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Implementierung einer komplexen Intervention zur Verbesserung der Teilhabe von älteren Menschen mit Gelenkkontrakturen in Pflegeheimen – eine Prozessevaluation

Dissertation

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INHALTSVERZEICHNIS

Zusammenfassung

Hintergrund: Ältere Menschen in Pflegeheimen sind besonders häufig von Gelenkkontrakturen betroffen. Obwohl Gelenkkontrakturen massive Auswirkungen auf die Gesundheit und Teilhabe von älteren Menschen haben, sind bislang keine Interventionen bekannt, welche die individuelle Lebenssituation der Betroffenen berücksichtigen. Die vorliegende Dissertation entstand im Rahmen eines Projektes zur Entwicklung und Pilotierung einer komplexen Intervention zur Verbesserung der Teilhabe von Menschen mit Gelenkkontrakturen in Pflegeheimen. In einem mehrstufigen Prozess wurde die „Participation Enabling Care in Nursing“ (PECAN) Intervention entwickelt. Der Schwerpunkt dieser Dissertation liegt auf der parallel zur Pilotstudie verlaufenden Prozessevaluation. Ziel war es, die Durchführbarkeit der PECAN Implementierungsstrategie zu überprüfen sowie Förderfaktoren und Barrieren für eine erfolgreiche Implementierung zu identifizieren.

Methoden: Zur Implementierung von PECAN wurden Pflegefachkräfte in einem eintägigen Workshop zu PECAN-Experten ausgebildet. Die PECAN-Experten waren für die Begleitung der Veränderungsprozesse in den Pflegeheimen zuständig und wurden durch ein Mentorenprogramm (Vor-Ort-Besuch, telefonisches Peer-Mentoring) unterstützt. Die Implementierung der Intervention wurde in einer 6-monatigen cluster-randomisierten kontrollierten Pilotstudie (c-RCT) untersucht. In die Pilotstudie eingeschlossen wurden Bewohner mit einer diagnostizierten Gelenkkontraktur und einem Alter von mindestens 65 Jahren. Bewohnerdaten wurden mittels persönlicher Interviews zur Baseline, nach drei und sechs Monaten erhoben. Teilhabe wurde als primärer Outcome mit den PaArticular Scales gemessen. Begleitend wurde eine Mixed-Methods Prozessevaluation durchgeführt. Befragt wurden alle an der Implementierung beteiligten Personengruppen. Die Datenerhebung erfolgte über Fragebögen, Dokumentation, Tagebücher und qualitative Einzel- und Gruppeninterviews. Quantitative Daten wurden mittels deskriptiver Statistik und qualitative Daten mittels Inhaltsanalyse ausgewertet.

Ergebnisse: Von 12 angefragten Pflegeheimen aus den Regionen Halle und München nahmen sieben an der Pilotstudie teil (n = 4, Intervention; n = 3, Kontrolle). Die Einschlusskriterien erfüllten 265 Bewohner, 129 wurden aufgenommen und 109 schlossen die Studie nach sechs Monaten ab. Das durchschnittliche Alter der zu 80 % weiblichen Bewohner lag bei 85,7 Jahren (SD 7,0). Die PECAN-Experten nahmen die Qualifizierungsmaßnahmen insgesamt gut an (Teilnahme am Workshop: 14/14; Workshop Bewertung: „gut“; Teilnahme am Peer-Mentor-Besuch: 10/14). Das anschließende telefonische Peer-Mentoring wurde sehr unterschiedlich wahrgenommen (eine bis sieben Beratungen pro Cluster). Förderfaktoren einer erfolgreichen Implementierung waren eine aktive Unterstützung durch die Einrichtungsleitung, die Offenheit gegenüber Veränderungen, eindeutige Zuständigkeiten und die Anerkennung der Expertise der beteiligten Akteure. Als Barrieren wurden ein geringer Einfluss auf organisatorische Rahmenbedingungen, Zeit- und Fachkräftemangel benannt.

Schlussfolgerung: Eine erfolgreiche Implementierung beginnt mit einer aktiven Beteiligung der Einrichtungsleitung, um Veränderungen initiieren zu können. Zudem sollten bereits vorhandene Strukturen wie das Qualitätsmanagement zur Veränderung organisatorischer Prozesse, oder Fallkonferenzen zur Anpassung individueller Maßnahmen auf Bewohnerebene genutzt werden. Ein zentraler Aspekt zur Unterstützung der PECAN-Experten ist ein erweitertes Peer-Mentoring mit obligatorischen Kontakten. Die Erkenntnisse dieser Pilotierungsphase ermöglichen die Optimierung der PECAN Implementierungsstrategie in Vorbereitung einer Hauptstudie.

Abstract

Background: Older people in nursing homes are especially frequent affected by joint contractures. Although joint contractures have serious impacts on health and participation of older people, there are no interventions that consider the individual life situation of those affected. The present dissertation was part of a project to develop and pilot a complex intervention to improve the participation of nursing home residents with joint contractures. The "Participation Enabling CAre in Nursing" (PECAN) intervention was developed in a multi-stage process. This dissertation focuses on the process evaluation parallel to the pilot trial. The aim was to examine the feasibility of the PECAN implementation strategy and to determine enablers and barriers for a successful implementation.

Methods: The implementation included a one-day workshop to train skilled nurses as facilitators. The facilitators were responsible for guiding the change processes in the nursing homes and were supported by a mentoring approach (on-site visit, telephone peer-mentoring). The implementation of the intervention was examined in a 6-month cluster-randomised controlled pilot trial (c-RCT). The pilot trial included residents with diagnosed joint contracture and at least aged 65 years. Residents' data were collected by face-to-face interviews at baseline, after three and six months. Participation was measured as the primary outcome with the PaArticular Scales. Parallel to the trial, a mixed-methods process evaluation was conducted. All person groups involved in the implementation were examined. Questionnaires, documentation forms, diaries, qualitative interviews, and group discussions were used for data collection. Descriptive statistics were used to analyse quantitative data and content analysis for qualitative data.

Results: Out of 12 nursing homes from the regions Halle and Munich, seven participated in the pilot trial (n = 4, intervention; n = 3, control). The inclusion criteria were met by 265 residents, 129 were enrolled and 109 completed the trial after six months. Residents' were 80 % female with a mean age of 85.7 years (SD 7.0). The facilitators responded to the qualification measures overall well (workshop participation: 14/14; workshop evaluation: "good"; peer-mentor visit participation: 10/14). The use of the subsequent telephone peer-mentoring varied (one to seven consultations per cluster). Enablers for a successful implementation were an active support from the nursing home management, an open-mindedness to changes, clear responsibilities, and the respect for the expertise of the actors involved. Barriers mentioned were a low influence on organisational conditions and limited time and staff competence.

Conclusion: A successful implementation starts with an active involvement of the nursing home management to initiate changes. In addition, already existing structures such as quality management to change organisational processes, or case conferences to adapt individual measures for the residents should be used. A central aspect in supporting the facilitators is an extended peer-mentoring with obligatory contacts. The findings from this pilot phase will allow the optimisation of the PECAN implementation strategy in preparation for a main trial.

Einleitung

1. Hintergrund

Eine wesentliche Voraussetzung für die Durchführung zahlreicher Aktivitäten im Alltag ist die freie Beweglichkeit der Gelenke eines menschlichen Körpers [1]. Einschränkungen des Bewegungs- und Funktionsausmaßes von Gelenken aufgrund von Deformierungen, Immobilität und Schmerzen, bezeichnet man als Gelenkkontrakturen [2]. Die Entstehung von Gelenkkontrakturen wird durch verschiedenste Erkrankungen (z.B. neurologische oder muskuloskelettale) begünstigt und ist durch die Verkürzung von umgebenden Körperstrukturen wie Muskeln, Sehnen oder Bändern bedingt [1-3]. Menschen in Pflegeheimen sind mit einer Prävalenz von 20 bis 75 % besonders häufig von Gelenkkontrakturen betroffen [1-7]. Die breiten Schwankungen in der Prävalenz ergeben sich neben Unterschieden in der Studienpopulation vor allem aus einer uneinheitlichen Definition von Gelenkkontrakturen. Die Spannbreite der Definitionen reicht von jeglichem messbaren Verlust des Bewegungsausmaßes in einem Gelenk bis hin zu Einschränkungen, die auch funktionell von Relevanz sein müssen [1].

Neben einer hohen Prävalenz haben Gelenkkontrakturen massive Auswirkungen auf die Gesundheit und Lebensführung von älteren Menschen und können die Pflegebedürftigkeit erhöhen [3, 5, 8]. Kontrakturen der oberen Extremität führen zu Einschränkungen bei der Körperpflege, beim An- und Auskleiden oder beim Essen und Trinken. Kontrakturen der unteren Extremität schränken die Fortbewegung ein, erhöhen das Sturzrisiko und können wiederum zu Immobilität führen [8-12]. Da Gelenkkontrakturen im Wesentlichen als Folge von Immobilität gelten, werden zu ihrer Behandlung und Prävention vor allem Maßnahmen zur Förderung der Mobilität empfohlen [1]. Für Maßnahmen wie aktive und passive Dehnungsübungen oder Lagerungsprogramme konnte bisher keine Wirksamkeit nachgewiesen werden. Der Einsatz von Schienen gilt sogar als kontraproduktiv [13]. Obwohl das Thema gesundheitliche Einschränkungen durch Gelenkkontrakturen bei älteren Menschen in Pflegeheimen in den letzten Jahren an Bedeutung gewonnen hat, gibt es bislang keine wirksamen Interventionen zur Behandlung von Gelenkkontrakturen [13-15].

