account stakeholders and the local context. The possibility to adapt components of research lessens its rigour, but strengthens its immediate usefulness [29]. INTERCARE focuses on the implementation of a locally adapted model in highly motivated NHs, which hinders the generalizability of its results. However, the use of implementation theory and future reporting based on standards for implementation studies [30] will allow to identify transferable elements and share with other regions lessons learned about adaptations in order to support the scale-up of the care model.

CONCLUSION

INTERCARE aims to both develop and implement a nurse-led care model for NHs in the real-life context in the German-speaking part of Switzerland. Once implemented, it is expected to give insight in ways to improve delivery of quality and professional geriatric care for NH residents, and to reduce avoidable hospitalizations. The described implementation science methodology can be used internationally as a framework for future implementation studies to support the uptake of complex, multilevel interventions in NHs.

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Conflict of interest: none of the authors declare a conflict of interest

Authors' roles: FZ, MS and SDG developed the study concept and design, all other authors (RG, KB, DN, RWK, AZ, NIHW, CDP, EV, MD, CS) contributed to it. FZ, SDG, and RAG prepared

the manuscript, all others authors (KB, DN, RWK, AZ, NIHW, CDP, EV, MD, CS, MS) substantially added to it, by critically revising it.

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LEGENDS

Figure 1: Overview INTERCARE study

Notes: A1: Evidence-based description of a nurse-led care model for NHs; A2: Stakeholder assessment of the model's appropriateness and adaptation to the Swiss context; B1: Tailoring of nurse-led care model to participating NHs and preparatory training; B2: Testing of nurse-led care model; B3: Data analyses, interpretation and reporting

<u>Table 1:</u> Operationalization and data collection for effectiveness outcomes at resident level in INTERCARE

SUPPLEMENTAL FILES

Supplementary Figure S1: Stepped-wedge design: start and duration of intervention; data collection points

Supplementary Table S1: Inclusion and exclusion criteria

Supplementary Table S2: Core and peripheral elements

Supplementary Table S3: Implementation strategies

Supplementary Table S4: Operationalization and data collection for secondary effectiveness outcomes at staff level

Supplementary Table S5: Operationalization and data collection for economic outcomes at NH level

Supplementary Table S6: Operationalization and data collection for implementation outcomes

Supplementary Table S7: Assessment of implementation strategies

Supplementary Table S8: PRECIS assessment of INTERCARE

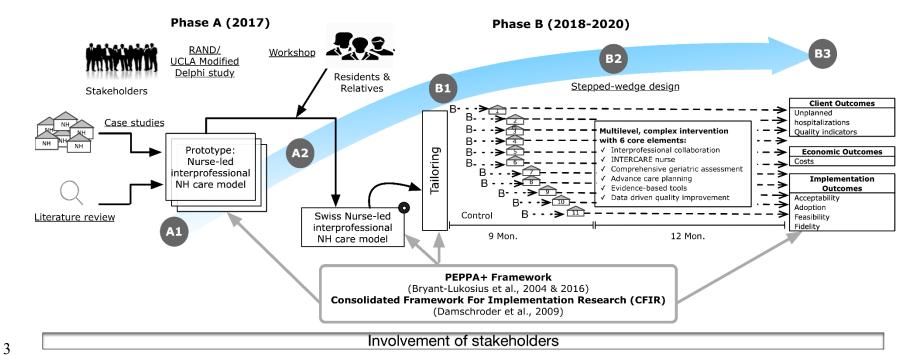


Table 1: Operationalization and data collection for effectiveness outcomes at resident level in INTERCARE

Outcome	Operationalization	Data collection
Unplanned hospitalizations (primary outcome)	n of unplanned ¹ hospitalizations /1000 care days Exclusion criteria: planned hospitalizations (e.g., non-emergency surgical procedure, blood transfusion, chemotherapy), and ED visits with discharge within 24h	Local coordinator enters data for each hospitalization in CASTOR EDC ® n of care days/month provided by NH administration
Avoidable hospitalizations	n of hospitalizations for ACS primary diagnoses /1000 care days Avoidable hospitalizations will be defined according to ACS primary diagnoses at hospital discharge [23]. Exclusion criteria: cf. primary outcome	Cf. primary outcome ACS diagnoses assessed via hospital discharge reports
Unplanned ED visits	n of unplanned ¹ ED visits /1000 care days Inclusion criterion: ED visits of <24h (stays >24h are classed as hospitalization)	Cf. primary outcome
ED visits for ACS primary diagnoses	n of ED visits for ACS primary diagnoses /1000 care days Inclusion criterion: ED visits of <24h (stays >24h are classed as hospitalization)	Cf. primary outcome and hospitalizations for ACS primary diagnoses
Pain (differentiating self-reported and observed pain)	% of residents with self-reported pain, resp. % of residents with observed pain (i.e. daily pain of moderate intensity or non-daily pain of severe intensity)	Operationalization is based on measurement of national quality indicators to be introduced in Switzerland in 2019. Their
Weight loss	% of residents with weight loss of 5% or more during the preceding 30 days, or of 10% or more in the preceding 180 days	measurement is integrated in the routine assessment instrument (Resident Assessment Instrument–Minimal Data Set:
Polypharmacy	% of residents receiving 9 or more medications (active components) over the preceding 7 days	RAI-MDS). Resident assessments are performed at least every 180
Physical restraint use (differentiating bedrails and fixation of trunk)	% of residents with daily fixation of the trunk or seating that does not allow standing during the preceding 7 days, or with daily use of bedrails over the preceding 7 days	days and stored in local NH databases [25]. This continuously collected data will be exported every 3 months as .csv-file.

