

Implementation of a complex intervention to improve participation in older people with joint contractures living in nursing homes: A process evaluation of a cluster-randomised pilot trial

Hanna Klingshim

Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig-Maximilians-Universität München <https://orcid.org/0000-0001-6223-6447>

Martin Müller

Faculty of Applied Health and Social Sciences, Rosenheim Technical University of Applied Sciences

Katrin Beutner

Institute of Health and Nursing Sciences, Medical Faculty, Martin Luther University, Halle-Wittenberg

Julian Hirt

Institute of Health and Nursing Sciences, Medical Faculty, Martin Luther University, Halle-Wittenberg

Ralf Strobl

Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig-Maximilians-Universität München

Eva Grill

Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig-Maximilians-Universität München

Gabriele Meyer

Institute for Health and Nursing Sciences, Medical Faculty, Martin Luther University, Halle-Wittenberg

Susanne Saal (✉ susanne.saal@uk-halle.de)

<https://orcid.org/0000-0002-2493-601X>

Research article

Keywords: Joint contractures, Nursing homes, Participation, Complex intervention, Cluster-randomised controlled trials, Pilot study, Implementation strategy, Process evaluation

Posted Date: September 20th, 2019

DOI: <https://doi.org/10.21203/rs.2.14602/v1>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published on August 5th, 2020. See the published version at <https://doi.org/10.1186/s12877-020-01655-z>.

Abstract

Background Joint contractures in frail older people are associated with serious restrictions in participation. We developed the Participation Enabling CAre in Nursing (PECAN) intervention, a complex intervention to enable nurses to promote participation in nursing home residents with joint contractures. The aim of this study was to examine the feasibility of the implementation strategy and to identify enablers and barriers for a successful implementation. **Methods** The implementation of PECAN was investigated in a 6-month pilot cluster-randomised controlled trial (c-RCT). As a key component of the implementation strategy, nominated nurses were trained as facilitators in a one-day workshop and supported by peer-mentoring (visit, telephone counselling). A mixed-methods approach was conducted in conjunction with the pilot trial and guided by a framework for process evaluations of c-RCTs. Data were collected using standardised questionnaires (nursing staff), documentation forms, problem-centred qualitative interviews (facilitators, therapists, social workers, relatives, peer-mentors), and a group discussion (facilitators). A set of predefined criteria on the nursing home level was examined. Quantitative data were analysed using descriptive statistics. Qualitative data were analysed using directed content analysis. **Results** Seven nursing homes (n=4 intervention groups, n=3 control groups) in two German regions took part in the study. Facilitators responded well to the qualification measures (workshop participation: 14/14; workshop rating: “good”; peer-mentor visit participation: 10/14). The usage of peer-mentoring via telephone varied (one to seven contacts per nursing home). Our implementation strategy was not successful in connection with supplying the intervention to all the nursing staff. The clear commitment of the entire nursing home and the respect for the expertise of different healthcare professionals were emphasised as enablers, whereas a lack of impact on organisational conditions and routines and a lack of time and staff competence were mentioned as barriers. **Conclusion** The PECAN intervention was delivered as planned to the facilitators but was unable to produce comprehensive changes in the nursing homes and subsequently for the residents. Strategies to systematically include the management and the nursing team from the beginning, are needed to support the facilitators during implementation in the main trial.

Background

Joint contractures are characterised as restrictions of the physiological movement of any joint because of deformity, disuse or pain [1]. Older people living in nursing homes are particularly often affected by joint contractures due to the association with several health conditions, immobility and age. Prevalence varies between 20% and 75% in studies involving nursing home residents as a result of different definitions and hardly comparable populations [1-5]. Irrespective of the underlying aetiology, living with a joint contracture can be severely disabling for the affected individual. An impairment of the upper extremities may reduce the capacity to perform daily activities like dressing or eating, while an impairment of the lower extremities may reduce the ability to walk independently and increase the risk of bed confinement [6, 7]. Recent research, using the International Classification of Functioning, Disability and Health (ICF) [8] as a framework, indicates that joint contractures are associated with numerous limitations in categories of functioning such as mobility, self-care, sensory function and pain, domestic life and community, social

and civic life [9]. Limitations on activities (i.e., “the execution of a task or action”) and restrictions on participation (i.e., “the involvement in a life situation”) are the most relevant problems for the affected individuals [10, 9, 11-13]. Moreover, interviews with affected individuals in geriatric care revealed that immobility does not necessarily lead to restrictions in participation, rather the restrictions are induced by environmental and personal factors [9].

Existing interventions do not consider the phenomenon of joint contracture in its complexity. Despite the multiple causes of joint contractures, which often occur simultaneously and interact with each other, for example pain and reduced mobility due to knee arthrosis, currently used interventions for prevention and treatment are mainly single interventions [14-16]. In addition, most of these single interventions are not effective in multimorbid, older people [16]. Studies examining interventions on joint contractures mainly focus on body structures and functions and do not consider the outcomes that are most relevant to residents like activities and participation [16]. Due to diverse treatment priorities a wide range of health care professionals is involved in the care of individuals with joint contractures, for example nurses, therapists, physicians, and informal caregivers [12]. A successful intervention aimed at improving participation in nursing home residents with joint contractures should consider the interaction between joint contractures, the individuals’ daily life and the influencing environmental and personal factors, and should also address all health care professionals involved in the treatment of the affected individuals [17]. Therefore, the intervention must by its very nature be complex.

In the JointConImprove project [18] we carefully developed such a complex intervention called the “Participation Enabling CAre in Nursing” (PECAN) intervention [17]. The development followed the UK Medical Research Council (MRC) framework [19] and systematically integrated existing evidence [16], best practice models, the expertise of healthcare professionals [12], and the perspective of the affected individuals [9, 11]. The development of the PECAN intervention is reported in detail elsewhere [17]. For newly developed interventions, the UK MRC framework recommends a pilot testing phase [19]. Consequently, the second part of the JointConImprove project [18] was to test the PECAN intervention in a pilot cluster-randomised controlled trial (c-RCT) accompanied by a detailed process evaluation.

The key function of a process evaluation for a complex intervention is to examine of the implementation process, the mechanisms of change, the context and their interaction with each other [20]. Especially in a pilot trial, process evaluation is essential to understand the feasibility and acceptability of the implementation strategy and the proposed evaluation design [20]. A successful implementation into practice does not depend solely on the quality and type of the transmitted intervention content, but also on the context and the chosen implementation strategy [21].

Since the examination of the proposed evaluation design and the feasibility of the implementation strategy raise different sets of research questions, we decided to report the results separately. The results of the PECAN pilot trial with focus on the feasibility of the proposed study design is reported elsewhere [22].

This paper aims to examine the feasibility and acceptability of the PECAN implementation strategy and to identify enablers and barriers for a successful implementation.

Methods

The PECAN pilot trial

The full pilot trial details are reported elsewhere [22]. In summary, the PECAN pilot trial was planned as a multi-centre pragmatic trial with a two-armed, parallel group design. Ethical approval was obtained from the responsible ethics committees. Residents were included if they were aged 65 years or older and affected by at least one joint contracture diagnosed by a physician, therapist or nurse. Residents at the terminal stage of a disease were excluded. Seven nursing homes (i.e. the clusters) with a total of 129 residents were recruited from a convenience sample in two German regions. Prior to the start of the study, all the residents (and/or the legal guardians) were asked for a written informed consent by the research team. Structured face-to-face interviews by blinded assessors were used to collect residents' data at baseline, then after three and six months. The primary outcome was defined as the residents' participation and measured with the PaArticular Scales [23]. The secondary outcomes were defined as residents' activities, instrumental activities of living, health-related quality of life, as well as falls and fall-related consequences to ensure the safety of the intervention. After baseline assessment four nursing homes with 64 participating residents were randomised to the intervention group (PECAN) and three nursing homes with 65 residents were randomised to the control group (optimised standard care i.e., standard care including an information session addressing general aspects of care for residents with joint contractures).

Study design of the process evaluation

A mixed-methods process evaluation was employed with data collection in conjunction with the PECAN pilot c-RCT. As recommended for process evaluation studies, we applied quantitative methods to assess whether the key processes of the implementation followed the study protocol and qualitative methods to determine enablers and barriers during the implementation [20]. Quantitative and qualitative data were given equal consideration, as they complement each other in a deeper interpretation of the findings [24].

We applied the MRC guidance for the evaluation of complex interventions by Moore et al. [20] along with the framework proposed by Grant et al. for the design and reporting of process evaluations for c-RCTs [25]. Grant et al. differentiate in their framework between processes involving clusters, processes involving individuals and their interaction with the context in which the trial is embedded [25]. Since the PECAN intervention is delivered first to the nursing homes and not directly to the residents, this process evaluation focuses on processes involving the nursing homes (i.e. the clusters) in order to improve the implementation strategy for the main trial. We used the Standards for Reporting Implementation Studies (StaRI) Statement [26] for reporting our implementation and the Template for Intervention Description and Replication (TIDieR) checklist [27] for reporting our intervention.

The PECAN intervention

The core idea of PECAN is to facilitate a participation-oriented understanding of care in nursing homes, based on the biopsychosocial model of the ICF [8] to allow improved analysis of the residents' situation and to guide the nursing home staff in their decision-making. The mechanisms of the expected changes in the nurses' professional behaviour to improve the residents' participation are based on the principles of the Theory of Planned Behaviour (TPB) [28]. This theory describes attitudes, subjective norms, and the felt degree of control over behaviour as the essential determinants of behavioural change and states that a change in behaviour can be initiated through appropriate interventions [28]. The approach of the TPB is proven to predict or explain the behaviour of healthcare professionals [29, 30]. Intermediate intervention goals to change the behaviour of the nursing home staff are presented in the logic model of the PECAN intervention in Additional file 1.