Basierend auf den Kenntnissen sich wechselseitig bedingender Faktoren rund um das Phänomen Gelenkkontraktur, sollte eine Intervention zur Behandlung von Gelenkkontrakturen nicht nur die geschädigten Körperfunktionen und -strukturen berücksichtigen, sondern vor allem auch die individuelle Lebenssituation der betroffenen Personen [8-10]. Nach dem bio-psycho-sozialen Modell der Internationalen Klassifikation der Funktionsfähigkeit, Behinderung und Gesundheit (ICF) [16] lässt sich die Funktionsfähigkeit eines Menschen als Ergebnis einer Wechselwirkung zwischen seinem Gesundheitsproblem, seinen Körperfunktionen und -strukturen, seinen Aktivitäten und seiner Teilhabe sowie seinem individuellen Lebenshintergrund beschreiben. Aktuelle Studien basierend auf dem Modell der ICF zeigen, dass Menschen mit Gelenkkontrakturen besonders in ihren Aktivitäten (d.h. „die Durchführung einer Aufgabe oder Handlung“ [16]) und ihrer Teilhabe (d.h. „das Einbezogensein in eine Lebenssituation“ [16]) Einschränkungen erleben [8-10, 17, 18]. In welchem Umfang Gelenkkontrakturen ein selbstbestimmtes Leben erschweren, wird zudem von Umweltfaktoren (z.B. einer barrierefreien Umgebung) und personbezogenen Faktoren (z.B. einer positiven Lebenseinstellung) beeinflusst [8, 16]. Aus der Perspektive der ICF ergeben sich vielfältige neue und

komplexe Interventionsansätze für die Behandlung von Gelenkkontrakturen bei Menschen in Pflegeheimen.

Die Besonderheit einer komplexen Intervention besteht darin, dass jede Komponente der Intervention für sich allein, aber auch in Interaktion mit den anderen Komponenten oder dem zugrundeliegenden Kontext unterschiedlich wirken kann [19]. Das UK Medical Research Council (MRC) [19] hat zur Entwicklung und Evaluation komplexer Interventionen ein zirkuläres vier-Phasen Modell erstellt: Phase I beschreibt die „Entwicklung" einer komplexen Intervention und beinhaltet die Identifikation der Evidenzbasis, die Auseinandersetzung mit Wirkmechanismen sowie die initiale Modellierung der Intervention. Phase II beschäftigt sich mit der „Pilotierung" oder auch mit der Evaluation der Machbarkeit. In dieser explorativen Phase werden neben den Studienprozeduren verschiedene Bedingungen der Implementierung untersucht. Phase III, die „Evaluation", untersucht die Effektivität der Intervention und Phase IV, die „Implementierung", schließt den Prozess mit einer Langzeitbeobachtung unter realen Bedingungen ab.

Gegenstand der Dissertation

Die vorliegende Dissertation entstand im Rahmen des JointConImprove Projektes [20]. Ziel dieses Projektes war es eine komplexe Intervention zur Verbesserung der Teilhabe von Menschen mit Gelenkkontrakturen in Pflegeheimen nach dem MRC Modell [19] zu entwickeln und zu pilotieren (Phase I und II) [20]. Die Entwicklung der Intervention basiert auf dem Modell der ICF [16], nutzt die beste zur Verfügung stehende Evidenz und integriert „Best Practice" Modelle. Unterstützt durch die Expertise von professionellen Gesundheitsfachkräften und Menschen mit Gelenkkontrakturen entstand in einem mehrstufigen Entwicklungsprozess die „Participation Enabling CAre in Nursing" (PECAN) Intervention. ▶ **Publikation I**, Ko-Autorenschaft [21].

In der anschließenden Pilotierungsphase wurde die neu entwickelte PECAN Intervention mit einer cluster-randomisierten kontrollierten Pilotstudie (c-RCT) hinsichtlich der Machbarkeit und Durchführbarkeit verschiedener Studienprozeduren überprüft. Nach Eldridge *et al.* [22] leitet sich die Vorgehensweise einer Pilotstudie von ihrer primären Zielsetzung ab und dient dazu Bereiche der Unsicherheit für die Vorbereitung einer Hauptstudie zu untersuchen. ▶ **Publikation II**, geteilte Erst-Autorenschaft [23].

Den Schwerpunkt dieser Dissertation stellt die den c-RCT begleitende Prozessevaluation dar. In der Pilotierungsphase liegt die zentrale Funktion einer Prozessevaluation neben der Überprüfung des gewählten Evaluationsdesigns auf der Umsetzbarkeit der Implementierungsstrategie [24]. Das Ziel der Prozessevaluation war deshalb die Überprüfung der Durchführbarkeit der PECAN Implementierungsstrategie und die damit verbundene Identifikation von Förderfaktoren und Barrieren für eine erfolgreiche Implementierung. ▶ **Publikation III**, Erst-Autorenschaft [25].

2. Methoden

Die PECAN Intervention

Die PECAN Intervention wurde als eine aus mehreren Komponenten bestehende komplexe Intervention entwickelt (▶ **Publikation I** [21]). Durch eine Professionalisierung der Pflegekräfte wird die Perspektive des bio-psycho-sozialen Modells der ICF [16] in die Pflegepraxis integriert. PECAN beinhaltet individuelle, auf die Bedürfnisse des Bewohners[1] abgestimmte Maßnahmen zur Verbesserung der Teilhabe. Eine Übersicht zur PECAN Implementierungsstrategie ist in **Abbildung 1** dargestellt.

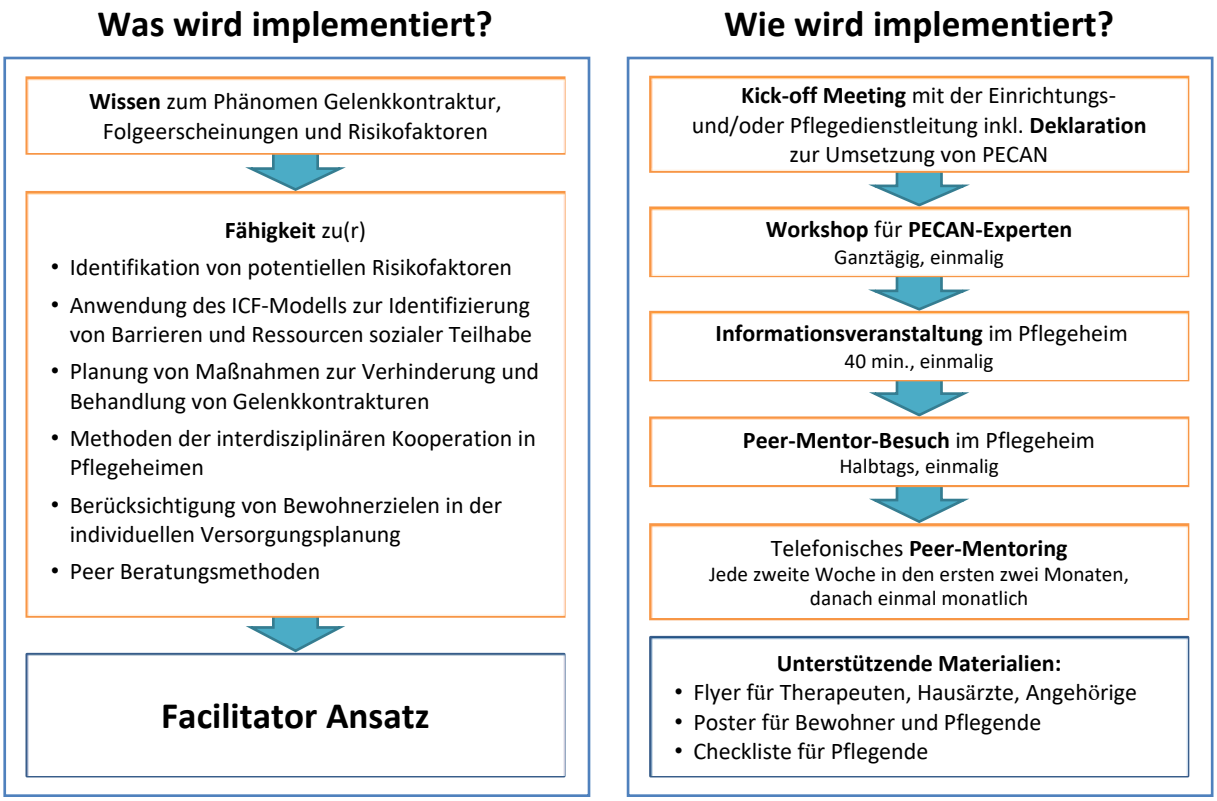

Abbildung 1 Übersicht zur PECAN Implementierungsstrategie adaptiert von Saal *et al.* [21]

Als Kernkomponente der Implementierung wurden ausgewählte Pflegefachkräfte in einem eintägigen Workshop zu PECAN-Experten ausgebildet. Basierend auf dem Prinzip der „facilitation" [26, 27] waren die PECAN-Experten für den aktiven Teil der Implementierung und für die Begleitung der Veränderungsprozesse in den Pflegeheimen zuständig. Neben der Vermittlung von wesentlichen Inhalten der Intervention und Übungen zur Umsetzung individueller Maßnahmen, fand eine Schulung zu Peer-Beratungsmethoden statt. Anschließend war es die Aufgabe der PECAN-Experten, die Inhalte der Intervention an ihr Pflegeteam weiterzugeben und weitere Akteure wie Hausärzte, Therapeuten, soziale Betreuer oder Angehörige einzubinden. Während des Implementierungsprozesses wurden die PECAN-Experten durch ein Mentorenprogramm begleitet. Dieses begann mit dem Peer-Mentor-Besuch im jeweiligen Pflegeheim, bei dem die PECAN-Experten von einem externen Berater und ihrem

[1] Aus Gründen der besseren Lesbarkeit wird in der vorliegenden Dissertation auf die gleichzeitige Verwendung männlicher und weiblicher Sprachformen verzichtet. Sämtliche personenbezogenen Bezeichnungen sind geschlechtsneutral zu verstehen.