¹ In INTERCARE, an unplanned hospitalization is defined as an unexpected or urgent admission to the hospital in contrast to a planned admission, where a resident is referred to a hospital by the physician for a condition that needs a surgery or treatment and an admittance date and time is agreed upon with the hospital.

Abbreviations: ACS, ambulatory care-sensitive; ED, Emergency department, NH, nursing home

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Supplementary Figure S1: Stepped-wedge design: start and duration of intervention; data collection points

Overview phase B INTERCARE

	2018					2019							2020								
	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
NH1	Q0			R M1		M2		M3		M4	Q1/I1	M5		M6		M7	Q2/I2	M8		M9	
NH2		Q0			R M1		M2		M3		M4	Q1/I1	M5			M6		Q2/I2 M7		M8	
NH3		Q0			R M1		M2		M3		M4	Q1/I1	M5			M6		Q2/I2 M7		M8	
NH4		Q0			R M1		M2		M3		M4	Q1/I1	M5			M6		Q2/I2 M7		M8	
NH5		Q0			R M1		M2		М3		M4	Q1/I1	M5			M6		Q2/I2 M7		M8	
NH6		Q0			R M1		M2		M3		M4	Q1/I1	M5			M6		Q2/I2 M7		M8	
NH7			Q0			R M1		M2		M3		M4	Q1/I1	M5		M6		M7	Q2/I2	M8	
NH8			Q0			R M1		M2		M3		M4	Q1/I1	M5		M6		M7	Q2/I2	M8	
NH9				Q0			R M1		M2		M3		M4	Q1/I1	M5		M6		M7	Q2/I2 M8	
NH10					Q0			R M1		M2		M3		M4	Q1/I1	M5		M6		Q2/I2 M7	
NH11						Q0			R M1		M2		M3			Q1/I1 M4		M5		Q2/I2 M6	
	QR			QR			QR			QR			QR			QR			QR		
Hospitalizations	2) Cont	tinuous d	lata colle	ection on	all unpla	anned ho	spitalizat	ions wit	h CAST	on tool st OR EDC Jul 17 and	, quarter	ly report	s (QR) to	o NHs	udy,						
Quality indicators	Quarter	ly repor	ts (QR)	of QI dat	a from R	AI-NH	from Jul	17 to en	d of stud	y (data b	efore mo	del start	as contro	ol for NI	Hs)						

Abbreviations:

I1/I2: Interviews with nursing home staff, general practitioners, INTERCARE nurse;

M1 to $M8\colon meetings$ with nursing home leadership and INTERCARE nurses;

Q0/Q1/Q2: Questionnaire surveys with NH staff, INTERCARE nurse, Q0/Q2: facility and unit data;

QR: quarterly reports; R: Run-in period

Supplementary Table S1- inclusion and exclusion criteria						
Unit of Analysis	Method	Sample	Inclusion criteria	Exclusion criteria		
NHs	Implementation of nurse-led model of care	Non-probabilistic	 Size: ≥60 long-term care beds Hospitalization rates: ≥0.8/1000 resident days German-speaking Work with RAI-NH (Resident Assessment Instrument – Nursing home version) have a NH physician(s) agreeing to work collaboratively with the INTERCARE nurses, if the physician is hired by the NH how willingness to provide for the INTERCARE nurse's salary willingness and high commitment of NH leadership to participate 	• Italian and French speaking		
Residents	 CASTOR EDC: clinical data about hospitalizations, ED visits RAI-NH quality indicators Discharge reports 	All residents/NH	Long-term care residents	 Holiday guests Short stay Day care residents		
NH staff	Questionnaire surveys	All staff/NH	 Care workers of all educational levels, including students Other health professionals 	• Non-health professionals (e.g., administration)		
INTERCARE nurse	Focus group interviews Questionnaire survey Individual interviews	Per NH: • 4-6 registered nurses / licensed practical nurses • 4-6 nurse aides All INTERCARE nurses	 Readiness to participate in focus group In direct care as registered nurse, licensed practical nurse or nurse aide In NH for at least 3 months Hired by NH Understands and speaks German Hired as INTERCARE nurse or their substitutions¹ 			

