BRIEF REPORT

Strengthening Geriatric Expertise in Swiss Nursing Homes: INTERCARE Implementation Study Protocol

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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 situation 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 2 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 were recruited. The sample size was estimated assuming an average of .8 unplanned hospitalizations/1000 resident days and a reduction of 25% in NHs with the nurse-led care model.

INTERVENTION: The multilevel complex context-adapted intervention consists of six core elements (eg, specifically trained INTERCARE nurses or evidence-based tools like Identify, Situation, Background, Assessment and Recommendation [ISBAR]). Multilevel implementation strategies include leadership and INTERCARE nurse training and support.

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

CONCLUSION: The INTERCARE study will provide evidence about the effectiveness of a nurse-led care model in the real-world setting and accompanying implementation strategies. **J Am Geriatr Soc 00:1-6, 2019.**

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

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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 NH after a hospital stay. Although 80% of NH residents receive long-term 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

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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 is 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] That is, the condition for which the resident was admitted could have been prevented with adequate chronic disease management.

Interprofessional nurse-led healthcare 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 (eg, 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 called 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 Nurse-led model in Swiss NHs: improving INTERprofessional CARE for better resident outcomes (INTERCARE) implementation science study is to develop, implement, and evaluate a Swiss model (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 (eg, feasibility, acceptability). This protocol focuses on the model's implementation and evaluation in phase B.

We adhere to active principles of public patient involvement 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 healthcare 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 participatory, evidence-based patient-centered process for APN (PEPPA) 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

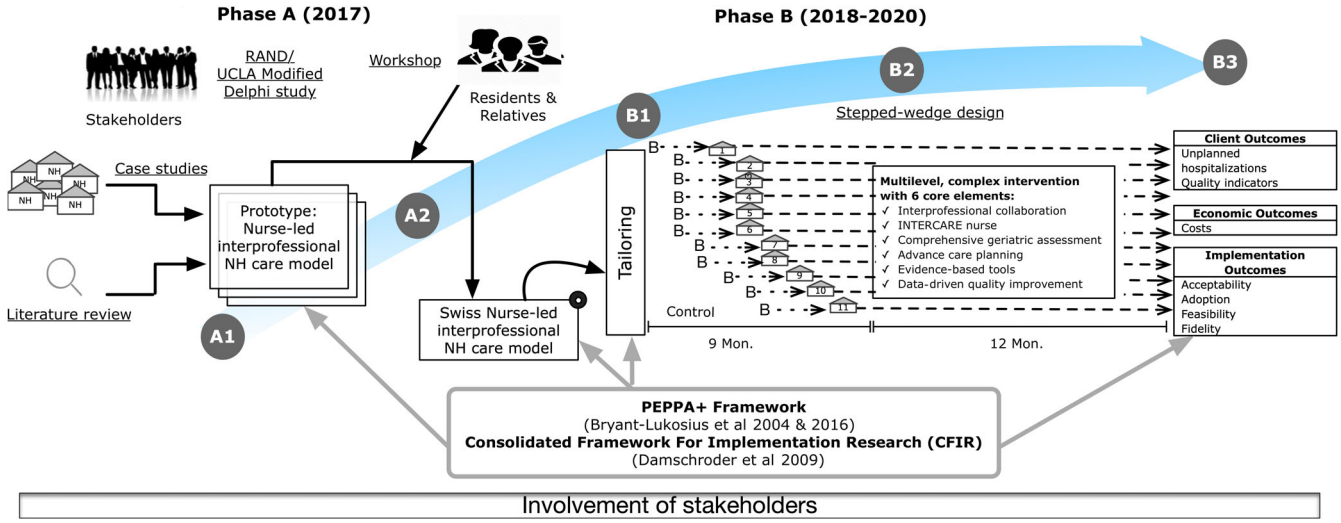

Figure 1. Overview of INTERCARE study.
A1: Evidence-based description of a nurse-led care model for nursing homes (NHs).
A2: Stakeholder assessment of the model's appropriateness and adaptation to the Swiss context.
B1: Tailoring of nurse-led care model to participating NHs and preparatory training.
B2: Testing of nurse-led care model.
B3: Data analyses, interpretation, and reporting.
PEPPA, participatory, evidence-based patient-centered process for APNs (advanced practice nurses).

(1) a literature review of the international evidence, and (2) 17 case studies of both evaluated and nonevaluated 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 role of the RNs. Last, we gained feedback from 7 residents and 11 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 the primary outcome, that is, unexpected admissions to a hospital, hypothesizing a significant reduction. Secondary outcomes at the resident level are avoidable hospitalizations, unplanned and avoidable emergency department visits, national quality indicators (physical restraints, pain, weight loss, polypharmacy). At the staff level, we assess job satisfaction, satisfaction with care quality, interprofessional collaboration, and self-efficacy in clinical situations. For economic outcomes, we 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 the use of questionnaire surveys.