Mentor bei der Entwicklung von maßgeschneiderten Umsetzungsstrategien zur Implementierung der PECAN Intervention unterstützt wurden. Mit strukturierten Checklisten erstellten sie eine individuell angepasste Pflegeplanung für die Bewohner (Individualebene) und identifizierten Ressourcen und Barrieren für die Teilhabe der Bewohner in ihrem Pflegeheim (Organisationsebene). Anschließend begann das telefonische Peer-Mentoring mit regelmäßigen Beratungsgesprächen.

Die PECAN Pilotstudie

In der Pilotierungsphase wurde die PECAN Intervention mit einer multizentrischen, pragmatischen Studie hinsichtlich ihrer Machbarkeit überprüft (▶ **Publikation II** [23]). Ein wichtiger Aspekt war dabei die Überprüfung der Durchführbarkeit der Studienprozeduren in Vorbereitung auf eine Hauptstudie. Die Pilotstudie wurde zweiarmig mit einem Parallelgruppendesign durchgeführt. Als Cluster wurden Pflegeheime aus den Regionen Sachsen-Anhalt (Halle) und Bayern (München) definiert. Vor Beginn der Studie wurde die Zustimmung der zuständigen Ethikkommissionen eingeholt.

Aus datenschutzrechtlichen Gründen fand die Rekrutierung der Bewohner über die jeweiligen Pflegedienstleitungen statt. Eingeschlossen wurden Bewohner mit diagnostizierter Gelenkkontraktur (ärztlich, therapeutisch oder pflegerisch) und einem Alter von mindestens 65 Jahren. Ausgeschlossen wurden Bewohner im Terminalstadium einer Erkrankung. Alle Studienteilnehmer wurden persönlich aufgeklärt, ehe sie zur Studienteilnahme einwilligten. Die Randomisierung der teilnehmenden Pflegeheime in die Interventions- (PECAN) oder Kontrollgruppe (optimierte Standardversorgung) wurde, stratifiziert nach den beiden Studienregionen, direkt nach der Baseline-Erhebung durchgeführt.

Die Bewohnerdaten wurden zur Baseline, nach drei und nach sechs Monaten mit strukturierten, persönlichen Interviews mit den Bewohnern und den Pflegekräften erhoben. War es dem Bewohner nicht möglich für sich selbst zu sprechen (z.B. bei kognitiver Einschränkung) wurde das Interview als Proxyversion mit der jeweiligen Bezugspflegekraft durchgeführt. Sozioökonomische- und klinische Daten wurden aus der Bewohnerdokumentation entnommen. Der kognitive Status wurde mit der Dementia Screening Scale (DSS) [28] erhoben. Teilhabe wurde als primärer Outcome mit der Subskala „Partizipation“ der ICF-basierten und patientenzentrierten PaArticular Scales gemessen [29]. Als sekundäre Outcomes wurden Aktivitäten (Subskala „Aktivitäten“ der PaArticular Scales) [29], instrumentelle Aktivitäten des täglichen Lebens (Lawtons IADL Scale) [30], gesundheitsbezogene Lebensqualität (EQ-5D-3L) [31] sowie Stürze und sturzbedingte Konsequenzen (Bewohnerakte) erhoben. Parallel dazu wurden Daten zur Durchführbarkeit verschiedener Studienprozeduren mit standardisierten Dokumentationsbögen erhoben.

Prozessevaluation

Begleitend zur Pilotstudie wurde eine Mixed-Methods Prozessevaluation durchgeführt (▶ **Publikation III** [25]). Entsprechend der Empfehlungen für die Prozessevaluation komplexer Interventionen von Moore *et al.* [24] wurden quantitative Methoden angewandt, um Kernprozesse der Implementierung zu untersuchen und qualitative Methoden, um Förderfaktoren und Barrieren für eine erfolgreiche Implementierung zu identifizieren. Qualitative und quantitative Daten wurden gleichwertig behandelt und miteinander in Beziehung gesetzt, um ein umfassendes Bild über die Implementierung zur erhalten [32]. Das Studiendesign der Prozessevaluation wurde auf Basis des Modells von Grant *et al.* [33] für die Entwicklung und Berichterstattung speziell für c-RCTs erarbeitet. Das Modell unterscheidet zwischen Prozessen auf Cluster- (d.h. Pflegeheim) und Individualebene (d.h.

Bewohner mit Gelenkkontrakturen) und deren Interaktion mit dem zugrundeliegenden Kontext [33]. Da die PECAN Intervention nicht beim Bewohner direkt ansetzt, sondern zunächst über eine Professionalisierung der Pflegekräfte Veränderungen bewirken soll, liegt der Schwerpunkt dieser Untersuchung auf den Prozessen der Clusterebene.

Im Rahmen der Prozessevaluation wurden alle Personen befragt, die an der Implementierung der PECAN Intervention beteiligt waren. Anhand vordefinierter Kriterien wurde mit standardisierten Dokumentationsbögen überprüft, ob der Implementierungsprozess gemäß dem Studienprotokoll verlief. Die PECAN-Experten wurden gebeten ihre Erfahrungen im Implementierungsprozess in einem Tagebuch zu dokumentieren. Um die Einstellung und das Verhalten der Pflegekräfte bezüglich der pflegerischen Versorgung von Bewohnern mit Gelenkkontrakturen zu erfassen, wurden in jedem Pflegeheim zur Baseline und nach 6 Monaten 20 % der Pflegekräfte eingeladen an einer standardisierten Fragebogenerhebung teilzunehmen.

Nach Abschluss der Interventionsphase (nach 6 Monaten) wurden problemzentrierte qualitative Einzel- oder Gruppeninterviews [34, 35] mit PECAN-Experten, Therapeuten, sozialen Betreuern, Angehörigen und Peer-Mentoren durchgeführt, um Förderfaktoren und Barrieren für eine erfolgreiche Implementierung zu identifizieren. Der Ablauf der Prozessevaluation in der Pilotierungsphase ist in **Abbildung 2** dargestellt.

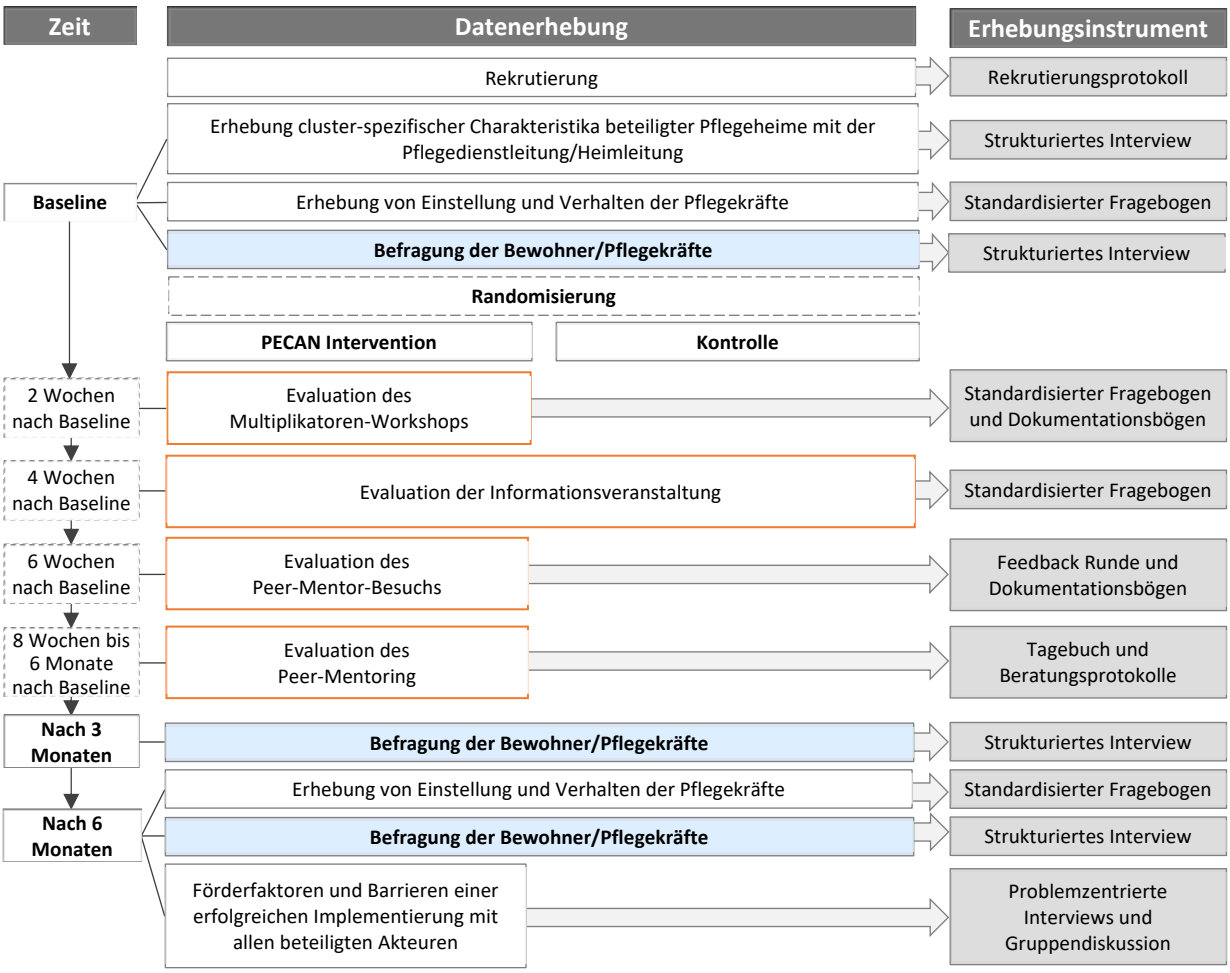

Abbildung 2 Ablauf der Prozessevaluation in der Pilotierungsphase

Quantitative Daten wurden mittels deskriptiver Statistik analysiert. Qualitative Daten wurden mit einem deduktiv-induktiven Ansatz mittels qualitativer Inhaltsanalyse ausgewertet [36]. Dazu wurden Audiodateien transkribiert und mit einem von zwei unabhängigen Forschern entwickelten Kategoriensystem codiert.