Supplementary Table S1- inclusion and exclusion criteria

Unit of Analysis	Method	Sample	Inclusion criteria	Exclusion criteria
General physicians	Individual phone interviews	All GPs treating residents in NHs	Physician: • Responsible for at least 1 resident in last 3 months	• Temporary substitute GPs, specialists or consultant

¹ Some participating NHs defined persons who could substitute the INTERCARE nurse in case she was on holidays or otherwise absent. These substitute nurses did the full curriculum of the INTERCARE nurse, but had another main role in the NH.

Abbreviations: ED emergency department; EDC electronic data capture; GP general practitioner; NH nursing home; RAI-NH Resident Assessment Instrument – Nursing Home version

The following table provides the list of core components of the nurse-led model of care, which correspond to the minimal requirements and the peripheral components, which can be tailored to each NH (CFIR).

Core elements (including minimal requirements)	Additional information for minimal requirements	Peripheral
Interprofessional collaboration		
 A structure in place to facilitate interprofessional communication (e.g. meetings) between at least two different professions. Noticing a resident issue and liaising with the relevant health care professional to establish the residents' care goal. 	Each NH is free to decide how communication between different professions may occur, for instance regular team meetings or unit rounds.	Number of structures in place and type of staff involved in the communication structures.
 Interpretation of assessment results and formulation of a resident care plan in collaboration with a member of the health care team. 		
The INTERCARE nurse supports the communication process between physicians and health care staff.	This can occur by having a prior discussion (in person or phone call) with the care staff before they contact the physician. The INTERCARE nurse might guide the care staff to think through a situation and think about potential questions the physician may ask.	
INTERCARE nurse		
According to the INTERCARE nurse's skills and expertise residents are assessed in acute situations, when called by a member of the care team.		Range of educational backgrounds RN, BSN, MSN, MAS, HöFa I and
The INTERCARE nurse provides coaching to care staff on daily resident bedside needs.	The INTERCARE nurse supports care staff by assisting, guiding or advising them during bedside care, for instance helping staff to communicate with a resident showing aggression	 II The INTERCARE nurse can be hired from outside the nursing

The following table provides the list of core components of the nurse-led model of care, which correspond to the minimal requirements and the peripheral components, which can be tailored to each NH (CFIR).

Core elements (including minimal requirements)	Additional information for minimal requirements	Peripheral
The INTERCARE nurse plans educational sessions with care staff on a regular basis. The INTERCARE nurse drives team reflections for each	The INTERCARE nurse can chose a topic of interest to help care staff improve their competences and knowledge. These educational sessions can be conducted as formal presentations or by the bedside depending on the topic chosen. The INTERCARE nurse can use their own experience to help care staff manage often occurring difficult situations. The INTERCARE nurse plans informal team meetings	home or she can be a person currently employed for whom this could be a next career step. Number of patients the INTERCARE nurse is responsible for in each NH. Number of units the INTERCARE nurse works on in the NH.
reflection tool filled in.	to reflect and learn from each reflection tool, with the staff present at the time of the acute situation leading to the hospitalization.	The way and frequency in which the educational sessions are delivered
• The INTERCARE nurse must have 3 years-experience in long-term-care.	The experience could have been acquired in the same or another NH.	
• A position of 60% minimum per 80 beds for which the INTERCARE nurses are responsible for.		-
Comprehensive geriatric assessment (CGA)		
• The INTERCARE nurse collaborates with the leadership and/or interprofessional team to discuss and define which assessment instrument they work with, for each of the 5 CGA dimensions in their institution, within the first 6 months of the implementation of the model.	The CGA includes the following dimensions: O Physical dimension O Functional dimension O Social dimension O Economic dimension O Mental dimension	 Each INTERCARE nurse is free to define how involved they are and the degree of responsibility they have for each dimension. Any care staff can be involved in
• The INTERCARE nurse's role is clearly defined with regards to their input in the 5 dimensions of CGA.		the 5 dimensions of the CGA, corresponding to their degree of
• The INTERCARE nurse is involved and supports the care team in integrating the 5 dimensions of CGA in daily practice.	Provides information and guidance to the care team about the 5 different dimensions and is able to suggest how each dimension can be assessed and evaluated.	training and experience

The following table provides the list of core components of the nurse-led model of care, which correspond to the minimal requirements and the peripheral components, which can be tailored to each NH (CFIR).