METHODS

Design

For phase B, running from June 2018 to February 2020, INTERCARE uses an effectiveness-implementation hybrid type 2 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 nonrandomized quasi-experimental stepped-wedge design (21 months) will be used[20] (Figure S1). This unidirectional crossover design allows each NH to be first a control and then an intervention site. For the evaluation of implementation outcomes, a concurrent mixed-method design will be used. INTERCARE is 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 or more long-term care beds, (2) have .8 or more hospitalizations per 1000 resident days, (3) are in the German-speaking part of Switzerland, (4) collect Resident Assessment Instrument–NH version (RAI-NH) data for each resident (Resident Assessment Instrument–NH 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 a 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," that is, binding intervention components, and "peripheral," that is, locally adaptable intervention components.[18] Based on our preliminary work, we defined six core elements for this multilevel complex intervention: (1) An interprofessional care team, (2) INTERCARE nurse, (3) comprehensive geriatric assessment, (4) advance care planning, (5) evidence-based instruments (eg, Identify, Situation, Background, Assessment, and Recommendation [ISBAR]), and (6) data-driven quality improvement (detailed description in Table S2). A basic prerequisite was that the NH leadership be engaged in promoting INTERCARE. For the NHs with responsible physicians, they were fully involved in the project and in onsite 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 et al in the Expert Recommendations for Implementing Change,[21] we use implementation strategies on the levels of planning, education, and quality management (further information in Table S3). 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 coworkers, 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 twice 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 twice weekly phone calls and twice monthly meetings with the leadership and research team. The implementation strategies were flexible at rollout and locked once the last NH had finished the 1-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] (Table 1), where unplanned refers to unexpected hospitalizations when a resident needs attention for his or her 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, because diagnoses alone cannot account for the need for 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 (http://www.pathway-interact.com/tools/), adapted to the Swiss context. This allows them 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 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 of INTERCARE nurse, staff-related expenses to implement program; material cost: eg, new devices) (Table S5). We will also assess the incremental cost-effectiveness ratio for hospital days for unplanned hospitalizations. This ratio will be measured as an increase in staff costs during the intervention phase (after a run-in period of 1 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] (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 in focus groups with NH staff. Fidelity will be measured quantitatively (eg, in quarterly reports about the number of residents with a clarified do-not-resuscitate order for the core element advance care planning). Additionally, the twice 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 twice monthly meetings and twice weekly phone calls 12 and 18 months after the intervention start in group discussions with NH leadership and INTERCARE nurses (Table S7).

Data Collection

As shown in Figure S1, each NH will start with a 3-month baseline phase before 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 Figure S1 and include quantitative questionnaire surveys of NH leadership, NH staff, and INTERCARE nurses at baseline and 6 months, respectively, 12 months 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 exports of quality indicators per institution every 3 months 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 11 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 .8 unplanned hospitalizations/1000 resident days and a reduction of 25% in NHs with the nurse-led care model.[4,10] Eleven NHs will allow us to detect a 25% reduction of unplanned hospitalization with a power of 80% using a significance level of $\alpha = 5\%$. 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 analyzed using the R statistical programming language (R v.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 logistical 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 analyzed deductively using the framework method, identifying and refining descriptive

Table 1. Operationalization and Data Collection for Effectiveness Outcomes at Resident Level in INTERCARE

Outcome	Operationalization	Data collection
Unplanned hospitalizations (primary outcome)	No. of unplanned[a] hospitalizations/1000 care days Exclusion criteria: Planned hospitalizations (eg, nonemergency surgical procedure, blood transfusion, chemotherapy) and ED visits with discharge within 24 h	Local coordinator enters data for each hospitalization in CASTOR EDC No. of care days/month provided by NH administration
Avoidable hospitalizations	No. of hospitalizations for ACS primary diagnoses/1000 care days Avoidable hospitalizations will be defined according to ACS primary diagnoses at hospital discharge[1] Exclusion criteria: cf. primary outcome	Cf. primary outcome ACS diagnoses assessed via hospital discharge reports
Unplanned ED visits	No. of unplanned[1] ED visits/1000 care days Inclusion criterion: ED visits <24 h (stays >24 h are classed as hospitalization)	Cf. primary outcome
ED visits for ACS primary diagnoses	No. of ED visits for ACS primary diagnoses/1000 care days Inclusion criterion: ED visits <24 h (stays >24 h 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, respectively % of residents with observed pain (ie, daily pain of moderate intensity or nondaily pain of severe intensity)	Operationalization is based on measurement of national quality indicators to be introduced in Switzerland in 2019. Their measurement is integrated in the routine assessment instrument (Resident Assessment Instrument–Minimal Data Set [RAI-MDS]). Resident assessments are performed at least every 180 d and stored in local NH databases.[25] This continuously collected data will be exported every 3 mo as .csv-file
Weight loss	% of residents with weight loss ≥5% during the preceding 30 d or ≥10% in the preceding 180 d	
Polypharmacy	% of residents receiving nine or more medications (active components) over the preceding 7 days	
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 d or with daily use of bedrails over the preceding 7 d	

Abbreviations: ACS, ambulatory care sensitive; ED, emergency department, NH, nursing home.

[a]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 surgery or treatment and an admittance date and time is agreed upon with the hospital.

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] (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 ensures 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 healthcare resources, thereby 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 NHs with high leadership involvement.

Limitations

Implementation research provides the possibility to evaluate programs in real-life settings by taking into account stakeholders and the local context. The possibility to adapt components of research lessens its rigor but strengthens its immediate usefulness.[29] INTERCARE focuses on the implementation of a locally adapted model in highly motivated NHs that hinders the generalizability of its results. However, the use of implementation theory and future reporting based on standards for implementation studies[30] will allow us to identify transferable

elements and share with other regions the lessons learned about adaptations to support the scale-up of the care model.

In conclusion, IINTERCARE aims to both develop and implement a nurse-led care model for NHs in the real-life context of the German-speaking part of Switzerland. Once implemented, it is expected to offer insight into 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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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

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

Table S1. Inclusion and exclusion criteria.

Table S2. Core and peripheral elements.

Table S3. Implementation strategies.

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

Table S5. Operationalization and data collection for economic outcomes at nursing home level.

Table S6. Operationalization and data collection for implementation outcomes.

Table S7. Assessment of implementation strategies.

Table S8. Precis assessment of INTERCARE.