3. Ergebnisse

Machbarkeit und Pilotierung

Von zwölf eingeladenen Pflegeheimen, stimmten sieben der Teilnahme an der Pilotstudie zu. In den teilnehmenden Pflegeheimen erfüllten insgesamt 265 Bewohner die Einschlusskriterien und 129 (49 %) davon nahmen an der Studie teil. Die Gründe für eine Nicht-Teilnahme waren ein schlechter Gesundheitszustand (n = 62), persönliche Gründe (n = 12) oder ein Tod vor dem Einschluss in die Studie (n = 1). Weitere 61 Bewohner gaben keinen Grund für ihre Nicht-Teilnahme an.

Die Prävalenz von Gelenkkontrakturen lag in den Pflegeheimen insgesamt bei 28 % (Spannweite: 19 bis 96 %). Die 129 teilnehmenden Bewohner hatten ein Durchschnittsalter von 85,7 Jahren (SD 7,0) und waren zu 80 % weiblich. Bei der Hälfte der Bewohner (51 %) ergab die DSS eine kognitive Einschränkung, weshalb 65 Interviews in einer Proxyversion durchgeführt werden mussten. Basierend auf ihrer Pflegestufe waren 44 (34 %) Bewohner nicht bis mäßig beeinträchtigt, 51 (40 %) Bewohner schwer beeinträchtigt und 34 (26 %) Bewohner schwerstens beeinträchtigt.

Alle sieben Pflegeheime blieben bis zum Ende in der Studie (n = 4, Intervention; n = 3, Kontrolle). Fünfzehn Bewohner (12 %) verstarben im Studienverlauf, ein Bewohner schied aufgrund einer massiven Verschlechterung seines Gesundheitszustandes aus, ein Bewohner zog um und drei weitere Bewohner zogen ihre Einwilligung zur Studienteilnahme zurück. Die Studie wurde insgesamt von 109 (84 %) Bewohnern nach sechs Monaten abgeschlossen. Die Erhebung von Stürzen und sturzbedingten Frakturen zeigte keine Unterschiede in der Frequenz zwischen Interventions- und Kontrollgruppe.

Prozessevaluation

Insgesamt wurden 14 Pflegefachkräfte (zwei bis sechs pro Pflegeheim) aus den vier Interventionsheimen zu PECAN-Experten ausgebildet. Die Qualität des Workshops wurde von den Teilnehmern mit „gut“ bzw. der Schulnote 1,7 (SD 0,45) bewertet. Die vermittelten Inhalte wurden von der Mehrzahl der Teilnehmer als hoch relevant für die Pflegepraxis bewertet (hoch n = 10; teils n = 4; wenig n = 0). Die Informationsveranstaltung wurde in allen Pflegeheimen durchgeführt und ebenfalls mit „gut“ bzw. der Schulnote 1,9 (SD 0,76) bewertet.

Das Peer-Mentoring startete in den jeweiligen Interventionsheimen mit dem Peer-Mentor-Besuch. Aufgrund von Urlaub und Krankheit konnten nur 10 der 14 PECAN-Experten an dem Besuch teilnehmen. In den Interviews wurde der Peer-Mentor-Besuch als wichtiger Baustein für die Einführung in die Umsetzung der PECAN Intervention hervorgehoben. Das anschließende telefonische Peer-Mentoring wurde mit unterschiedlicher Intensität wahrgenommen. Die Anzahl der Beratungsgespräche ist assoziiert mit den zuständigen Peer-Mentoren (Mentor A: Cluster 1 und 2; Mentor B: Cluster 3 und 4). Während Mentor A von Beginn an verbindlich auftrat und kontinuierlich feste Termine für die Beratung vereinbarte, kommunizierte Mentor B einen bedarfsorientierten

Ansatz, der von den PECAN-Experten ausgehen sollte. Der Ansatz von Mentor A, mit verbindlichen und regelmäßigen Terminen, wurde von den PECAN-Experten in den Interviews als zielführender bewertet. Die Implementierung der PECAN Intervention ist in **Tabelle 1** dargestellt.

Tabelle 1 Implementierung der PECAN Intervention

	Cluster 1	**Cluster 2**	**Cluster 3**	**Cluster 4**
Kick-off Meeting				
Deklaration unterschrieben	✓	✓	✓	✓
Workshop für PECAN-Experten				
Anzahl ausgebildete PECAN-Experten	2/2	2/2	4/4	6/6
Informationsveranstaltung				
Anzahl Teilnehmer pro Veranstaltung	5	10	16	15
Peer-Mentoring				
Teilnahme Peer-Mentor-Besuch	2/2	2/2	2/4	4/6
Anzahl telefonische Beratungsgespräche	6	7	1	2
Beratungsdauer Minuten, *Mean (Range)*	85 (105-30)	31 (75-10)	10 (10-10)	12 (15-10)
Unterstützende Materialien				
Flyer Therapeuten, Ärzte, Angehörige	35	40	21	21
Poster Bewohner und Pflegende	3	3	4	6

Die PECAN-Experten ergriffen ein breites Spektrum an Maßnahmen, um die PECAN Intervention in ihrem Pflegeheim zu implementieren. In den Tagebüchern (10 von 14 Tagebücher wurden abgegeben) werden beispielsweise Maßnahmen wie die Anpassung der Pflegeplanung, die Durchführung von Fallkonferenzen oder die Überprüfung des Hilfsmittelbedarfs genannt. Die Dokumentation der Beratungsgespräche lieferte konkrete Beispiele für maßgeschneiderte Interventionsbausteine:

Individualebene (Cluster 2): In Zusammenarbeit mit den Therapeuten gelang es, einen Bewohner, der bei seinem Einzug in das Pflegeheim an den Rollstuhl gebunden war, wieder zu ermutigen seine Gehhilfe zu benutzen und kurze Strecken mit Unterstützung zu laufen.

Organisationsebene (Cluster 1): Mit dem Ziel die Hilfsmittelversorgung zu optimieren wurde in Zusammenarbeit mit dem Sanitätshaus ein interprofessioneller Inhouse-Workshop für Pflegende, Therapeuten und Hilfsmittelversorger organisiert.

Insbesondere in Cluster 2 gab ein hoher Anteil der Pflegekräfte an nicht zufrieden mit der Implementierung der Intervention zu sein (5/12, 42 %). Aus den Interviews mit den Peer-Mentoren geht hervor, dass die PECAN-Experten in Cluster 2 keine Möglichkeit hatten ihre Rolle zu erfüllen und Veränderungsprozesse zu initiieren, da die notwendige Unterstützung der Einrichtungsleitung fehlte. Die Zufriedenheit der Pflegenden mit der Implementierung von PECAN nach sechs Monaten ist in **Tabelle 2** dargestellt.

Tabelle 2 Zufriedenheit der Pflegenden mit der Implementierung von PECAN nach sechs Monaten

Zufriedenheit mit Implementierung	**Cluster 1**		**Cluster 2**		**Cluster 3**		**Cluster 4**		**Gesamt**	
	n	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**	**n**	**(%)**
Sehr bis überwiegend	10	(100)	1	(8)	4	(67)	12	(71)	27	(60)
Eher zufrieden	0		2	(17)	1	(17)	5	(29)	8	(18)
Eher nicht bis überwiegend nicht	0		5	(42)	1	(17)	0		6	(13)
Weiß ich nicht	0		4	(33)	0		0		4	(9)
Gesamt	10	(100)	12	(100)	6	(100)	17	(100)	45	(100)

Im Rahmen der Interviews konnten Förderfaktoren und Barrieren für eine erfolgreiche Implementierung identifiziert werden. An erster Stelle ist eine grundsätzliche Einsatzbereitschaft des gesamten Pflegeheimes erforderlich. Dazu gehört eine aktive Unterstützung durch die Einrichtungsleitung, eine Offenheit gegenüber Veränderungen im Pflegeteam und eindeutige Zuständigkeiten im interprofessionellen Team. Ein weiterer zentraler Erfolgsindikator ist die Anerkennung der Expertise der an der Gesundheitsversorgung beteiligten Akteure. Zwei Beispielzitate veranschaulich hier Unterschiede zwischen den Clustern:

> PECAN-Experte (P6, C3): *[…] dieses Miteinander fehlte mir […] Ich hatte am Anfang mit der Pflegedienstleitung gesprochen […], ich hatte aber den Eindruck, „ja das ist schön, dass Sie dort waren" aber […] dieses Dahinterstehen und das Interesse fehlte mir.*
>
> PECAN-Experte (P1, C1): *Und ich muss auch sagen, der ganze Zusammenhalt untereinander, Pflege, Physios, Ärzte, Ergos. Das ist mittlerweile ein richtig schönes Zusammenarbeiten. Das funktioniert, man ergänzt sich, man bekommt Tipps.*

Ein geringer Einfluss auf organisatorische Rahmenbedingungen sowie Zeit- und Fachkräftemangel wurden als wesentliche Barrieren einer erfolgreichen Implementierung genannt. Zwei Beispiele verdeutlichen hier die Schwierigkeiten, die sich dadurch für die interprofessionelle Zusammenarbeit ergaben.

> Soziale Betreuung (S2, C2): *Also es ist jetzt nicht so, dass ich zum Beispiel verschlossen bin was Kommunikation betrifft, aber es ist sehr häufig auch ein Zeitproblem, dass man sich eben nicht ausreichend Zeit nimmt, um Übergaben zu machen oder zu kommunizieren.*
>
> Therapeut (T3, C3): *Wir haben eine Dokumentationspflicht als Therapeuten. Die Dokumentation läuft aber über unsere Praxis und nicht über das Heim. Also ich muss dort nicht darlegen was ich gemacht habe im Heim, das ist aber so üblich.*

4. Diskussion

Mit der PECAN Intervention wurde eine aus mehreren Komponenten bestehende, komplexe Intervention zur Verbesserung der Teilhabe von Menschen mit Gelenkkontrakturen in Pflegeheimen pilotiert. Der Entwicklungsprozess war durch die Einbindung der bio-psycho-sozialen Perspektive der ICF eindeutig theoriegeleitet. Ausgehend von einer geringen Evidenzbasis, wurden alle relevanten Interessensgruppen in den Entwicklungsprozess eingebunden, um eine möglichst breite und unverfälschte Sichtweise abzubilden. Die anschließende Pilotierungsphase bestätigt sowohl die Machbarkeit und Durchführbarkeit des Studiendesigns als auch die Umsetzbarkeit der PECAN Intervention im Setting Pflegeheim.