Core elements (including minimal requirements) Additional information for minimal requirements Peripheral The INTERCARE nurse insures that resident and relatives are involved in the decision-making process. Advance care planning (ACP) • For every newly admitted resident, the following points Presence of physician during initial conversation and subsequent must be documented in the residents' records: Do Not Resuscitate order conversations with Do not hospitalize order residents/relatives. Use of antibiotics Degree of involvement of the NH The leadership team decides who is responsible in the NH staff in ACP discussions The INTERCARE nurse is in to guide the ACP process. For residents in unstable condition before weekends: charge of insuring that every physician orders and care plans are clarified (Notfallplan), question is clarified with residents and relatives. by the appointed responsible person(s) in each NH. The INTERCARE nurse checks for each new resident admission if the resident has an advance care plan.

Evidence-based tools

STOP & WATCH

(tool to facilitate communication in health care team and allow early identification of change in resident status or behavior with 12 observations (e.g. eats less, has pain, is different than usual). Observations can be checked on tool and tool passed on to supervisor for him/her to assess resident and plan adequate interventions)

- The INTERCARE nurse is responsible for the implementation of the STOP&WATCH and supervises the usage of the STOP&WATCH tool in daily practice.
- Implementation of the STOP&WATCH tool on each participating unit, within the first 6 months of implementation of the model.
- Used by nurse assistants to inform the responsible person about changes in resident condition.

- Degree of penetration of the STOP&WATCH tool, e.g. used by housekeeping staff, therapists.
- Internal process of how the tools are handled and stored after completion.

The following table provides the list of core components of the nurse-led model of care, which correspond to the minimal requirements and the peripheral components, which can be tailored to each NH (CFIR).

Core elements (including minimal requirements)	Additional information for minimal requirements	Peripheral
 It is clearly defined who will use the STOP&WATCH tool, if extended to other staff. All staff using the STOP&WATCH must be trained. The situation for which the STOP&WATCH tool is used, is recorded in the resident's documentation, if a change in resident situation has been recognized. 		 Implementation of other tools such as care pathways, to help guide assessment for chronic conditions. Using the tools to hand over information non-verbally, e.g. emails, fax.
The nurse responsible should perform the adequate assessment after being given the STOP&WATCH.		
• The transmission of the STOP&WATCH tool is either indirect (e.g. storage in a designated compartment for the person in charge of the day) or it is handed over directly to the person in charge of the day / the responsible qualified nurse.		
The STOP&WATCH tool must be filled in and, if necessary, the appropriate letters should be marked as soon as a change in the residents' condition has been identified.		
 General information about the resident and the person who filled in the instrument must be added. 		
• All unit staff on are informed about implementation of the STOP&WATCH tool.		
Distribution of the STOP&WATCH notepads to all employees who will use the tool. COLUMN COLUM		

ISBAR

(Tool to facilitate communication between nurse and physician concerning resident issues by guiding the conversation in 5 steps: Identification, Situation, Background, Assessment, and Recommendation)

- The INTERCARE nurse is responsible for the implementation and monitoring of the use of ISBAR and in giving feedback.
- Implementation of the ISBAR tool on each participating unit within the first 6 months of implementation of the model.

The following table provides the list of core components of the nurse-led model of care, which correspond to the minimal requirements and the peripheral components, which can be tailored to each NH (CFIR).

Co	ore elements (including minimal requirements)	Additional information for minimal requirements	Peripheral
•	Used by registered nurses in communicating with physician and with the INTERCARE nurse in acute situations.		
•	It is clearly defined who will use the ISBAR tool, if extended to the members of the care team.	-	
•	All staff using the ISBAR tool must be trained.	-	
•	Distribution of the ISBAR Pocket version to all registered nurses and all staff trained to use the ISBAR tool.	-	
•	All unit staff are informed about implementation of the ISBAR tool.	-	
Da	nta driven quality improvement		
,	Continuous data collection for all hospitalizations and emergency department (ED) visits, with exports every 3 months for SPC charts and 6 months for benchmarking.		 Each NH can decide who participates in the SPC/Benchmarking discussion. Each NH can decide who takes part in the discussion and
•	A member of the leadership team with or without/ INTERCARE nurse should discuss the SPC charts and benchmarking reports together and prepare discussion points for leadership meetings with the research group.		completing one PDCA cycle
,	A member of the leadership team and INTERCARE nurse should meet and discuss which steps are needed to improve quality improvement and complete one PDCA cycle for one identified quality indicator.	For an identified issue, a Plan-Do-Check-Act cycle is carried out. Plan Pre-defined persons should think about how they will analyze a situation, how information will be collected, what the goal of the planned change is. Do	<u>-</u>

The following table provides the list of core components of the nurse-led model of care, which correspond to the minimal requirements and the peripheral components, which can be tailored to each NH (CFIR).