The PECAN intervention focuses on the dynamic interaction between an individual's health condition and existing personal and environmental factors that can act as facilitators or barriers in performing activities and participation [17, 8]. The policy of the PECAN intervention is to improve the residents' participation by adapting environmental factors, taking personal factors into consideration, and supporting mobility. Therefore, an individually tailored approach is used, including both the individual (i.e., resident) and the organisational (i.e., nursing home) levels to achieve the intervention goals [17].

On the individual level, the residents' activities and participation are addressed by defining individual participation goals. Accordingly, the residents' care plans and daily routines are reviewed and adapted. Measures to meet the participation goals on the individual level contain, for example, the use of a biographical approach to identify the residents' potential motivation for activities and participation, the optimisation of the provision of medical or technical aids and the involvement of additional persons in the daily care, such as external therapists or relatives.

On the organisational level, the review and change process to integrate the perspective of the ICF is guided by using a checklist with predefined criteria. For example, changes on the organisational level can comprise the adaption of the care concept, as well as the redistribution of tasks involving the nursing home management, the nursing team and the interprofessional team (i.e., social workers, physicians and therapists) [17].

Implementation strategy

The PECAN implementation strategy used a facilitation approach [21]. Facilitation is the active part of the implementation, carried out by trained facilitators, who guide individuals or organisations through a challenging change process [31, 21]. As change agents, facilitators were responsible for guiding the implementation and for offering education and counselling to their colleagues. The implementation of PECAN proceeds in multiple steps: In the first step, the intervention is introduced to skilled nurses, who are trained as facilitators. The research team guided the delivery of the intervention across all nursing homes. In the second step, the facilitators are responsible for the integration of the PECAN intervention into the daily practice by involving the nursing team, physicians, therapists, social workers and relatives. During this process of the implementation the facilitators were supported by experienced peer-mentors, who were

members of the research team. The targeted changes in the nurses' professional behaviour was expected to improve the residents' participation [17].

An overview of the PECAN implementation strategy is presented in Figure 1.

Kick-off meeting with the head nurse/nursing home director

In the *kick-off meeting*, the intervention was introduced to the head nurse and/or the director of the nursing home, who signed a declaration ensuring their commitment.

Facilitators' workshop

The key component of the implementation was a one-day *facilitators' workshop* to prepare nominated skilled nurses who have received a degree for their role as facilitator following at least three years of formal vocational education. Based on predefined qualification criteria (e.g., formal vocational education) the facilitators were selected by the head nurse. During the workshop, the intervention was explained, including comprehensive information on the phenomenon of joint contractures, a training session on how to implement residents' participation goals in individual care planning using the biopsychosocial model of the ICF, and a training session on peer counselling methods to involve all team members in the implementation process and to improve interprofessional collaborations.

Information session

A single *information session* lasting 40 minutes was held by a member of the research team in each nursing home for the residents, relatives, nursing staff and other interested health-care professionals (regardless of their participation in the study). In the intervention group the aim of the session was to introduce the PECAN intervention, the facilitators and their tasks, and to provide ideas about how everybody could support the implementation. In the control group the aim of the session was to inform about risks and consequences of joint contractures, to introduce the study, and provide contact to the research team.

Peer-mentoring

The facilitators were supported via a mentoring approach, where they received counselling by a trained mentor (a nurse in the research team). Starting with the *peer-mentor visit* in each nursing home, a mentor and an external peer expert gave the facilitators counselling and support in evaluating and adapting implementation measures tailored for their institution. Using structured assessment tools, the facilitators reviewed the residents' individual care plans and the organisational procedures (in collaboration with the head nurse) in order to identify barriers and enablers for the residents' participation. Following the visit, *peer-mentoring* was conducted via phone calls from their mentors every second week in the first two months and later once a month. The peer-mentors were free to offer fixed and regular counselling appointments or to provide counselling only if required. The peer-mentors at both study centres shared

their experiences in regular telephone meetings and discussed with a third member of the research team any problems that arose during peer-mentoring.

Supportive materials

Posters and other written materials were provided to inform and remind nursing home staff and residents. Outpatient therapists, physicians and relatives were addressed by leaflets with customised information about the intervention and contact details of the facilitators.

Standard care – the context

In Germany, nursing homes are financed by the German statutory long-term care insurance and additional payment from the residents. On a legal basis, 50% of the nursing staff had to be skilled nurses with at least three years of vocational training. Nursing home residents are frequently affected by age-related disorders and multimorbidity. Social activities are usually planned by in-house social care assistants and social workers. Physicians and therapists typically do home visits to the nursing homes. Medical and technical aids as well as physical therapy, occupational therapy and speech and language therapy need to be prescribed by a physician and are financed by the German statutory long-term care insurance with a co-payment from the residents.

Study population of the process evaluation

The study population of this process evaluation included all persons who were closely engaged in the implementation of PECAN and provided the perspective:

1. of the facilitators, responsible for the implementation of PECAN.
2. of the nurses, who were introduced to the intervention by the facilitators.
3. of additional persons, who were closely engaged in the care of residents with joint contractures, i.e., therapists, social workers and relatives.
4. of the research team, especially the trained peer-mentors, who were responsible for support of the facilitators during implementation.

The nursing team included skilled nurses, nursing assistants, nursing students and social care assistants, since they represent the nursing team in each nursing home ward. Therapists were defined as physical or occupational therapists employed by the nursing home or by an outpatient practice. Social workers were employed by the nursing home and were responsible for supporting residents in independent living and social participation, e.g., organisation and coordination of individual and group offers. Relatives were defined as a family member or a legal guardian of a participating resident and were randomly selected by the research team based on the participants' list of the residents. The residents had already been involved in the feasibility testing of the study procedures and were asked to participate in structured face-to-face interviews. We decided to exclude residents from the process evaluation of the interventions'

implementation to keep the burden of questioning as low as possible for the residents in this pilot trial [22].

Data collection

Data were collected prior to, during and post- intervention to illustrate changes over time [20]. Figure 2 displays the flow of the process evaluation. During data collection we focus on the component's "delivery to clusters" (i.e., process where the research team delivers intervention content to the nursing home), "response of clusters" (i.e., process where the nursing home adopt intervention content into daily nursing care), and "the context" (i.e., anything external to the intervention) which might be an interacting component [25]. An overview of the components and data collection methods of the process evaluation for the PECAN intervention adapted from Grant et al. [25] is presented in Table 1.

Characteristic of nursing homes – the context

Characteristics of the included nursing homes were collected at baseline via structured interviews with the head nurse or the director of the nursing home.

Delivery to and response of clusters

Process of implementation

The *facilitators' workshop* and the *information session* were evaluated by their participants with standardised questionnaires to assess content-related (e.g., relevance for professional development, practical relevance) and educational aspects (e.g., structure, comprehensibility, quality of training materials). As overall feedback, the participants rated the events on a scale ranging from 1="excellent" to 6="inadequate". The predefined qualification for the role of facilitators was reviewed in detail as part of the survey (e.g., formal vocational education). The participants in the *information session* were asked whether they were nurses, relatives, residents, or members of other groups.

Standardised documentation forms were used by the research team to review the implementation process according to protocol. We assessed the attendance in the *information session* (number and group affiliation of participants), the fidelity of the *peer-mentor visit* (number of participants, procedure according to protocol), the fidelity of the counselling interviews during *peer-mentoring by telephone* (content, number of interviews per facilitator, interview duration), and amount and type of *supportive materials* used (e.g., leaflets, poster). To gain insight into the "what" of the intervention at the nursing home level, the facilitators' activities during the implementation process were summarised in the facilitators' diary.

Attitude and behaviour of nurses

A standardised questionnaire was used for a survey on the nurses' professional attitude and behaviour in order to reach the target 20% subgroup of nursing staff in a short time. The questionnaires were

distributed by the head nurse in the intervention group and control group at baseline and at the 6-month follow-up (convenience sample). Participants were randomly selected based on their presence (staff roster) during the data collection period. Nurses were asked to rate six statements about the care of residents with joint contractures to verify to what extent the PECAN intervention is associated with a professional change in behaviour. Three additional statements regarding the reach of the intervention were rated exclusively in the intervention group at the 6-month follow-up. All statements were rated on a 5-point Likert scale (1="strongly agree" to 5="strongly disagree"; with "don't know" as a sixth option).

Enablers and barriers of implementation

After the intervention period a detailed insight into the experiences of all stakeholders was needed. Therefore, all the facilitators were invited to join a group discussion in their respective study centre. Facilitators who could not join in were asked to participate in a problem-centred interview. Relatives, therapists, social workers, and the trained peer-mentors were also invited to take part in problem-centred interviews.

Both the problem-centred interviews and the group discussion followed semi-structured interview guides. To identify key enablers and barriers of a successful implementation, questions were asked regarding how the intervention was delivered, who was reached, how every single implementation component was experienced, and which outside factors were influencing the implementation.

The group discussion was moderated by one researcher (HK) and a study assistant at the study centre. The problem-centred interviews were conducted by single researchers (HK, JH, KB) at the participants' workplace or at home via telephone. All the interviewers were trained by the research team in methods of leading group discussions [32] and problem-centred interviews [33]. The interviews and the group discussion were audio recorded. Field notes were taken and summarised in a post-script.