Unsere Pilotierungsphase gewährt einen Einblick in das noch wenig erforschte Gebiet der multizentrischen, pragmatischen Studien in Pflegheimen. Die Rekrutierung von Pflegeheimbewohnern wird in vielen Studien als Herausforderung beschrieben [37-40]. Der Einbezug der Pflegedienstleitung in den Rekrutierungsprozess war aus datenschutzrechtlichen Gründen unumgänglich und führte durch die Funktion als „Gatekeeper" zu einer angemessenen Teilnehmerrate von 49 %. In unserer Pilotstudie lag die Prävalenz von Gelenkkontrakturen trotz einer standardisierten Begriffsdefinition und einer

vergleichbaren Studienpopulation je nach Pflegeheim zwischen 19 und 96 %. Wir vermuten, dass das Fehlen eines standardisierten Diagnoseinstruments und unsere breite Definition von Gelenkkontrakturen einen zu großen Interpretationsspielraum ermöglichen. Für die Hauptstudie sollen deshalb die Einschlusskriterien konkretisiert werden und auf Bewohner fokussieren, die eine Gelenkkontraktur in mindestens einem großen Gelenk aufweisen, welche zu einer Einschränkung in ihrem täglichen Leben führt. Die Bewohner sollten außerdem mindestens in eine sitzende Position mobilisiert werden können. In unserer Pilotstudie blieben alle sieben Pflegeheime unabhängig von ihrer Gruppenzugehörigkeit bis zum Ende in der Studie. Aus anderen Studien ist bekannt, dass Probleme mit der Retention in Kontrollgruppen nicht ungewöhnlich sind [41]. Unser Angebot die PECAN-Schulung nach Abschluss der Studie auch in den Kontrollheimen durchzuführen, könnte ein attraktiver Anreiz für die Pflegeheime gewesen sein.

Unsere Prozessevaluation beschreibt die Implementierung der PECAN Intervention im Setting Pflegeheim und veranschaulicht, wie individuell angepasste Maßnahmen in die tägliche Pflegepraxis integriert werden können. Obwohl die Intervention wie geplant an die PECAN-Experten übermittelt wurde, ist es den PECAN-Experten nicht gelungen alle Pflegekräfte zu erreichen und Veränderungsprozesse zu initiieren. Aasmul *et al.* [42] betonen, dass für die Erhöhung der Reichweite einer Intervention nicht nur einzelne Personen verantwortlich sein können und schlagen ein systematisches Training des gesamten Pflegeteams zur Einführung neuer Inhalte vor. Das Peer-Mentoring, insbesondere die Besprechung von individuellen Bewohnerfällen im Rahmen von Fallkonferenzen, wurde von den PECAN-Experten besonders hilfreich für die Anpassung maßgeschneiderter Interventionsinhalte empfunden. Die Beratung im Rahmen des telefonischen Peer-Mentorings wurde hingegen nur dann genutzt, wenn ein obligatorischer Ansatz mit regelmäßigen Terminen vorgegeben war. Auch andere Studien berichten vom Einsatz individueller Fallkonferenzen [43-45] oder einer kontinuierlichen Begleitung via E-Mail, Telefon und Vor-Ort-Besuch, um die Implementierung von Interventionen extern zu unterstützen [42, 46, 47]. Die Teilnahme des Peer-Mentors an einer regulären Fallkonferenz könnte eine weitere sinnvolle Maßnahme sein, um Veränderungen im Pflegeheim zu initiieren. Die Nutzung bereits etablierter Kommunikationsmechanismen ist eine bewährte Strategie, um Pflegekräfte in Implementierungsprozesse einzubinden [48].

In unserer Studie wurde die Implementierung oftmals durch Barrieren wie Zeit- und Personalmangel erschwert. Zahlreiche andere Studien bestätigen diese typischen Barrieren [42, 49-51]. Unsere Ergebnisse zeigen außerdem, dass es den PECAN-Experten möglich sein muss Einfluss auf relevante organisatorische Strukturen zu nehmen, um Veränderungen herbeizuführen. Die Initiierung dieser Veränderungen benötigt die Unterstützung durch die Einrichtungsleitung. Verschiedene Studien bestätigen, dass die Initiierung organisatorischer Veränderungen von der Einrichtungsleitung ausgehen muss, um eine Einbindung des Pflegeteams bei der Umsetzung von Interventionsinhalten sicherzustellen [52, 53]. Außerdem bietet es sich an die bereits existierenden Strukturen des Qualitätsmanagements zu nutzen, um Veränderungsprozesse in Gang zu setzen.

Es ist weiterhin bekannt, dass eine erfolgreiche Implementierung wesentlich von cluster-spezifischen Charakteristika und den vorhanden Unterstützungsmöglichkeiten abhängt [27]. Unterschiede zwischen unseren Pflegeheimen verdeutlichen, dass Merkmale wie die Größe der Einrichtung, die Unterstützung der Einrichtungsleitung, die Inanspruchnahme der Peer-Beratung oder auch die

Stellung des PECAN-Experten innerhalb des Teams den Erfolg der Implementierung beeinflussen. In unserer Studie sehen wir das am deutlichsten im Vergleich von Cluster 1 und 2. Cluster 1 war ein vergleichsweise kleines Pflegeheim, dass mit einem PECAN-Experten in der Position der stellvertretenden Einrichtungsleitung Einfluss auf notwenige organisatorische Veränderungen nehmen konnte. Hingegen kam es in Cluster 2 zu einer Stagnierung im Implementierungsprozess, da die Unterstützung der Einrichtungsleitung aufgrund von Personalwechsels schlichtweg fehlte.

Stärken und Limitationen

Die PECAN Intervention erfüllt die Forderung einer kürzlich veröffentlichten Metaanalyse nach neuen teilhabeorientierten Interventionen, welche die individuellen Bedürfnisse von älteren Menschen in ihrer persönlichen Umwelt berücksichtigen [54]. Obwohl unsere Intervention bereits mit Experten aus Forschung und Praxis entwickelt wurde [21], konnten wir mit unserer Prozessevaluation wichtige Optimierungsbedarfe bezüglich unserer Implementierungsstrategie identifizieren. Eine wesentliche Stärke unserer Studie ist die konsequente Integration von qualitativen und quantitativen Methoden, entsprechend der Empfehlungen für Prozessevaluationen [24]. Durch diese Vorgehensweise ist es gelungen, komplexe Veränderungsmechanismen zu entschlüsseln. Die Variabilität der untersuchten Cluster verdeutlicht außerdem, wie verschiedene Gegebenheiten in den Pflegeheimen zu unterschiedlichen Erfahrungen bei der Implementierung der PECAN Intervention beitragen können.

Die Interpretation unserer Ergebnisse muss vor dem Hintergrund einiger Limitationen stattfinden. Befragungen in Pflegeheimen sind durch häufigen Personal- und Zeitmangel mit großen organisatorischen Herausforderungen verbunden [55]. Die Rücklaufquote einiger unserer Fragebögen fiel möglicherweise deshalb etwas geringer aus. Ebenso könnte durch ein sozial erwünschtes Antwortverhalten die Rückmeldungen zur Intervention allgemein positiver ausgefallen sein. Trotz der Sicherstellung einer Anonymität kann dies nicht vollständig ausgeschlossen werden [56]. Aufgrund ungenauer und fehlender Angaben hat sich letztendlich auch das Tagebuch der PECAN-Experten nicht als Messinstrument im Prozess der Implementierung bewährt. Mehr Erfolg könnten hingehen individuelle Interviews [57], gekoppelt an die ohnehin stattfindende Beratung, versprechen.

Schlussfolgerungen

Aus den Erfahrungen unserer Pilotierungsphase ergeben sich Empfehlungen zur Optimierung von Rekrutierungsprozessen wie die Konkretisierung der Einschlusskriterien für die Bewohner mit Gelenkkontrakturen. Unsere Prozessevaluation verdeutlicht, dass es für eine erfolgreiche Implementierung das Engagement des gesamten Pflegeheimes benötigt. Dies beginnt mit einer aktiven Beteiligung der Einrichtungsleitung, die maßgeblich ist, um Veränderungen auf Organisationsebene initiieren zu können. Zudem müssen bereits vorhandene Strukturen zur Implementierung genutzt werden. Auf Organisationsebene könnten Strukturen des Qualitätsmanagements die Implementierung leiten. Auf Individualebene bieten sich Fallkonferenzen an, um Maßnahmen für die Bedürfnisse einzelner Bewohner anzupassen und das Pflegeteam von Beginn an in den Implementierungsprozess einzubinden. Ein zentraler Aspekt zur Unterstützung der PECAN-Experten ist ein erweitertes Peer-Mentoring mit obligatorischen Kontakten und einer Einbindung der Einrichtungsleitung. Die Erkenntnisse dieser Pilotierungsphase ermöglichen eine Optimierung von Prozessen der Studienplanung und Implementierung, um die PECAN Intervention im Rahmen einer Hauptstudie hinsichtlich ihrer Effektivität zu überprüfen.