Core elements (including minimal requirements)	Additional information for minimal requirements Peripheral	
	Pre-defined persons should think about how they plan to carry out the change, what is needed, from whom and who is responsible for guiding the change. • Check Pre-defined persons should reflect on what was initially planned and what happened during the change. • Act Pre-defined persons should discuss and describe which improvement measures were implemented and if change occurred.	

Abbreviations: ACP: advance care planning; BSN: Bachelor of Nursing Science; CFIR: Consolidated Framework for Implementation Research; CGA: comprehensive geriatric assessment; ED: emergency department; HöFa I and II: higher education in nursing, levels I and II; ISBAR: identify, situation, background, assessment and recommendation; MSN: Master of Nursing Science; MAS: Master of Advanced Studies; NH: nursing home; PDCA: Plan-Do-Check-Act cycle; RN: Registered Nurse; SPC-Chart: statistical process control chart

Supplementary Table S3- Implementation strategies Summary of implementation strategies used to support and facilitate the implementation of the core elements of the intervention Implementation strategy and definition according **Implementation strategy Description for INTERCARE** to Powell et al. [31] International and During a preliminary phase A of INTERCARE, 15 case studies were conducted Visit other sites in Swiss NHs to assess structures, processes, outcomes as well as barriers and national nursing home facilitators to facilitate the implementation and planned strategies to reduce visits Capture local knowledge from implementation sites on how implementers and clinicians made something barriers and insure sustainability of the intervention. 2 international models were work in their setting and then share it with other sites. also visited to help gain an insight into ANP roles and model differences. Stakeholder meetings Conduct local consensus discussion A stakeholder group formed of nursing home leaders, physicians, Swiss policy makers, patient and cantonal association representatives, are included in Include local providers and other stakeholders in important decisions regarding the intervention, such as decision making discussions that address whether the chosen problem regarding the appropriateness of the clinical tasks and responsibilities of the new is important and whether the clinical innovation to nurse expert role, defining the core elements of the intervention and to help address it is appropriate. identify barriers and facilitators for the implementation of the intervention, as well as discussing the outcomes for the Swiss setting. Bi-annual meetings to exchange and discuss major points relating to the intervention. A signed contract was established between the research site and the participating **Binding contract between** Obtain formal commitments NHs and research site NHs. Obtain written commitments from key partners that state what they will do to implement the innovation. The model consists of 6 core elements and peripheral elements which allows **Determining core and** Promote adaptability the intervention to be tailored to meet the specific intervention site needs. Core peripheral components of the nurse-led model of Identify the ways a clinical innovation can be tailored elements are considered to be mandatory to be implemented and peripheral to meet local needs and clarify which elements of the components can be adapted individually. Core elements were developed and care innovation must be maintained to preserve fidelity. described to reach the specific clinical outcomes of the study. Nursing home leadership Assess for readiness and identify barriers and Specifically, tailored training sessions for NH leadership and additional staff training and support such as NH accountants, physicians and nurses to insure buy-in and tailoring of facilitators the nurse-led model to individual NHs through identification of barriers and Assess various aspects of an organization to determine facilitators. 1 full day and 2 half day follow-up training sessions were offered to its degree of readiness to implement; barriers that may all 11 NHs participating. impede implementation, and strengths that can be used Support in the recruitment of the INTERCARE nurse with consultation and in the implementation effort.

templates for job announcements and job description.