Data analysis

Quantitative data were analysed by descriptive statistics using SAS Version 9.4 [34].

Qualitative data from the problem-centred interviews and group discussions were analysed using a mixed deductive-inductive approach based on the structured approach of directed content analysis [35]. Audio records of the group discussion and the interviews were "abridged transcribed" [32] with priority given to relevant contents by members of the research team (HK, JH, KB). Meaningful examples of quotations from the participants were transcribed verbatim. For quality assurance reasons, the participants were offered the opportunity to review and modify the transcripts.

Two researchers (HK, KB) developed a coding guideline based on one transcript from each group of participants. To finalise the coding guideline, categories were cross-compared and discussed until a consensus was reached [36]. The final coding guideline was reviewed by two senior researchers (MM, SuS). Any data that could not be categorised with the initial coding guideline were assigned to a new sub-category. Where reasonable, the description of the categories was based on the categories of the ICF,

which was the conceptual model used to design the intervention [37, 8]. The data analysis was supported by MAXQDA Version 12 [38]. The results were classified into enablers and barriers.

Qualitative data from documentation forms or minutes and field notes were classified inductively into categories, based on the content of the given answers.

Results

Characteristic of nursing homes – the context

Seven nursing homes (n=4 intervention groups, n=3 control groups) in two German regions took part in the study. The number of long-term care beds varied between 40 and 171 across the nursing homes. Within the nursing homes, the number of wards ranged from two to six wards, the ratio of nursing staff to residents for skilled nurses was 0.19 in total (cluster-variation between 0.16 and 0.28), and the prevalence of joint contractures varied between 19% and 96%. All nursing homes conducted interprofessional case conferences (five on a regular basis, two on an occasional basis). The services in the local environment varied, but four of the seven nursing homes were in walking distance to parks, stores, churches, and coffee bars. Five of the seven nursing homes have a physical activity promoting environment with therapeutic gardens or walking circuits. The characteristics of the nursing homes are presented in Table 2.

Delivery to and response of clusters

Process of implementation

The implementation of the PECAN intervention is presented in Table 3.

The head nurse or nursing home director of each nursing home signed the declaration to ensure the commitment to improve residents' participation and to support the implementation of PECAN. In the *facilitators' workshop*, 14 nurses from two study regions and four nursing homes (2 to 6 nurses per nursing home) were trained as facilitators as planned. All the facilitators fulfilled the predefined qualification criteria and had at least one year of professional experience (range: 1 to 11 years). In addition, seven facilitators had at least one advanced vocational training in nursing (gerontological psychiatry nursing n=2; palliative care nursing n=3; case management n=1; nursing management n=4; clinical instructor n=3). The topics of the workshop were mainly rated as highly relevant for practice (high n=10; partly n=4; low n=0). After the workshop 13 out of 14 facilitators felt competent to be active in the adaptation of care plans. Further information about the self-assessed preparedness for the role as facilitator is presented in Additional file 2, Table A1. Overall, the quality of the *facilitators workshop* was rated with 1.7 points (SD 0.45; range: 1 to 2 points), indicating a good acceptance of the workshop.

A total of 136 participants from seven nursing homes (intervention n=61; control group n=75) attended the *information session*; 102 participants (range: 5 to 16 participants per nursing home) completed a questionnaire (response rate: 75%). Out of these 102 attendants, the proportion of nursing staff, residents,

and relatives varied widely between the clusters (Table 3). Overall, the quality of the *information session* was rated with 1.9 points (SD 0.76; range: 1 to 4 points), indicating a good acceptance of the session.

Peer-mentoring (peer-mentor visit, peer-mentoring by telephone, supportive material) was offered to all nursing homes. Due to sick leave and vacation occurrences, four out of 14 facilitators were unable to participate. In total, 16 counselling interviews were conducted, with strong variation between clusters (between one and seven counselling interviews per nursing home), and facilitators (6 of 14 facilitators received counselling). The mean interview duration was 48 minutes with a range from 10 to 85 minutes (Table 3). The main topics were individual residents' care, therapeutic care, use of technical and medical aids, interprofessional collaboration, collaboration with relatives, organisational needs, and implementation activities. The number of counselling interviews is associated with the different methods of both peer-mentors (the first peer-mentor was responsible for cluster 1 and 2; the second peer-mentor was responsible for cluster 3 and 4). Whereas the first peer-mentor imparted a mandatory procedure with fixed appointments right from the start and structured counselling based on specific objectives, the second peer-mentor imparted an optional approach and invited the facilitators to initiate contact themselves whenever counselling was needed.

All the nursing homes used the offered *supportive materials*, especially leaflets offering information on the PECAN intervention and the study procedure for relatives, therapists and physicians, as well as posters for promoting physical activity. Additional materials were used in accordance with the individual needs of the nursing homes (Table 3).

The facilitators adopted various measures to implement the PECAN intervention in their nursing home. The analysis of the facilitators' diaries (n=10 diaries returned out of 14) revealed that the following measures were conducted in all nursing homes: Adaptation of nursing records and care planning, development of an institution-specific guidance for managing joint contractures, inclusion of residents' participation goals in case conferences with the nursing staff and the interprofessional team, counselling of colleagues and relatives, discussions with superiors, social workers, therapists and physicians, review of technical and medical aids, and environmental adaptations in the residents' area and the nursing home.

Attitude and behaviour of nurses

The response of nursing staff to the PECAN intervention after six months is presented in Table 4. All in all, some of the nurses disagreed ("strongly disagree" and "disagree") that they felt well informed about PECAN (13/45, 29%), that *supportive materials* were provided comprehensively (13/45, 29%) and that the facilitators provided counselling whenever it was needed (12/45, 27%). After six months, the overall satisfaction of the nurses ("extremely" and "very satisfied") with the implementation of PECAN varied strongly between the nursing homes (cluster-variation between 8% and 100%).

To identify changes in daily routines due to the PECAN intervention, the nurses in the intervention group as well as in the control group were asked to rate statements towards organisational aspects that contribute

to the residents' participation (Additional file 2; Table A2). For example, in the intervention group, two thirds of the nurses (30/45, 67%) agreed ("strongly agree" and "agree") to the statement "We often discuss how to improve the care of residents with joint contractures to enable them to participate in social life in the best possible way" at the 6-month follow-up, while less than half of the nurses agreed to this statement at baseline (22/51, 43%) or at the 6-month follow-up in the control group (17/36, 47%).

Enablers and barriers

Of the 57 persons invited to problem-centred interviews 28 persons took part: thirteen facilitators (13/14), five relatives (5/24), four therapists (4/13), four social workers (4/4), and the two peer-mentors (2/2). The response was particularly high among internal stakeholders (facilitators and social workers), while only few of the external stakeholders (therapists and relatives) did respond to the invitation distributed by the head nurse.

Enablers and barriers of the implementation strategy

Enablers and barriers of the implementation strategy of the PECAN intervention are shown in Table 5. They were categorised as factors for the overall strategy and for single components of the implementation (i.e., *facilitators' workshop, information session, peer-mentoring and supportive materials*). Regarding the overall implementation strategy, the lack of involvement of the various stakeholders was named as a serious barrier. An essential enabler of the *facilitators' workshop* was the practical elements (e.g., the training on the use of technical and medical aids).

Relative (R2): *(...) of course, we did not discuss any common or possible goals regarding activity and participation... I honestly haven't noticed anything now either..*

Facilitator (F3) about the workshop: *What I liked very much was that someone from the medical supply store was there. I thought it was really good that he had said something too.*

During the *peer-mentoring*, the *peer-mentor visit* was highlighted by the facilitators as a useful introduction to implementing PECAN. Furthermore, the standardised procedure of *peer-mentoring via telephone* with routines for communication and regular appointments was emphasised as being supportive.

Facilitator (F1) about the peer-mentor: *The mentoring by someone from the researchers who continually inquired or provided incentives and motivations... it has always been quite good that there was someone else to ask.*

Peer-mentor (P1): *What worked well was my commitment to my contacts. (...) I had defined clear communication paths and tools right from the start.*

Enablers and barriers to contextual factors

Enablers and barriers to contextual factors during the implementation of PECAN are displayed in Table 6. They were categorised into personal and organisational factors. The personal factors comprised social relationships as well as individual motives and motivation. The facilitators named poor motivation or little interest of the various stakeholders as an important barrier.

Facilitator (F1): *It's hard... to really convince these die-hard nurses to actively participate, to implement, to think, to observe. That is difficult (...), and the will has to be there.*

Two organisational factors were named as key enablers: the clear commitment of the entire nursing home and the respect for the expertise of different healthcare professionals and relatives. We identified a lack of impact on organisational conditions and routines, as well as a lack of time and staff competence as the major barriers.

Facilitator (F9): *We were always exempted from work for appointments. For discussions, we got extra time. Everyone was interested in the topic; nobody was bored, or said "I don't care", that didn't happen at all; it was a very, very close collaboration.*

Therapist (T3): *(...) we have a documentation obligation... as therapists. However, the documentation is run via our practice... and not the nursing home. Well, I don't have to explain what I did in the nursing home, but that's normal.*

Social worker (S2): *Well, it's not like I'm closed off to communication, for example. But very often it's a time problem, that you don't take enough time to share information or to communicate.*

Discussion

This process evaluation describes the implementation of the PECAN intervention for the first time and emphasises enablers and barriers for a successful implementation. The implementation process was coordinated by the facilitators and included tailored measures to integrate the perspective of the ICF into daily nursing care. Although the intervention was delivered to the facilitators by the research team as planned, it was not sufficiently passed on to the nurses, healthcare professionals, relatives and, subsequently, to the residents.