Abkürzungsverzeichnis

Abkürzung	*Bedeutung*
DSS	Dementia Screening Scale
IADL	Instrumental Activities of Daily Living
ICF	International Classification of Functioning, Disability and Health
MRC	Medical Research Council
PECAN	Participation Enabling CAre in Nursing
SD	Standardabweichung (*englisch:* Standard Deviation)

Referenzen

1. Wagner LM, Clevenger C: **Contractures in nursing home residents**. *Journal of the American Medical Directors Association* 2010, **11**(2):94-99.
2. Harrington C, Carrillo H, Garfield R, Musumeci MB, Squires E: **Nursing Facilities, Staffing, Residents and Facility Deficiencies, 2009 Through 2016.** In. San Francisco: Department of Social and Behavioral Sciences, University of California 2018.
3. 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**:22-29.
4. Mollinger LA, Steffen TM: **Knee flexion contractures in institutionalized elderly: prevalence, severity, stability, and related variables**. *Physical therapy* 1993, **73**(7):437-444; discussion 444-436.
5. Resnick B: **Functional performance and exercise of older adults in long-term care settings**. *Journal of gerontological nursing* 2000, **26**(3):7-16.
6. Wagner LM, Capezuti E, Brush BL, Clevenger C, Boltz M, Renz S: **Contractures in frail nursing home residents**. *Geriatric nursing* 2008, **29**(4):259-266.
7. Yip B, Stewart DA, Roberts MA: **The prevalence of joint contractures in residents in NHS continuing care**. *Health bulletin* 1996, **54**(4):338-343.
8. Fischer U, Bartoszek G, Müller 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):2225-2232.
9. Fischer U, Müller 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):269-279.
10. Fischer U, Müller 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):170-178.
11. 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.
12. Sackley C, Brittle N, Patel S, Ellins J, Scott M, Wright C, Dewey ME: **The prevalence of joint contractures, pressure sores, painful shoulder, other pain, falls, and depression in the year after a severely disabling stroke**. *Stroke; a journal of cerebral circulation* 2008, **39**(12):3329-3334.
13. Saal S, Beutner K, Bogunski J, Obermüller K, Müller M, Grill E, Meyer G: **Interventions for the prevention and treatment of disability due to acquired joint contractures in older people: a systematic review**. *Age Ageing* 2017:1-10.

14. Katalinic OM, Harvey LA, Herbert RD, Moseley AM, Lannin NA, Schurr K: **Stretch for the treatment and prevention of contractures**. In: *Cochrane Database of Systematic Reviews.* John Wiley & Sons, Ltd; 2010.

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):111-116.

16. World Health Organization: **International Classification of Functioning, Disability and Health (ICF)**. Geneva: WHO; 2001.

17. Bartoszek G, Fischer U, von Clarenau SC, Grill E, Mau W, Meyer G, Strobl R, Thiesemann R, Nadolny S, Müller M: **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):61-66.

18. Heise M, Müller M, Fischer U, Grill E: **Quality of life in older individuals with joint contractures in geriatric care settings**. *Qual Life Res* 2016, **25**(9):2269-2281.

19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, Medical Research Council G: **Developing and evaluating complex interventions: the new Medical Research Council guidance**. *BMJ* 2008, **337**:a1655.

20. Müller M, Bartoszek G, Beutner K, Klingshirn H, Saal S, Stephan AJ, Strobl R, Grill E, Meyer G: **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.

21. Saal S, Meyer G, Beutner K, Klingshirn H, Strobl R, Grill E, Mann E, Kopke S, Bleijlevens MHC, Bartoszek G *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.

22. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA, group Pc: **CONSORT 2010 statement: extension to randomised pilot and feasibility trials**. *BMJ* 2016, **355**:i5239.

23. Saal S, Klingshirn H, Beutner K, Strobl R, Grill E, Müller M, Meyer G: **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.

24. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D *et al*: **Process evaluation of complex interventions: Medical Research Council guidance**. *Bmj* 2015, **350**:h1258.

25. Klingshirn H, Müller M, Beutner K, Hirt J, Strobl R, Grill E, Meyer G, Saal S: **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**. *BMC Geriatr* 2020, **20**(1):270.

26. 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.

27. Harvey G, Kitson A: **PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice**. *Implement Sci* 2016, **11**:33.

28. Köhler L, Weyerer S, Schaufele M: **Proxy screening tools improve the recognition of dementia in old-age homes: results of a validation study**. *Age Ageing* 2007, **36**(5):549-554.

29. Müller M, Oberhauser C, Fischer U, Bartoszek G, Saal S, Strobl R, Meyer G, Grill E: **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**:107-117.

30. Lawton MP, Brody EM: **Assessment of older people: self-maintaining and instrumental activities of daily living**. *The Gerontologist* 1969, **9**(3):179-186.

31. **EuroQol--a new facility for the measurement of health-related quality of life**. *Health Policy* 1990, **16**(3):199-208.

32. 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):377-380.

33. 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.

34. Kvale S: **InterViews: An introduction to qualitative research interviewing.** In. Thousand Oaks, CA: Sage Publications; 1996.

35. Krueger RA, Casey MA: **Focus Groups: A Practical Guide for Applied Research**, 5 edn. Thousand Oaks, CA: SAGE Publications; 2015.

36. Hsieh HF, Shannon SE: **Three approaches to qualitative content analysis**. *Qual Health Res* 2005, **15**(9):1277-1288.

37. Davies K, Collerton JC, Jagger C, Bond J, Barker SA, Edwards J, Hughes J, Hunt JM, Robinson L: **Engaging the oldest old in research: lessons from the Newcastle 85+ study**. *BMC Geriatr* 2010, **10**:64.

38. Hall S, Longhurst S, Higginson IJ: **Challenges to conducting research with older people living in nursing homes**. *BMC Geriatr* 2009, **9**:38.

39. Shepherd V, Nuttall J, Hood K, Butler CC: **Setting up a clinical trial in care homes: challenges encountered and recommendations for future research practice**. *BMC Res Notes* 2015, **8**:306.

40. Zermansky AG, Alldred DP, Petty DR, Raynor DK: **Striving to recruit: the difficulties of conducting clinical research on elderly care home residents**. *J R Soc Med* 2007, **100**(6):258-261.

41. Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, Young Z, Morris J: **Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study)**. *BMC Geriatr* 2017, **17**(1):143.

42. 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.

43. Halcomb EJ, Shepherd BM, Griffiths R: **Perceptions of multidisciplinary case conferencing in residential aged care facilities**. *Aust Health Rev* 2009, **33**(4):566-571.

44. Kim H, Park YH, Jung YI, Choi H, Lee S, Kim GS, Yang DW, Paik MC, Lee TJ: **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.

45. Reuther S, Dichter MN, Buscher I, Vollmar HC, Holle D, Bartholomeyczik S, Halek M: **Case conferences as interventions dealing with the challenging behavior of people with dementia in nursing homes: a systematic review**. *Int Psychogeriatr* 2012, **24**(12):1891-1903.

46. Abraham J, Möhler R, Henkel A, Kupfer R, Icks A, Dintsios CM, Haastert B, Meyer G, Köpke S: **Implementation of a Multicomponent intervention to Prevent Physical Restraints In Nursing home residenTs (IMPRINT): study protocol for a cluster-randomised controlled trial**. *BMC Geriatr* 2015, **15**:86.

47. 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.

48. Godfrey M, Young J, Shannon R, Skingley A, Woolley R, Arrojo F, Brooker D, Manley K, Surr C. In: *The Person, Interactions and Environment Programme to improve care of people with dementia in hospital: a multisite study.* Southampton (UK); 2018.

49. 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.

50. 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.

51. Low LF, Fletcher J, Goodenough B, Jeon YH, Etherton-Beer C, MacAndrew M, Beattie E: **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.

52. Colon-Emeric C, Toles M, Cary MP, Jr., Batchelor-Murphy M, Yap T, Song Y, Hall R, Anderson A, Burd A, Anderson RA: **Sustaining complex interventions in long-term care: a qualitative study of direct care staff and managers**. *Implement Sci* 2016, **11**:94.

53. 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):737-763.

54. Beauchamp MK, Lee A, Ward RF, Harrison SM, Bain PA, Goldstein RS, Brooks D, Bean JF, Jette AM: **Do Exercise Interventions Improve Participation in Life Roles in Older Adults? A Systematic Review and Meta-Analysis**. *Physical therapy* 2017, **97**(10):964-974.

55. Garcia C, Kelley CM, Dyck MJ: **Nursing home recruitment: trials, tribulations, and successes**. *Appl Nurs Res* 2013, **26**(3):136-138.

56. van de Mortel TF: **Faking it: social desirability response bias in self-report research**. *Aust J Adv Nurs* 2008, **25**(4):40-48.

57. Elliott H: **The Use of Diaries in Sociological Research on Health Experience**. *Sociological Research Online* 1997, **2**(2):38-48.

Fachartikel

Publikation I

Development of a complex intervention to improve participation of nursing home residents with joint contractures: a mixed method study

Susanne Saal, Gabriele Meyer, Katrin Beutner, Hanna Klingshirn, Ralf Strobl, Eva Grill, Eva Mann, Sascha Köpke, Michel H. C. Bleijlevens, Gabriele Bartoszek, Anna-Janina Stephan, Julian Hirt, Martin Müller

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Kurzzusammenfassung

In dieser ersten Publikation wurde die Entwicklung einer komplexen Intervention zur Verbesserung der Teilhabe von Menschen mit Gelenkkontrakturen in Pflegeheimen beschrieben. Die Entwicklung erfolge nach dem Konzept des Medical Research Council (MRC) unter Anwendung eines mehrstufigen Mixed-Methods-Ansatzes. Im Ergebnisteil wurde die Participation Enabling CAre in Nursing (PECAN) Intervention inklusive Implementierungsstrategie erstmalig vorgestellt.

Ko-Autorenschaft, Eigenanteil: *Interventionsentwicklung (Logic Model, Implementierung), Interpretation der Daten, Korrekturlesen des Manuskriptes.*

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Development of a complex intervention to improve participation of nursing home residents with joint contractures: a mixed-method study

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Abstract

Background: Joint contractures in nursing home residents limit the capacity to perform daily activities and restrict social participation. The purpose of this study was to develop a complex intervention to improve participation in nursing home residents with joint contractures.