Implementation strategy	Implementation strategy and definition according to Powell et al. [31]	Description for INTERCARE
INTERCARE nurse blended learning curriculum	• Create new clinical teams Change who serves on the clinical team, adding different disciplines and different skills to make it more likely that the clinical innovation is delivered (or is more successfully delivered)	• Implementation of the INTERCARE nurses acquires new competencies and skills expanding the usual profile. Thus, position profile was developed and new competencies described to ensure the ability to deliver the intervention.
	Conduct ongoing training Plan for and conduct training in the clinical innovation in an ongoing way	 Continuous education of INTERCARE nurses starting before the mode implementation and further developed throughout the implementation phase Eight modules are included in the curriculum: Clinical leadership (e.g. methods of successful leadership, emotiona intelligence and leadership, leadership styles according to Goleman, self reflection, case studies) Communication (e.g. model of interpersonal and intrapersona communication based on Schulz von Thun, communication techniques and styles, DISC behaviour assessment tool based on the DISC theory of psychologist William Moulton Marston) Comprehensive geriatric assessment / Advance care planning Geriatric syndromes (delirium, falls, vision and hearing losses, sarcopenia & frailty, malnutrition, pain, immobility, elimination disorders, BPSD) Chronic conditions (COPD & asthma, diabetes, congestive heart failure hypertension) Acute care situations (angina pectoris and myocardial infarction, acute cerebrovascular insults), symptoms (e.g. acute dyspnoea, abdominal pain hypoglycaemia) Pharmacology (e.g. polypharmacy, drug-drug interactions, medication management) Data-driven quality improvement (e.g. statistical process control chart benchmarking, PDCA cycle)
	• Resource sharing agreements Develop partnerships with organizations that have resources needed to implement the innovation	 Partnerships with nursing educational institutions who have the geriatric expertise and/or experience in curriculum development to support the development of the curriculum

Supplementary Table S3- Implementation strategies Summary of implementation strategies used to support and facilitate the implementation of the core elements of the intervention

Implementation strategy	Implementation strategy and definition according to Powell et al. [31]	Description for INTERCARE
	Make training dynamic Vary the information delivery methods to cater to different learning styles and work contexts, and shape the training in the innovation to be interactive	 Blended learning curriculum including: e-learnings, readings, tests, reflections and case studies and face to face meeting accounts for variation in delivering the education. It maximizes the learning outcomes considering that adults have different learning styles and working environments.
	• Develop and distribute educational materials Distribute educational materials (including guidelines, manuals, and toolkits) in person, by mail, and/or electronically	• Various materials as e.g. guidelines on how to implement evidence based tools, algorithms how and when to use reflection tools, staff handouts to inform and power point presentations to educate staff about the communication instruments, manuals on how to enter residents' data into data management system, will be developed and distributed. All materials should help facilitate the implementation and adherence to the intervention. All materials were posted on an online learning platform and/ or sent by email.
Data collection for benchmarking and internal quality control	• Audit and provide feedback Collect and summarize clinical performance data over a specified time period and give it to clinicians and administrators to monitor, evaluate, and modify provider behaviour.	• Quarterly exports for quality indicators and on-going collection of data for hospitalizations to help NHs identify where better quality of care can be provided and which actions they may take. This will be discussed during the 2 monthly meetings in each NH.
Continuous support of NH	Provide local technical assistance Develop and use a system to deliver technical assistance focused on implementation issues using local personnel	 Study coordinator available to provide assistance and ensure good communication between NHs and research team. Face to face two monthly meetings with the leadership teams.
	Provide ongoing consultation Provide ongoing consultation with one or more experts in the strategies used to support implementing the innovation	• A networking platform is available for NHs to share experiences and documentation, as well as 2 monthly in-person meetings and 2 weekly phone calls to support the INTERCARE nurse during the implementation process.

Abbreviations: BPSD: Behavioral and psychological symptoms of dementia; COPD: Chronic obstructive pulmonary disease; DISC: Dominance, Influence, Steadiness, Conscientiousness; NH: nursing home; PDCA: Plan-Do-Check-Act cycle

Supplementary Table S4 - Operationalization and data collection for secondary effectiveness outcomes at staff level

Outcome	Operationalization	Data collection
Job satisfaction	Self-developed single item: "How satisfied are you with	At baseline, month 6 and
	your job overall?" rated on a 4-point Likert scale ranging from very dissatisfied to very satisfied.	12
Satisfaction with quality of care	Nine self-developed items assessing satisfaction with the quality of care related to core themes of INTERCARE, e.g. hospitalizations, pain, falls, weight loss, physical restraints, polypharmacy. Rated on a 5-point Likert scale ranging from very dissatisfied to very satisfied.	
Interprofessional collaboration	Interprofessional collaboration scale [32] assessing the collaboration between nurses and physicians with three subscales: communication (5 items), accommodation (5 items), and isolation (3 items). Rated on a 4-point Likert scale ranging from disagree to agree.	
Self-efficacy in clinical situations	Fourteen self-developed items assessing self-efficacy based on Bandura [33]. Respondents are asked how confident they feel in handling situations such as acute residential situations, prevention of falls or assessing and taking measures in polypharmacy on an 11-point Likert scale ranging from not at all confident to very confident.	