Within our study, we identified the clear commitment of the entire nursing home and the respect for the expertise of different healthcare professionals as main enablers for a successful implementation. The most important barriers were a lack of impact on organisational conditions and routines, and a lack of time and staff competence. Therefore, our study reveals strengths and difficulties of the PECAN implementation strategy and suggests that specific optimisations are required.

The applied facilitation approach is a proven strategy for implementing interventions in nursing homes and for supporting changes in the daily nursing routine [39-42]. A successful implementation of knowledge into practice depends on the quality and type of the evidence, existing specific nursing home characteristics and the modalities of facilitation [21]. Our results confirmed the stepwise training of

facilitators as an appropriate implementation strategy to empower facilitators. Nevertheless, it turned out that the facilitators can only act successfully when they can rely on a working environment which is supportive to inducing changes. This includes existing time resources and the colleagues' open-mindedness for training and counselling. Considering that only two thirds of the nursing staff felt well informed about the PECAN intervention, it is apparent that further implementation strategies are needed to ensure the reach of the intervention. Aasmul et al. indicate that a successful implementation did not depend on the facilitator alone [39]. Therefore, a systematic training of all the nursing staff could support the introduction of new routines. In the main trial, we will conduct a standardised brief information session about the PECAN intervention for the entire nursing staff.

Another issue is that since 2008, social care assistants (qualified in 12 weeks) have been introduced in nursing homes to support nurses by managing and offering leisure activities for residents [43]. Accordingly, it might be reasonable to initiate joint care planning between nurses and social care assistants. This could be encouraged by inviting the head of the social care assistants to participate in the *facilitators workshop*, emphasising their common responsibility regarding activities for and participation of residents.

The *peer-mentor visit* was regarded as very beneficial, especially when the residents' individual care plans were reviewed within case conferences, which are an established approach to improve the care of nursing home residents [44-46]. Within our study, case conferences have also proven to be a useful implementation strategy for the adoption of tailored intervention measures. The *peer-mentoring via telephone* was mainly considered as an enabler, although the utilisation varied widely. Continuous support of facilitators via email, telephone or on-site visits is part of many interventions when working with facilitators [39, 40, 42]. The strong variation in the number of counselling interviews is associated with the different communication strategies of the two peer-mentors. In our study, a mandatory approach with fixed appointments right from the start, and a structured counselling based on specific objectives have proven themselves. Such standardised procedures with regular contacts during the implementation process have been reported as successful in other studies [39, 41]. Therefore, the training of peer-mentors should be extended, and the paths of communication should be further standardised. Our study found that *supportive materials* that are appropriate for everyday use and tailored for the targeted population were beneficial to imparting the intervention as simply and practically as possible. This is in line with Colón-Emeric et al. [47], who found that the balance between complexity and simplicity as well as the variety of delivery methods support the implementation success of behavioural change interventions in long-term care. Overall, the facilitators realised that a six-month study period was too short to complete the implementation, since some processes needed more time. This short follow-up period was because the pilot study was not intended to reach full implementation or proof of effectiveness and will be prolonged to one year in the main trial.

Although there was a clear commitment by the entire nursing home, ensured by the adoption of a declaration to the PECAN intervention, we identified a lack of engagement of staff in organisational and practical change. During the implementation process, it became clear that the nursing management and

the nursing staff had different priorities, responsibilities were unclear, and time slots for unscheduled tasks were not provided. As in other studies [47, 48], we experienced that an active leadership component is important for initiating necessary organisational changes. For a stronger involvement of the head nurse a structured approach with clearly defined responsibilities is needed. Moreover, an intensified relationship between the nursing home management and the collaborating partners is associated with the improvement of the residents' health outcomes [49]. Our results suggest that a successful implementation needs mutual respect towards the expertise of different healthcare professionals, whereas a lack of impact on organisational conditions (i.e., unclear allocation of responsibilities, insufficient collaboration and interprofessional exchange) was identified as an important barrier. This finding is supported by D'Amour et al. [50], who identified two key elements for interprofessional collaboration: the creation of a common action that targets the complexity of client needs and the creation of a confident and respectful team culture that integrates the perspectives of all the professionals involved. Other studies indicate that a change of culture and staff practice is complex but feasible [51, 48]. The PECAN intervention tries to overcome existing barriers of interprofessional collaboration through the combination of measures on organisational and resident levels that are tailored to the needs of each nursing home and each individual resident.

In accordance with the results from a systematic review [51], we found that organisational factors such as a lack of time and staff competence or problems with maintaining routines were significant barriers for a successful implementation. The staffing situation was also highlighted as a context-specific barrier for the implementation. Staff shortages and excessive workloads are often described as barriers when providing an intervention [52, 53, 39]. The time pressure in nursing not only affects the nurses' health-related quality of life but is also associated with a decreased quality of nursing care, and consequently, patient health outcomes [54]. Against this background, the PECAN intervention aims to qualify nurses in optimising organisational procedures and residents' care without including additional time-consuming measures [17].

Overall, our study confirms the multi-step change mechanisms hypothesised with the underlying Theory of Planned Behaviour (TPB) [28]. The assumptions of the PECAN logic model, which indicated that the residents' health status, time resources and the collaboration with different stakeholders are the influencing factors for a successful implementation, have been confirmed in this piloting phase [17].

Strengths and limitations

This process evaluation has clear strengths. The PECAN intervention was developed according to the UK MRC framework [19], and is, with the background of the ICF [8], founded on a strong theoretical base in a field where evidence is sparse [17]. We used a multitude of proven implementation strategies in combination, which is in line with the expert recommendations for implementing change [55]. A feasibility testing stage is strongly recommended to avoid implementation or evaluation failure [20]. Although our intervention was developed with practitioners and nursing home experts [17], our piloting stage identified important optimisation needs for our implementation strategy. In addition, as a participation-orientated

complex intervention, PECAN responds to a demand from a recent meta-analysis [56]. Herein, physical exercise interventions did not improve participation in older adults, and it was concluded that novel interventions are needed that should consider the individuals' preferences as well as the physical, social and cultural environments. The PECAN intervention meets these requirements.

Moreover, we successfully adopted the framework proposed by Grant et al. [25] for c-RCTs and focused on processes involving clusters. The detailed description of the methods facilitates the replicability of the study processes. The included clusters varied in terms of size and staffing, which promotes the generalisability. As recommended for process evaluations [20], we integrated qualitative and quantitative methods to explain complex causal mechanisms.

Our study also has limitations. The response rate for some questionnaires was rather low. The challenge of conducting surveys with nursing staff is a well-known problem due to existing organisational, administrative and staff barriers [57][54]. Although we have tried to reduce the occurrence of socially desirable responses by ensuring a maximum of anonymity, it cannot be fully ruled out [58]. Therefore, the questionnaires' results should be interpreted with caution. Qualitative interviews with the nursing staff and the residents in the main trial might be a more appropriate approach to get more in-depth information about the needs for support and perceptions of change in the nursing staff and residents. The recruitment of external stakeholders like therapists and relatives also proved difficult, since they were hardly included in the nursing home processes anyway.

Another limitation was the use of the facilitators' diary which did not provide enough meaningful data. Although diaries or logs were often used to describe implementation processes [39, 59], in our study the use of a diary was insufficient to analyse fidelity, reach, dose and adaptation in detail, as the response options were imprecise and the explanatory open-ended questions were not completed. We assume that in a setting where time resources are generally limited [60], methods with no additional documentation effort for the facilitators should be chosen. To reduce documentation efforts, increase the response rate, and avoid missing values a regular "diary interview" [61] during the peer-mentoring by telephone would be more appropriate for the data collection in the main trial. In addition, the measurement should include a rating scale with defined criteria to determine what was actually implemented.

Finally, our study did not focus on processes involving the target population. In this pilot testing stage, our emphasis was on the implementation strategy, especially on how skilled nurses should be prepared to be facilitators and how facilitators should be supported during the implementation process. In a next step, it will be necessary to assess in more detail to what extent the intervention truly reaches the residents and what experiences the residents' gain with the intervention.

Conclusions

This process evaluation provides important insights into the implementation of a newly developed participation-orientated complex intervention in nursing homes. Pilot-testing the PECAN intervention identified important optimisation needs for our implementation strategy. The intervention was delivered as

planned to the facilitators but was insufficient to change the professional behaviour of the whole nursing staff, and subsequently it failed to improve the residents' participation. The main recommendations resulting from our study are likely to be applicable to any new developed nursing intervention. Our study found that a successful implementation does not depend on the facilitator alone. Focused strategies are needed to address further key stakeholders and to ensure the clear commitment of the entire nursing home during the whole implementation process. We recommend a brief information session for all the nurses, the enhancement of the peer-mentoring procedure with mandatory and regular contacts, and an approach to ensure an active leadership style from the head nurse to gain impact on organisational conditions and routines. In a next step, the optimised PECAN intervention will be investigated for its effectiveness and cost-effectiveness in a main trial accompanied by a revised process evaluation.

Abbreviations

c-RCT: cluster-randomised controlled trial, **ICF**: International Classification of Functioning, Disability and Health of the World Health Organization, **MRC**: Medical Research Council, **PECAN**: Participation Enabling CAre in Nursing, **SD**: Standard deviation, **StaRI**: Standards for Reporting Implementation Studies, **TIDieR**: Template for Intervention Description and Replication, **TPB**: Theory of Planned Behaviour

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the responsible ethics committees of the Martin-Luther-University Halle-Wittenberg (ID: 2015-164) and the Ludwig-Maximilians-Universität München (ID: 760-15). All the participants gave their consent prior to data collection.