Methods: The development followed the UK Medical Research Council framework using a mixed-methods design with re-analysis of existing interview data using a graphic modelling approach, group discussions with nursing home residents, systematic review of intervention studies, structured 2-day workshop with experts in geriatric, nursing, and rehabilitation, and group discussion with professionals in nursing homes.

Results: Graphic modelling identified restrictions in the use of transportation, walking within buildings, memory functions, and using the hands and arms as the central target points for the intervention. Seven group discussions with 33 residents revealed various aspects related to functioning and disability according the International Classification of Functioning, Disability and Health domains body functions, body structures, activities and participation, environmental factors, and personal factors. The systematic review included 17 studies with 992 participants: 16 randomised controlled trials and one controlled trial. The findings could not demonstrate any evidence in favour of an intervention. The structured 2-day expert workshop resulted in a variety of potential intervention components and implementation strategies. The group discussion with the professionals in nursing homes verified the feasibility of the components and the overall concept. The resulting intervention, Participation Enabling CAre in Nursing (PECAN), will be implemented during a 1-day workshop for nurses, a mentoring approach, and supportive material. The intervention addresses nurses and other staff, residents, their informal caregivers, therapists, and general practitioners.

Conclusions: In view of the absence of any robust evidence, the decision to use mixed methods and to closely involve both health professionals and residents proved to be an appropriate means to develop a complex intervention to improve participation of and quality of life in nursing home residents. We will now evaluate the PECAN intervention for its impact and feasibility in a pilot study in preparation for an evaluation of its effectiveness in a definitive trial.

Trial registration: German clinical trials register, reference number DRKS00010037 (12 February 2016).

Keywords: Contractures, Nursing homes, Social participation, International classification of functioning, Disability and health (ICF), Complex intervention, Quality of life

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Background

Joint contractures are characterized by restrictions in physiological joint mobility and can even result in immobility [1]. Joint contractures have a wide range of causes, including immobility, pain, and neurological conditions [2–5]. Not surprisingly, joint contractures are a common problem among older, frail people living in nursing homes [6, 7] and greatly affect not only the capacity to perform daily activities (such as toileting, walking) or to participate in social life but also the need for nursing care [6, 8–10]. Studies have shown that participation restrictions are most relevant from the perspectives of both the affected individuals and the health professionals involved in their management and care [10–12].

Interventions that target the broader goal of improving social participation in nursing home residents with joint contractures face several challenges. According to the WHO' model of the International Classification od Functioning, Disability and Health participation restrictions are problems an individual may experience in involvement in life situations [13]. First, the population shows great clinical variation and includes both frail but ambulatory individuals and individuals who are already heavily restricted in their mobility or are even bedridden. Second, persons with joint contractures can have varying preferences regarding their social participation. Third, some individuals may already have one or several joint contractures, whereas others are at risk of developing joint contractures. In addition, because multimorbid residents with joint contractures might be cared for by many different individuals, a successful intervention should address all professionals in nursing homes, including qualified nurses and assistant staff, therapists, and physicians, as well as informal caregivers. With these challenges in mind, it is clear that a successful intervention aimed at improving participation in nursing home residents with joint contractures must by its very nature be complex. Careful development of such a complex intervention must consider both theoretical findings and empirically identified influencing factors.

Our aim was to develop a complex intervention to improve participation in nursing home residents with joint contractures that systematically integrates evidence and account for the perspectives of all stakeholders [14].

Methods

The development approach followed the UK MRC framework [15], the most widely used guidance for the development of nursing interventions [16]. The MRC framework proposes a four-phase approach to develop and evaluate complex interventions. This paper comprises all aspects of the development phase, including exploration of relevant theories, identification of the existing evidence, exploration of potential intervention components, modelling of the intervention components, and the implementation process. The study combines qualitative and quantitative methods in a mixed-methods design. To describe the development process in detail, we adhered to the criteria for reporting the development and evaluation of complex interventions in health care [17].

An overview of the intervention development process is presented in Fig. 1.

Identifying evidence and theory

We had previously conducted standardized [10, 11] and qualitative interviews [18] with nursing home residents and patients in geriatric rehabilitation hospitals. Our purpose was to assess and describe the prevalence of activity limitations and participation restrictions of older persons with joint contractures, and the impact of joint contractures on functioning and social participation from the patients' perspective. In addition, we explored the problems older people with joint contractures experience by conducting an Internet-based expert Delphi survey with international health professionals [12]. As a result of our preparatory studies, improvement of social participation and quality of life emerged as the primary objectives of our intervention, with emphasis on the role of contextual factors in participation and quality of life of nursing home residents with joint contractures.

As in the preparatory studies, we used the biopsychosocial model of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization (WHO) to guide the theoretical development of the intervention, especially to model potential interactions of the intervention components with the targeted outcomes. The ICF model can be understood as the operationalization of functioning and health as the outcome of the dynamic interaction between a person's health condition and his or her personal and environmental contextual factors [13].

For this study, we explored the theoretical underpinnings and the available evidence base using a stepwise approach (Fig. 1).

Graphical modelling of standardized interview data

To investigate potential intervention goals, we analysed data from our previous cross-sectional study by means of graphical modelling [10, 11] Graphical modelling is an approach to visualize conditional dependencies between various variables where most relevant dependencies are displayed in a netlike structure by drawing a graph. The associations within graphical models are estimated using generalized linear regression analysis [19–21]. We assumed that variables that are associated with multiple other variables as displayed in the graphs are valuable starting points for interventions. The cross-sectional study was conducted between February and July 2013 in three acute-geriatric

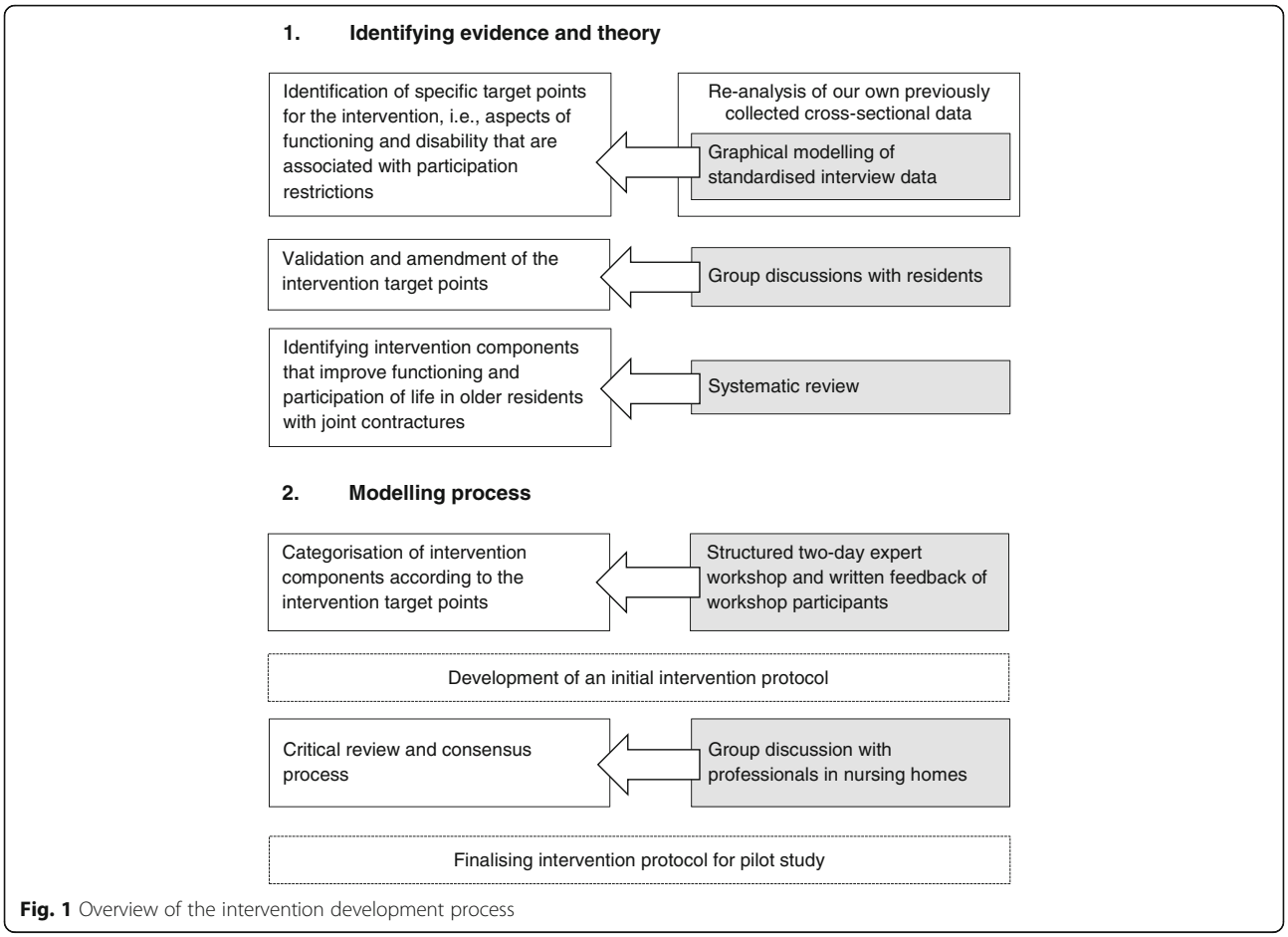

Fig. 1 Overview of the intervention development process

hospitals in and around Munich, Bavaria (Germany) and in eleven nursing homes and three geriatric rehabilitation hospitals in and around Witten, North Rhine–Westphalia (Germany). Two hundred ninety-four participants 65 years of age or older with at least one diagnosis of joint contracture were interviewed face-to-face via a standardized questionnaire. The study determined the extent of limitations and restrictions of functioning related to joint contracture in older persons in geriatric care.