Supplementary Table S5 - Operationalization and data collection for economic outcomes at NH level

Economic outcome	Operationalization	Data collection
Incremental cost- effectiveness ratio (ICER)	Increase in staff cost during intervention phase divided by decrease of days of unplanned hospitalizations (days of stay after run-in period of 1 month minus days of stay during control phase)	Staff cost: see cost of implementation below. Days of stay will be extracted from hospital discharge reports
Cost of implementation	Implementation cost in CHF for NHs: staff cost: salary and training nurse expert, staff- related expenses to implement program; material cost: e.g. new devices; service costs: e.g. use of mobile palliative care teams	Structured data collection sheets for NH leadership submitted in months 3, 6, 9, 12, and 15 (as applicable) after beginning of implementation

Abbreviations: CHF: Swiss francs; ICER: incremental cost-effectiveness ratio; NH: nursing home

Supplementary Table S6- Operationalization and data collection for implementation outcomes			
Implementation outcome	Operationalization and data collection	Time points	
Adoption	Adoption (initial uptake) of all core elements will assessed during the first two leadership meetings by the research group and discussed during the third leadership meeting in each NH by means of a structured data collection sheet to assess initial uptake of each component.	Months 1 to 6	
Acceptability and feasibility (qualitative data)	The acceptability and feasibility of the core elements interprofessional care team, INTERCARE nurse, comprehensive geriatric assessment and evidence-based tools will be explored qualitatively in interviews with INTERCARE nurses and telephone interviews with physicians; the core elements INTERCARE nurse and evidence-based tools will also be explored in focus groups with NH staff.	Months 6 and 12	
Acceptability and feasibility (quantitative data)	4-item Acceptability of Implementation Measure (AIM) and 4-item Feasibility of Intervention Measure (FIM) with answer options in a Likert-Scale ranging from "completely disagree" to "completely agree" [25] are integrated in questionnaire survey of NH staff and INTERCARE nurse.	Baseline, months 6 and 12	
Fidelity (quantitative data)	Fidelity to all core elements (except advance care planning): Structured phone interviews with INTERCARE nurses	Months 6 and 12	
	Fidelity to advance care planning (ACP): Documentation review by INTERCARE nurses about number of residents with elements of ACP clarified (do-not-resuscitate, do-not-hospitalize, no antibiotics) and documentation in CASTOR EDC®	Quarterly between Mar 19 and Mar 20	
Abbreviations: ACP: advance	e care planning; NH: nursing home;		

Supplementary Table S7- Assessment of implementation strategies

Strategy	Operationalization	Data collection	
INTERCARE nurse curriculum	Self-developed items to assess the usefulness and quality of the learning units	At the end of each of the 8 modules	
	Self-efficacy items for competencies	Baseline and month 12 INTERCARE nurse questionnaire survey	
	Evaluation of single learning units within the modules for clinical relevance in a Likert-Scale ranging from "completely disagree" to "completely agree" Open questions on missing, yet relevant topics to be included in the curriculum	Months 6 and 12 INTERCARE nurse questionnaire survey	
Nursing home leadership training and support	Evaluation of the uptake of the INTERCARE model and impact of the leadership meetings on overall preparation for implementation	Month 12 and 18: Conversations with NH leadership at overall meetings	
Determining core and peripheral components of the nurse-led model of care	Evaluation of each core component and how tailoring of each component helped each NH implement the intervention		
Data collection for benchmarking and internal quality control	Evaluation of how satisfied the NHs are with data and internal quality improvement and with items in the facility questionnaires		
Continuous support of NHs	Evaluation to assess how support provided during the implementation phase helped the NHs implement the model.		
	Evaluation of impact of the 2 weekly phone calls with INTERCARE nurses	Month 6 and month 12 during meeting with INTERCARE nurses	
Abbreviations: NH: nursing home;	with INTERCARE nurses		

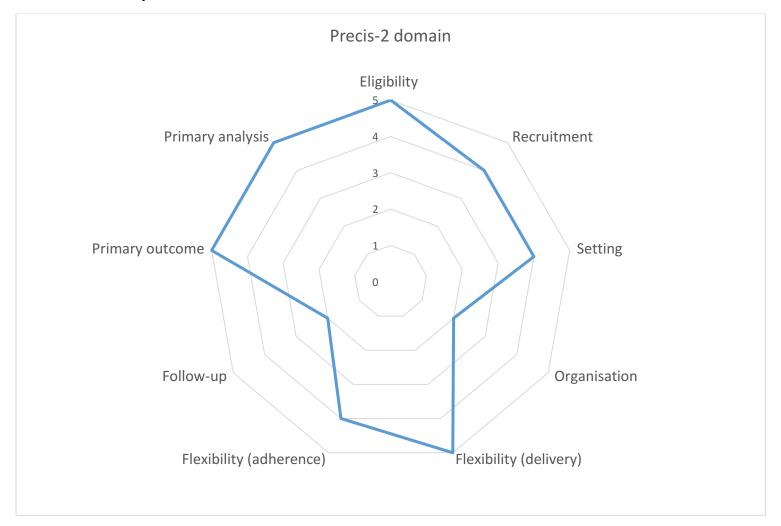
Supplementary Table S8: PRECIS Assessment of INTERCARE[34]