Consent for publication

All the participants gave their written consent for the publication of anonymised data.

Availability of data and materials

The analysed datasets and the measurements used during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

This process evaluation is part of the project "Developing and piloting a multifactorial intervention to address participation and quality of life in nursing home residents with joint contractures" (JointConImprove), funded by the German Federal Ministry of Education and Research (Grant

016Y1113A/B). This publication was funded by the German Federal Ministry of Education and Research (Grant 16PGF0092). The authors bear full responsibility for the content of this publication. Funders were not involved in data collection, access, analysis, interpretation and writing of the report.

Authors' contributions

GM, MM and EG contributed to the conception and design of the overall project. HK and SuS developed the concept for the process evaluation. HK, SuS, KB, and JH contributed to the acquisition of the data. HK conducted the group discussion with the facilitators. HK, KB and JH conducted the qualitative interviews. RS was responsible for data management. HK led the data analysis supported by RS and JH. All the authors contributed to the interpretation of the data. HK corresponded with the study authors and wrote the drafts of the manuscript with support from SuS, GM, and MM. All of the authors read and approved the final manuscript.

Acknowledgements

We would like to thank all the participating nursing homes, including their residents, relatives and healthcare professionals. We would like to thank Eva Mann from Rankweil, Michel HC Bleijlevens from Maastricht, and Sascha Köpke from Lübeck, as members of the scientific advisory board; Doreen Grund from Halle, Lena Otte from Munich, and Henriette Langner from Halle for supporting the facilitators; Gabriele Bartoszek in Dresden, and Angelika Zegelin in Witten, for their support as external peer-mentors; Kathrin Obermüller, Kristina Freyberg, and Kerstin Kronmüller, all from Munich, for their commitment and support during the process evaluation.

Authors' information

¹ Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig-Maximilians-Universität München, Marchioninstr. 17, 81377 Munich, Germany.

² Faculty of Applied Health and Social Sciences, Rosenheim Technical University of Applied Sciences, Hochschulstraße 1, 83024 Rosenheim, Germany.

³ Institute for Health and Nursing Sciences, Medical Faculty, Martin Luther University Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany.

⁴ German Centre for Vertigo and Balance Disorders, Ludwig-Maximilians-Universität München, Marchioninstr. 15, 81377 Munich, Germany.

References

1. Harrington C, Carrillo H, Garfield R, Musumeci MB, Squires E. Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2016. San Francisco: Department of Social and Behavioral Sciences, University of California 2018.

2. Mollinger LA, Steffen TM. Knee flexion contractures in institutionalized elderly: prevalence, severity, stability, and related variables. *Physical therapy*. 1993;73(7):437-44; discussion 44-6.
3. Resnick B. Functional performance and exercise of older adults in long-term care settings. *Journal of gerontological nursing*. 2000;26(3):7-16.
4. Wagner LM, Capezuti E, Brush BL, Clevenger C, Boltz M, Renz S. Contractures in frail nursing home residents. *Geriatric nursing*. 2008;29(4):259-66. doi:10.1016/j.gerinurse.2007.09.002.
5. Yip B, Stewart DA, Roberts MA. The prevalence of joint contractures in residents in NHS continuing care. *Health bulletin*. 1996;54(4):338-43.
6. Fergusson D, Hutton B, Drodge A. The epidemiology of major joint contractures: a systematic review of the literature. *Clinical orthopaedics and related research*. 2007;456:22-9. doi:10.1097/BLO.0b013e3180308456.
7. Rabiner A, Roach KE, Spielholz NI, Judson L. Characteristics of Nursing Home Residents with Contractures. *Physical & Occupational Therapy in Geriatrics*. 1996;13(4):1-10. doi:doi:10.1080/J148v13n04_01.
8. World Health Organization. *International Classification of Functioning, Disability and Health (ICF)*. Geneva: WHO; 2001.
9. Fischer U, Bartoszek G, Muller M, Strobl R, Meyer G, Grill E. Patients' view on health-related aspects of functioning and disability of joint contractures: a qualitative interview study based on the International Classification of Functioning, Disability and Health (ICF). *Disability and rehabilitation*. 2014;36(26):2225-32. doi:10.3109/09638288.2014.899634.
10. Bartoszek G, Fischer U, von Clarenau SC, Grill E, Mau W, Meyer G et al. Development of an International Classification of Functioning, Disability and Health (ICF)-based standard set to describe the impact of joint contractures on participation of older individuals in geriatric care settings. *Archives of gerontology and geriatrics*. 2015;61(1):61-6. doi:10.1016/j.archger.2015.03.005.
11. Fischer U, Muller M, Strobl R, Bartoszek G, Meyer G, Grill E. Prevalence of functioning and disability in older patients with joint contractures: a cross-sectional study. *Eur J Phys Rehabil Med*. 2015;51(3):269-79.
12. Fischer U, Muller M, Strobl R, Bartoszek G, Meyer G, Grill E. Examining Functioning and Contextual Factors in Individuals with Joint Contractures from the Health Professional Perspective Using the ICF: An International Internet-Based Qualitative Expert Survey. *Rehabilitation nursing : the official journal of the Association of Rehabilitation Nurses*. 2016;41(3):170-8. doi:10.1002/rnj.190.
13. Heise M, Muller M, Fischer U, Grill E. Quality of life in older individuals with joint contractures in geriatric care settings. *Qual Life Res*. 2016;25(9):2269-81. doi:10.1007/s11136-016-1262-1.
14. Katalinic OM, Harvey LA, Herbert RD, Moseley AM, Lannin NA, Schurr K. Stretch for the treatment and prevention of contractures. *Cochrane Database of Systematic Reviews* 2010 doi:10.1002/14651858.CD007455.pub2.
15. Lannin NA, Cusick A, McCluskey A, Herbert RD. Effects of splinting on wrist contracture after stroke: a randomized controlled trial. *Stroke; a journal of cerebral circulation*. 2007;38(1):111-6.

doi:10.1161/01.STR.0000251722.77088.12.

16. Saal S, Beutner K, Bogunski J, Obermuller K, Muller M, Grill E et al. Interventions for the prevention and treatment of disability due to acquired joint contractures in older people: a systematic review. *Age Ageing*. 2017;1-10. doi:10.1093/ageing/afx026.
17. Saal S, Meyer G, Beutner K, Klingshirn H, Strobl R, Grill E et al. Development of a complex intervention to improve participation of nursing home residents with joint contractures: a mixed-method study. *BMC Geriatr*. 2018;18(1):61. doi:10.1186/s12877-018-0745-z.
18. Muller M, Bartoszek G, Beutner K, Klingshirn H, Saal S, Stephan AJ et al. Developing and piloting a multifactorial intervention to address participation and quality of life in nursing home residents with joint contractures (JointConImprove): study protocol. *Ger Med Sci*. 2015;13:Doc13. doi:10.3205/000217.
19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655. doi:10.1136/bmj.a1655.
20. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W et al. Process evaluation of complex interventions: Medical Research Council guidance. *Bmj*. 2015;350:h1258. doi:10.1136/bmj.h1258.
21. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. *Implement Sci*. 2016;11:33. doi:10.1186/s13012-016-0398-2.
22. Saal S, Klingshirn H, Beutner K, Strobl R, Grill E, Muller M et al. Improved participation of older people with joint contractures living in nursing homes: feasibility of study procedures in a cluster-randomised pilot trial. *Trials*. 2019;20(1):411. doi:10.1186/s13063-019-3522-1.
23. Muller M, Oberhauser C, Fischer U, Bartoszek G, Saal S, Strobl R et al. The PaArticular Scales - A new outcome measure to quantify the impact of joint contractures on activities and participation in individuals in geriatric care: Development and Rasch analysis. *International journal of nursing studies*. 2016;59:107-17. doi:10.1016/j.ijnurstu.2016.04.002.
24. Klassen AC, Creswell J, Plano Clark VL, Smith KC, Meissner HI. Best practices in mixed methods for quality of life research. *Qual Life Res*. 2012;21(3):377-80. doi:10.1007/s11136-012-0122-x.
25. Grant A, Treweek S, Dreischulte T, Foy R, Guthrie B. Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for design and reporting. *Trials*. 2013;14:15. doi:10.1186/1745-6215-14-15.
26. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ et al. Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ*. 2017;356:i6795. doi:10.1136/bmj.i6795.
27. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687. doi:10.1136/bmj.g1687.
28. Ajzen I. The Theory of Planned Behavior. *Organ Behav Hum Dec*. 1991;50(2):179-211. doi:Doi 10.1016/0749-5978(91)90020-T.

29. Eccles MP, Grimshaw JM, MacLennan G, Bonetti D, Glidewell L, Pitts NB et al. Explaining clinical behaviors using multiple theoretical models. *Implement Sci.* 2012;7:99. doi:10.1186/1748-5908-7-99.
30. Godin G, Belanger-Gravel A, Eccles M, Grimshaw J. Healthcare professionals' intentions and behaviours: a systematic review of studies based on social cognitive theories. *Implement Sci.* 2008;3:36. doi:10.1186/1748-5908-3-36.
31. Berta W, Cranley L, Dearing JW, Dogherty EJ, Squires JE, Estabrooks CA. Why (we think) facilitation works: insights from organizational learning theory. *Implement Sci.* 2015;10:141. doi:10.1186/s13012-015-0323-0.
32. Krueger RA, Casey MA. *Focus Groups: A Practical Guide for Applied Research.* 5 ed. Thousand Oaks, CA: SAGE Publications; 2015.
33. Kvale S. *Interviews : an introduction to qualitative research interviewing.* Thousand Oaks, Calif. :: Sage Publications; 1996.
34. SAS Version 9.4. SAS Institute Inc. SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc., Cary, NC, USA. 2018.
35. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res.* 2005;15(9):1277-88. doi:10.1177/1049732305276687.
36. Denzin NK. *The research act: A theoretical introduction to sociological methods.* . Chicago, IL: Aldine; 1970.
37. Muller R, Geyh S. Lessons learned from different approaches towards classifying personal factors. *Disability and rehabilitation.* 2015;37(5):430-8. doi:10.3109/09638288.2014.923527.
38. MAXQDA. software for qualitative data analysis. Berlin, Germany: VERBI Software - Consult - Sozialforschung GmbH 1989-2016.
39. Aasmul I, Husebo BS, Flo E. Description of an advance care planning intervention in nursing homes: outcomes of the process evaluation. *BMC Geriatr.* 2018;18(1):26. doi:10.1186/s12877-018-0713-7.
40. Abraham J, Mohler R, Henkel A, Kupfer R, Icks A, Dintsios CM et al. Implementation of a Multicomponent intervention to Prevent Physical Restraints In Nursing home residenTs (IMPRINT): study protocol for a cluster-randomised controlled trial. *BMC geriatrics.* 2015;15:86. doi:10.1186/s12877-015-0086-0.
41. Franzmann J, Haberstroh J, Pantel J. Train the trainer in dementia care. A program to foster communication skills in nursing home staff caring for dementia patients. *Zeitschrift fur Gerontologie und Geriatrie.* 2016;49(3):209-15. doi:10.1007/s00391-016-1041-1.
42. Wang Y, Xiao LD, Ullah S, He GP, De Bellis A. Evaluation of a nurse-led dementia education and knowledge translation programme in primary care: A cluster randomized controlled trial. *Nurse Educ Today.* 2017;49:1-7. doi:10.1016/j.nedt.2016.10.016.
43. Eberhardt D, Sadowski K. [Implementation of section 87b of the guidelines of SGB XI—the point-of-view of the nurses aides]. *Pflege Z.* 2012;65(2):90-5.
44. Halcomb EJ, Shepherd BM, Griffiths R. Perceptions of multidisciplinary case conferencing in residential aged care facilities. *Aust Health Rev.* 2009;33(4):566-71.

45. Kim H, Park YH, Jung YI, Choi H, Lee S, Kim GS et al. Evaluation of a technology-enhanced integrated care model for frail older persons: protocol of the SPEC study, a stepped-wedge cluster randomized trial in nursing homes. *BMC Geriatr.* 2017;17(1):88. doi:10.1186/s12877-017-0459-7.
46. Reuther S, Dichter MN, Buscher I, Vollmar HC, Holle D, Bartholomeyczik S et al. Case conferences as interventions dealing with the challenging behavior of people with dementia in nursing homes: a systematic review. *Int Psychogeriatr.* 2012;24(12):1891-903. doi:10.1017/S1041610212001342.
47. Colon-Emeric C, Toles M, Cary MP, Jr., Batchelor-Murphy M, Yap T, Song Y et al. Sustaining complex interventions in long-term care: a qualitative study of direct care staff and managers. *Implement Sci.* 2016;11:94. doi:10.1186/s13012-016-0454-y.
48. Shield RR, Looze J, Tyler D, Lepore M, Miller SC. Why and how do nursing homes implement culture change practices? Insights from qualitative interviews in a mixed methods study. *J Appl Gerontol.* 2014;33(6):737-63. doi:10.1177/0733464813491141.
49. Anderson RA, Issel LM, McDaniel Jr RR. Nursing homes as complex adaptive systems: relationship between management practice and resident outcomes. *Nurs Res.* 2003;52(1):12-21.
50. D'Amour D, Ferrada-Videla M, San Martin Rodriguez L, Beaulieu MD. The conceptual basis for interprofessional collaboration: core concepts and theoretical frameworks. *J Interprof Care.* 2005;19 Suppl 1:116-31. doi:10.1080/13561820500082529.
51. Low LF, Fletcher J, Goodenough B, Jeon YH, Etherton-Beer C, MacAndrew M et al. A Systematic Review of Interventions to Change Staff Care Practices in Order to Improve Resident Outcomes in Nursing Homes. *PLoS ONE.* 2015;10(11):e0140711. doi:10.1371/journal.pone.0140711.
52. Clyne B, Cooper JA, Hughes CM, Fahey T, Smith SM, team O-Ss. A process evaluation of a cluster randomised trial to reduce potentially inappropriate prescribing in older people in primary care (OPTI-SCRIPT study). *Trials.* 2016;17(1):386. doi:10.1186/s13063-016-1513-z.
53. Hasson H, Blomberg S, Duner A. Fidelity and moderating factors in complex interventions: a case study of a continuum of care program for frail elderly people in health and social care. *Implement Sci.* 2012;7:23. doi:10.1186/1748-5908-7-23.
54. Sarafis P, Rousaki E, Tsounis A, Malliarou M, Lahana L, Bamidis P et al. The impact of occupational stress on nurses' caring behaviors and their health related quality of life. *BMC Nurs.* 2016;15:56. doi:10.1186/s12912-016-0178-y.
55. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. *Implement Sci.* 2015;10:21. doi:10.1186/s13012-015-0209-1.
56. Beauchamp MK, Lee A, Ward RF, Harrison SM, Bain PA, Goldstein RS et al. Do Exercise Interventions Improve Participation in Life Roles in Older Adults? A Systematic Review and Meta-Analysis. *Physical therapy.* 2017;97(10):964-74. doi:10.1093/ptj/pzx082.
57. Garcia C, Kelley CM, Dyck MJ. Nursing home recruitment: trials, tribulations, and successes. *Appl Nurs Res.* 2013;26(3):136-8. doi:10.1016/j.apnr.2013.01.001.

58. van de Mortel TF. Faking it: social desirability response bias in self-report research. *Aust J Adv Nurs.* 2008;25(4):40-8.
59. Roberts S, McInnes E, Bucknall T, Wallis M, Banks M, Chaboyer W. Process evaluation of a cluster-randomised trial testing a pressure ulcer prevention care bundle: a mixed-methods study. *Implement Sci.* 2017;12(1):18. doi:10.1186/s13012-017-0547-2.
60. Hall S, Longhurst S, Higginson IJ. Challenges to conducting research with older people living in nursing homes. *BMC Geriatr.* 2009;9:38. doi:10.1186/1471-2318-9-38.
61. Elliott H. The use of Diaries in Sociological Research on Health Experience. *Sociological Research Online.* 1797;2(2).

Tables

Table 1 Components and methods of the process evaluation for the PECAN intervention adapted from Grant et al. (2013) [25]

Domain	Research question	Research methods and measures	Participants	Stage of study
Delivery to clusters	What intervention is actually delivered to each nursing home? Were the components of the implementation introduced as planned?	Evaluation of the facilitators workshop using documentation forms	Research team	During and after each implementation component
		Evaluation of the information session using documentation forms	Research team	
		Evaluation of the peer-mentor-visit using documentation forms	Research team	
		Evaluation of the peer-mentoring using documentation forms	Research team	
Response of clusters	How is the intervention adopted by the nursing homes? Are there any differences between the nursing homes? Are there any changes in daily nursing routine?	Feedback on implementation components and process using standardised questionnaires, documentation forms, and facilitators' diary	Facilitators	During implementation and post-intervention
			Participants in the information session	
			Research team	
Context	In what context is the intervention implemented? How do contextual factors influence the implementation process?	Description of the wider context based on literature on national nursing home standards Collection of important structural characteristics using structured cluster-interviews Problem-centred group interviews and group discussion to ask about the influence of setting-specific factors during implementation	Nursing staff	At baseline and after 6 months
			Facilitators Therapists, social workers and relatives	Post-intervention
			Peer-mentors	
Context	In what context is the intervention implemented? How do contextual factors influence the implementation process?	Description of the wider context based on literature on national nursing home standards Collection of important structural characteristics using structured cluster-interviews Problem-centred group interviews and group discussion to ask about the influence of setting-specific factors during implementation	Literature search	Before baseline
			Head nurse	At baseline
			Facilitators	Post-intervention

Table 2 Characteristics of nursing homes adapted from Saal et al. (2019) [22]

	Intervention group				Control group			Total
	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Cluster 6	Cluster 7	
Study participants	9	20	11	24	24	23	18	129
Ownership ¹	<i>private</i>	<i>private</i>	<i>church-owned</i>	<i>church-owned</i>	<i>non-profit</i>	<i>non-profit</i>	<i>private</i>	
Long-term care beds	40	107	171	165	48	128	115	774
Nursing home wards	3	4	4	6	2	4	6	29
Residents per ward	13	27	43	28	24	32	18	27
Prevalence of joint contractures ²	0.40	0.96	0.19	0.21	0.50	0.31	0.60	0.28
Ratio of nursing staff to residents								
Skilled nurses and assistants	0.49	0.30	0.35	0.38	0.32	0.34	0.30	0.35
Skilled nurses	0.28	0.16	0.19	0.20	0.17	0.16	0.16	0.19
Interprofessional case conferences ³	<i>regularly</i>	<i>occasionally</i>	<i>regularly</i>	<i>regularly</i>	<i>regularly</i>	<i>occasionally</i>	<i>regularly</i>	
Local environment ⁴								
Park areas	<i>yes</i>	<i>yes</i>	<i>yes</i>	<i>yes</i>	<i>no</i>	<i>yes</i>	<i>yes</i>	
Stores (e.g. supermarket, drugstore)	<i>no</i>	<i>yes</i>	<i>yes</i>	<i>yes</i>	<i>no</i>	<i>yes</i>	<i>yes</i>	
Churches	<i>no</i>	<i>no</i>	<i>yes</i>	<i>yes</i>	<i>no</i>	<i>yes</i>	<i>yes</i>	
Coffee bars	<i>no</i>	<i>yes</i>	<i>yes</i>	<i>yes</i>	<i>no</i>	<i>yes</i>	<i>yes</i>	
Physical activity promoting environment ⁵	<i>no</i>	<i>no</i>	<i>yes</i>	<i>yes</i>	<i>yes</i>	<i>yes</i>	<i>yes</i>	
Degree of urbanisation ⁶	<i>rural</i>	<i>urban</i>	<i>urban</i>	<i>suburban</i>	<i>suburban</i>	<i>urban</i>	<i>suburban</i>	

¹ Categorisation of ownership = non-profit, private, state-owned, or church-owned.