Domain	Description	Label	Rational	Score
Eligibility	To what extent are the participants in the trial similar to those who would receive this intervention if it was part of usual care? For example, score 5 for very pragmatic criteria essentially identical to those in usual care; score 1 for a very explanatory approach with lots of exclusions (e.g. those who don't comply, respond to treatment, or are not at high risk for primary outcome, are children or elderly), or uses many selection tests not used in usual care.	5 Very pragmatic	Very soft inclusion criteria on the resident level, essentially accepting almost all NH residents.	5
Recruitment	How much extra effort is made to recruit participants over and above what that would be used in the usual care setting to engage with patients? For example, score 5 for very pragmatic recruitment through usual appointments or clinic; score 1 for a very explanatory approach with targeted invitation letters, advertising in newspapers, radio plus incentives and other routes that would not be used in usual care.	4 Rather pragmatic	Although rather broad inclusion criteria, nursing homes systematically approached residents and relatives with tailored invitation letters.	4
Setting	How different is the setting of the trial and the usual care setting? For example, score 5 for a very pragmatic choice using identical settings to usual care; score 1, for a very explanatory approach with only a single center, or only specialized trial or academic centers.	4 Rather pragmatic	Overall 11 nursing homes, however only highly motivated organizations were recruited.	4
Organization	How different are the resources, provider expertise and the organization of care delivery in the intervention arm of the trial and those available in usual care? For example, score 5 for a very pragmatic choice that uses identical organization to usual care; score 1 for a very explanatory approach if the trial increases staff levels, gives additional training, require more than usual experience or certification and increase resources.	2 Rather explanatory	Only nursing homes with organizational capacity (strong leadership, staffing resources) were recruited.	2
Flexibility (delivery)	How different is the flexibility in how the intervention is delivered and the flexibility likely in usual care? For example, score 5 for a very pragmatic choice with identical flexibility to usual care; score 1 for a very explanatory approach if there is a strict protocol, monitoring and measures to improve compliance, with specific advice on allowed co-interventions and complications.	5 Very pragmatic	Intervention consists of core and peripheral elements.	5

Supplementary Table S8: PRECIS Assessment of INTERCARE[34]

Domain	Description	Label	Rational	Score
Flexibility (adherence)	How different is the flexibility in how participants must adhere to the intervention and the flexibility likely in usual care? For example, score 5 for a very pragmatic choice involving no more than usual encouragement to adhere to the intervention; score 1 for a very explanatory approach that involves exclusion based on adherence, and measures to improve adherence if found wanting. In some trials e.g. surgical trials where patients are being operated on or Intensive Care Unit trials where patients are being given IV drug therapy, this domain is not applicable as there is no compliance issue after consent has been given, so this score should be left blank.	4 Rather pragmatic	Even for core components not 100% adherence is expected. However substantial support for organizations is provided.	4
Follow-up	How different is the intensity of measurement and follow- up of participants in the trial and the likely follow-up in usual care? For example, score 5 for a very pragmatic approach with no more than usual follow up; score 1 for a very explanatory approach with more frequent, longer visits, unscheduled visits triggered by primary outcome event or intervening event, and more extensive data collection.	2 Rather explanatory	Very comprehensive quantitative/qualitative data collection schedule	2
Primary outcome	To what extent is the trial's primary outcome relevant to participants? For example, score 5 for a very pragmatic choice where the outcome is of obvious importance to participants; score 1 for a very explanatory approach using a surrogate, physiological outcome, central adjudication or use assessment expertise that is not available in usual care, or the outcome is measured at an earlier time than in usual care.	5 Very pragmatic	Avoidable hospitalisations have high relevance for residents and relatives.	5
Primary analysis	To what extent are all data included in the analysis of the primary outcome? For example, score 5 for a very pragmatic approach using intention to treat with all available data; score 1 for a very explanatory analysis that excludes ineligible post-randomization participants, includes only completers or those following the treatment protocol	5 Very pragmatic	Intention to treat analysis will be conducted.	5

PRECIS-2 Summary Wheel



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