² Prevalence estimated by the head nurse.

³ Categorisation of the conduction of interprofessional case conferences = regularly, occasionally, or never.

⁴ Defined as close to the nursing home within walking distance for the residents.

⁵ Defined as movement-promoting architectural features in or outside the nursing home e.g. therapeutic garden, barrier-free walking circuits, handrails, wheelchair accessibility.

⁶ Defined by degree of urbanisation acc. to the statistical office of the European office (Eurostat) = urban, suburban, or rural.

Table 3 Implementation of the PECAN intervention

	Cluster 1	Cluster 2	Cluster 3	Cluster 4
Kick-off meeting				
Meeting conducted according to protocol	ü	ü	ü	ü
Declaration signed	ü	ü	ü	ü
Facilitators' workshop				
Agenda and content acc. to protocol	ü	ü	ü	ü
Number of trained facilitators	2/2	2/2	4/4	6/6
Qualification for the role as facilitator	2/2	2/2	4/4	6/6
Information session				
Session conducted according to protocol	ü	ü	ü	ü
Number of participants per session				
Nursing staff	0	2	11	11
Residents	4	3	3	0
Relatives	1	1	0	2
Others	0	1	1	1
Missing	0	3	1	1
Total	5	10	16	15
Peer-mentoring				
Peer-mentor visit				
Agenda and content acc. to protocol	ü	ü	ü	ü
Number of facilitators participating	2/2	2/2	2/4	4/6
Participation of the head nurse	ü	ü	ü	ü
Support by an external peer-expert	ü	ü	-	ü
Peer-mentoring via telephone				
Number of counselling interviews	6	7	1	2
Number of facilitators counselled	2/2	2/2	1/4	1/6
Interview duration in minutes, mean (range)	85 (105-30)	31 (75-10)	10 (10-10)	13 (10-15)
Supportive materials				
Project leaflets given to the nursing homes	10	10	30	30
Specific leaflets for relatives, therapists, physicians given to the nursing homes	35	40	21	21
Posters to promote physical activity given to the nursing homes	3	3	4	6
Set of material for nursing team training	-	-	4	7
Article for nursing home journal	-	-	1	-
Facilitators' diary				
Response of the diary	2/2	1/2	3/4	4/6
Monthly working time per facilitator in hours, mean (range)	20 (20-	5 (5-5)	19 (17-	5 (1-10)

Table 4 Response of the nursing staff to the PECAN intervention after 6 months

Do you agree with the following statements?	Cluster 1 (n = 10) n (%)	Cluster 2 (n = 12) n (%)	Cluster 3 (n = 6) n (%)	Cluster 4 (n = 17) n (%)	Total (N = 45) n (%)
I feel well informed about PECAN.					
Agree	10 (100)	1 (8)	4 (66)	13 (77)	28 (62)
Neutral	0	0	2 (33)	2 (12)	4 (9)
Disagree	0	11 (92)	0	2 (12)	13 (29)
Supportive materials (e.g., posters, handouts, leaflets) on PECAN were provided comprehensively.					
Agree	10 (100)	1 (8)	3 (50)	13 (77)	27 (60)
Neutral	0	3 (25)	0	2 (12)	5 (11)
Disagree	0	8 (66)	3 (50)	2 (12)	13 (29)
The facilitators provided counselling whenever it was needed.					
Agree	10 (100)	3 (25)	3 (50)	12 (71)	28 (62)
Neutral	0	1 (8)	0	2 (12)	3 (7)
Disagree	0	7 (58)	3 (50)	2 (12)	12 (27)
Missing	0	1 (8)	0	1 (6)	2 (4)
Overall, are you satisfied with the implementation of PECAN in your nursing home?					
Extremely / very satisfied	10 (100)	1 (8)	4 (67)	12 (71)	27 (60)
Moderately satisfied	0	2 (17)	1 (17)	5 (29)	8 (18)
Not at all / slightly satisfied	0	5 (42)	1 (17)	0	6 (13)
Don't know	0	4 (33)	0	0	4 (9)

Table 5 Enablers and barriers of the implementation strategy of the PECAN intervention

Categories	Enablers	Barriers
Overall strategy	<ul style="list-style-type: none"> · Stepwise training of facilitators (i.e., facilitators' workshop, peer-mentor visit, peer-mentoring via telephone) (F) · Clear defined PECAN content (F) · Personal contact initiated by the management or the facilitators to provide the different stakeholders with information on PECAN (T, F) 	<ul style="list-style-type: none"> · Lack of systematic involvement of all the different stakeholders (i.e., management, social workers, relatives, and therapists) (F, R, T, SW) · Available time period too short to complete implementation (F) · Difficulties in the implementation for residents with severe physical and cognitive impairment (F)
Facilitators' workshop	<ul style="list-style-type: none"> · Practical elements (e.g., training on the use of technical and medical aids) (M) 	<ul style="list-style-type: none"> · Unbalanced ratio between theory and practice (i.e., more active participation during workshop required) (F, RT)
Information session	<ul style="list-style-type: none"> · Use of plain language when addressing the different participant groups (RT) · Diverse groups of participants could be reached and informed about PECAN in one session (F, SW) 	<ul style="list-style-type: none"> · Lack of systematic involvement of the nursing staff (e.g., no presentation within the nursing team) (F) · Invitation to the session (i.e., poster at the entrance area) did not reached all potential participants (F, T, R, SW, RT)
Peer-mentoring	<ul style="list-style-type: none"> · The peer-mentor visit was highlighted as a useful introduction to the implementation of PECAN (F) · Continuous availability of the peer-mentors via telephone (F) · Standardised procedure of peer-mentoring via telephone (F, PM) <ul style="list-style-type: none"> - Routines for communication and regular appointments (F, PM) - Specific objectives based on the last counselling (PM) 	<ul style="list-style-type: none"> · Facilitators were usually not directly available via e-mail or telephone (e.g., appointments via the head nurse were necessary) (F, PM)
Supportive materials	<ul style="list-style-type: none"> · Supportive materials tailored for the target population (F, T, SW) <ul style="list-style-type: none"> - Training folder for facilitators (F) - Posters for the nursing wards (T, SW, F) - Materials for nursing team training (F) - Specific leaflets for relatives, therapists and physicians (F) 	<ul style="list-style-type: none"> · Lack of supportive materials with a simple and practical design (F, R) · Lack of supportive materials to guide the implementation (e.g., no standardised documentation forms, no overview of potential intervention measures) (F) · Leaflets should have more focus on personal tasks (R) · Supportive materials did not reach the targeted population (R, T, SW)

- Article regarding PECAN published in nursing home journal (SW)
 - Posters or other reminders in the nursing wards were not noticed (R)
 - Leaflets were not handed out (R, T, SW)
-

Abbreviations: RT, research team; F, facilitators; R, relatives; T, therapists; SW, social workers; PM, peer-mentors.

Data base: Statements from the research team based on documentation forms (2 protocols for the facilitators' workshop, 2 protocols for the information session); statements from the facilitators based on problem-centred interviews (9 participants) and one group discussion (4 participants); statements from relatives (5 participants), therapists (4 participants) and social workers (4 participants) based on problem-centred interviews; statements from the peer-mentors based on problem-centred interviews (2 participants).

Table 6 Enablers and barriers to contextual factors during the implementation of PECAN

Categories	Enablers	Barriers
Personal factors	<ul style="list-style-type: none"> · Social relationships (F) - Respect and social support of facilitators by the nursing team (F) 	<ul style="list-style-type: none"> · Social relationships (F) - Therapists perceive PECAN as an interference in their responsibilities (F) - Conflicting opinions and challenges within the interprofessional team regarding the care of residents with joint contractures (F, T) · Motives and motivation (F, SW, R) - Differing priorities of management and nursing team (F) - Poor motivation or little interest of the different stakeholders, i.e., nurses (F), physicians (F), therapists (F), social workers (SW) or residents (R) - Lack of interprofessional attitude among physicians (F) - Uncertainty and fear among relatives (e.g., additional costs, overburdening) (F)
Organisational factors	<ul style="list-style-type: none"> · Clear commitment of the entire nursing home (F) - Active leadership to support changes (e.g., regularly occurring agreements and exchange, adoption of organisational tasks, approved time slots for meetings, provision of technical and medical aids) (F) - Open-mindedness to changes in the nursing team (e.g., review of residents' care plans, implementation of measures to support participation, initiation of case conferences) (F) - Clear responsibilities within the interprofessional team (e.g., in collaboration 	<ul style="list-style-type: none"> · Lack of impact on organisational conditions and routines (F, SW, T, R) - Unclear and unspecified responsibilities (F, SW) - Lack of interprofessional collaboration (e.g., little exchange, strict separation of working areas) (F, SW, T, R) - No established culture of contact and exchange between relatives and nursing staff (R) - No interprofessional case conferences (SW, T)

- with social workers, therapists and physicians) (F)
- Respect for the expertise of different healthcare professionals and relatives (F, SW, T, R)
 - Respect for involved healthcare professionals (F, SW, T, R)
 - Recognition of various expertise and resources (T, SW, R)
- Lack of time and staff competences (F, R, T)
 - Staff shortage and high workload for nurses (F, R, T) and therapists (F, T)
 - No time slots for unscheduled tasks (F)
 - Skills shortage in the nursing staff (F, R, T)
 - Language barriers of the nursing staff (R)

Abbreviations: F, facilitators; R, relatives; T, therapists; SW, social workers.

Data base: Statements from the facilitators based on problem-centred interviews (9 participants) and one group discussion (4 participants). Statements from relatives (5 participants), therapists (4 participants) and social workers (4 participants) based on problem-centred interviews.

Additional Files

Additional file 1: Figure A1 Logic model of the Participation Enabling Care in Nursing intervention

Additional file 2: Table A1 Self-assessed preparedness for the role as facilitator after the workshop; **Table A2** Nursing care of residents with joint contractures;

Figures

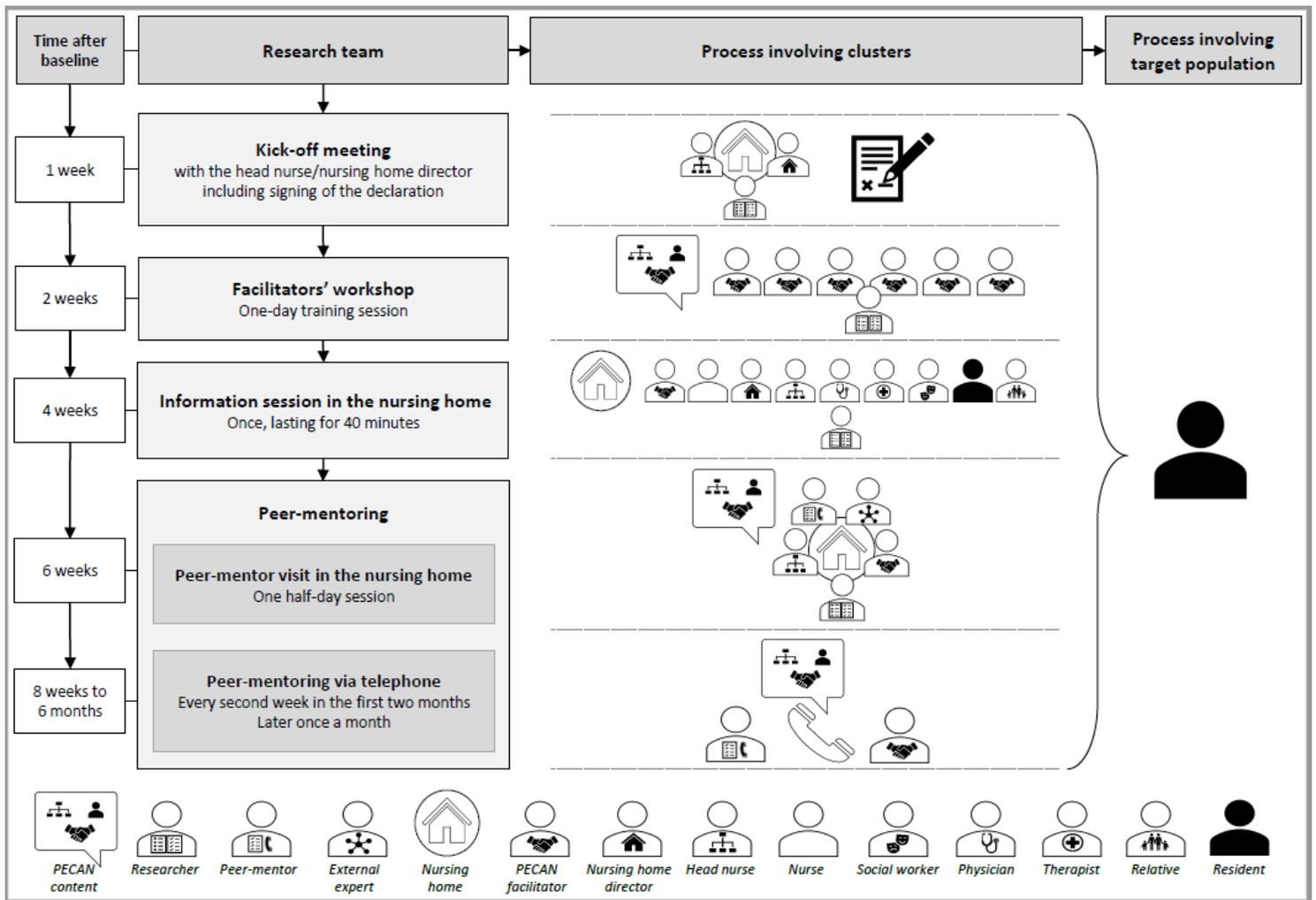


Figure 1

Overview of the PECAN implementation strategy

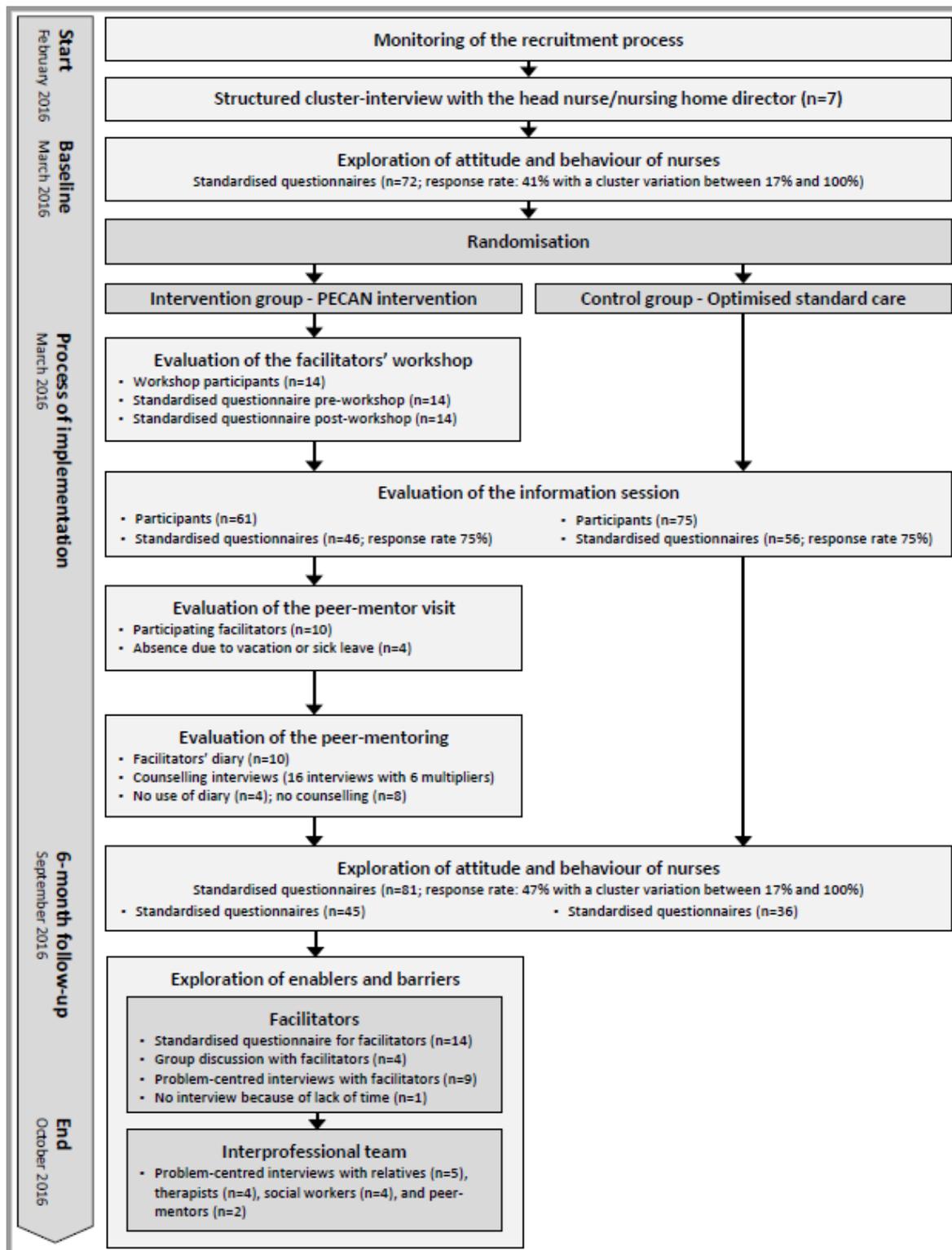


Figure 2

Flow of process evaluation

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Addfile1PECANLogicModelJCIKlingshirn.pdf](#)
- [Addfile2FurtherResultsJCIKlingshirn.pdf](#)