Group discussions with nursing home residents

To validate the findings from the graphical modelling, moderated group discussions with nursing home residents were carried out in nursing homes in two areas in Germany, Munich (Bavaria) and Witten (North Rhine–Westphalia), between March and June 2015. Two of the authors (GB, AS) used an interview guide that was developed to identify barriers and facilitators for activities and participation and to validate the intervention goals identified by graphical modelling. Before the start of the focus group meeting, we asked participants to complete a short questionnaire on their demographic characteristics, location of the joint contracture, and current care level and to classify their functioning using a visual analogue scale. Each group consisted of four to five nursing home residents selected according to predefined inclusion criteria and asked by the nursing home managers to participate. The inclusion criteria were (1) an age of 65 years or above with at least one diagnosis of joint contracture, (2) the ability to give informed consent for themselves, and (3) the cognitive ability to participate in and follow a group discussion, judged by an expert opinion of a nurse in charge. The sample size was determined by data saturation––i.e., the point at which an investigator has obtained sufficient information from the field [22]. A signed informed-consent form was obtained from each participant before the study began. One researcher moderated the group discussion interviews, and two persons recorded the minutes. To avoid a formal interview situation and foster a friendly and open-minded conversation, no audio recordings were collected. Two researchers (AS, JH) analysed the minutes independently using the meaning condensation procedure [23]––a qualitative content analysis approach––together with the ICF linking procedure, a method that utilizes the ICF as a fixed-category system [24]. The two researchers' versions were merged, and differences were discussed with support from a senior researcher (MM). All analyses were carried out in Microsoft Excel.

Systematic review

To identify potential intervention components for prevention and treatment of disability due to acquired joint contractures in older people and to determine positive and adverse effects of interventions, a systematic review was conducted (latest search August 2016). The full report can be found elsewhere [25]. In brief, the databases Cochrane Library, PubMed, EMBASE, PEDro, CINAHL, trial registries, reference lists of retrieved articles, and scientific congress pamphlets were systematically searched, including the following combined search terms, among others: contracture [MeSH], joint contracture, social participation, aged [MeSH], randomized controlled trial, controlled clinical trial. Controlled and randomized controlled trials in English or German that compared an intervention with another intervention or standard care were included. Critical appraisal followed the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0 [26]. Two researchers independently selected studies for inclusion/exclusion, assessed the methodological quality trials, and extracted data.

Modelling process

Structured expert workshop

In a 2-day workshop with a structured consensus process, geriatricians and experts in nursing and rehabilitation science identified relevant intervention components. After presentation and discussion of the findings from the first part of the study, experts collected ideas for potential interventions and discussed factors that might influence the intervention components and successful implementation. Methods used to structure and promote the discussion process included brainstorming, plenary discussion, group work, and the development and presentation of a poster. All proposed intervention components were evaluated regarding their ability to improve the residents' participation against the background of the ICF model.

Written feedback of workshop participants

After the workshop, the study team summarized and detailed the results of the workshop and asked the participants to give written feedback via e-mail. The experts were asked to amend missing information on the topics for which they were responsible during the workshop and to provide additional feedback on all other components. Disagreements were resolved in an iterative discussion via e-mail.

After completion of the feedback process, the research team prioritized the intervention components according to their assumed feasibility. Next, an implementation approach on the revised intervention components was developed. The initial intervention protocol was validated by five participants in the expert workshop. The implementation approach is based on the theory of planned behaviour [27] and uses nominated key nurses as multipliers, who act as a change agent in the nursing home. The appropriateness of this approach has been proven [28].

Group discussion with professionals in nursing homes

In a moderated group discussion, nursing professionals in North Rhine–Westphalia with experience in innovative change processes gave feedback on the intervention protocol regarding the interventions' relevance, comprehensiveness, and feasibility and on barriers that could be expected during the implementation. A member of the research team (GB) moderated the discussion using a structured interview guide, and a research assistant documented the interview in written form. This documentation was validated by the participants of the group discussion. Finally, in a telephone conference, all members of the research team discussed the intervention protocol and agreed on its final version.

Results

Graphical modelling

Standardized interview data from 294 persons were reanalysed. The participants' mean age was 80.4 years (range, 65.0 to 99.7 years; SD, 7.54 years); 195 participants (66%) received care in geriatric rehabilitation facilities and 99 (34%) in nursing homes; 198 (67%) were female. The graphic model revealed that restrictions in the use of transportation, walking within buildings, memory functions, and using hands and arms had the greatest association with other restrictions and might therefore be promising target points for the intervention.

Group discussions with nursing home residents

Seven group discussions (5 in Munich and 2 in Witten) were conducted with 33 nursing home residents with joint contractures (88% female; mean age, 85 years; SD, 6.99 years); 61% had joint contractures in the upper and the lower extremities, 15% solely in the upper extremities, and 24% in the lower extremities. The participants' characteristics are presented in Table 1. The interviews averaged 45 min (range, 30 to 60 min).

Restrictions in the ICF categories *Mobility and Self-care* and problems in the ICF domain "Environmental factors" were most often reported by nursing home residents with joint contractures. The reported ICF domains and categories are displayed in Table 2.

Systematic review

Seventeen studies with 992 participants met the inclusion criteria: 16 randomised controlled trials and one controlled trial (four in nursing homes, 13 in the community). Four studies reported on splints, nine on stretching exercises, and one each on ultrasound, passive movement therapy, a bed-positioning program, and a group exercise program.

Table 1 Characteristics of residents in the group discussion ($n = 33$)

Variables		
Age in years, mean (SD)	84.6	(7.0)
Female gender, *n* (%)	29	(88)
Self-rated functioning[a], mean (SD)	4.72	(1.9)
Localization of joint contracture, *n* (%)		
Lower extremity	8	(24)
Upper extremity	5	(15)
Lower and upper extremity	20	(61)
Level of care dependency[b], *n* (%)		
Minor	6	(18)
Considerable	15	(45)
Severe	10	(30)
Most severe	0	(0)

[a]Visual analogue scale, range 0 to 10 = sad face to smiling. Data not available for three participants
[b]For description of the functional and cognitive status, we used levels of care dependency as assessed by expert raters of the medical service of the German statutory health insurance system (0 = minor, 1 = considerable, 2 = severe, 3 = most severe). Data not available for two participants

Table 2 ICF domains and categories from group discussions with 33 nursing home residents

ICF domains and categories
Body functions
Mental functions
Sensory functions and pain
Genitourinary and reproductive functions
Neuromusculoskeletal and movement-related functions
Body structures
"General physical decline"
Activities and participation
General tasks and demands
Major life areas
Community, social, and civic life
Domestic life
Interpersonal interactions and relationships
Communication
Mobility
Self-care
Environmental factors
Products and technology
Service, systems, and policies
Attitudes
Support and relationships
Natural environment and human-made changes to environment
Personal factors

The methodological quality of the studies varied. Five of seven studies that assessed active stretching programs for healthy older people reported statistically significant effects on joint mobility in favour of the intervention. One of four studies that investigated the effects of splinting reported significant improvement of the passive range of motion. One study of a group exercise program observed significant improvements in activities. No positive effects were reported for active stretching programs for frail older people, ultrasound, passive movement therapy, and a bed-positioning program. Studies rarely assessed pain, quality of life, activity limitations, and participation restrictions. Overall quality of evidence was low and therefore not a reliable basis for further development. Detailed findings appear elsewhere [25].

Structured expert workshop and written feedback of workshop participants

The two-day expert workshop with eight participants (two experts of geriatric sciences, three experts of nursing sciences, and three experts of rehabilitation sciences) and the subsequent written feedback resulted in a variety of potential intervention components, such as useful assessments and measures to reduce environmental barriers, strategies to improve interprofessional care, and strategies to consider personal factors in promoting mobility and to engage residents in social activities. Several implementation strategies also identified were qualification of multipliers, peer mentoring of multipliers, qualification of the nursing home staff, and strategies to involve nursing home managers, social workers, informal caregivers, and therapists in change processes.

The research team prioritized suggestions regarding the intervention components according to the anticipated feasibility in the nursing home setting. The team developed a delivery approach for the revised intervention components according to the suggestions by the experts, and five participants of the expert workshop validated both the delivery approach and the revised intervention protocol.

Group discussion with professionals in nursing homes

We discussed the pre–final intervention protocol with four nursing professionals: a skilled nurse responsible for admission processes acting as a multiplier of nursing guidelines to support mobility, a head of nursing, a nursing home manager, and a skilled nurse responsible for quality management. The participants recommended an intensive collaboration of nurses with social workers and nursing assistants for social care in the nursing homes. They also highlighted the necessity to plan for sufficient time between each implementation step to allow the multipliers to deal with their regular tasks in addition to their new roles. The participants judged the implementation approach as feasible and comprehensive and

also considered the content of the workshop to be relevant and consistent. All discussed checklists and tools received confirmation of their usefulness and focus, except that participants did not consider that a developed guideline about goal setting in nursing plans was feasible. The logic model (Fig. 2) displays the final version of the complex intervention named Participation Enabling CAre in Nursing (PECAN).

PECAN intervention

The PECAN intervention is a multifactorial program to improve care of nursing home residents with joint contractures. The policy is to improve residents' social participation through reduction of hindering environmental factors, facilitation of personal factors, and support of mobility. Because nursing homes use a wide range of documentation formats, as well as different risk assessments and planning tools, the PECAN intervention does not aim to implement additional measures or assessments into standard care. The intervention enables nurses to critically review organizational procedures and residents' care plans according to predefined criteria, to initiate changes into daily care, and to prepare themselves to act as change agents of the nursing home's daily routines.

Kick-off meeting with the head of nursing/nursing home manager

In a first meeting with the head of nursing and the nursing home manager, the policy of the PECAN will be discussed and a declaration must be signed to formally document and reinforce the institutional commitment. The declaration will be placed in full view of all visitors.

Multipliers' workshop

The key component of the intervention is a 1-day workshop for nurses, who are nominated as multipliers of the intervention in the nursing homes to offer education and counselling to their colleagues.

The workshop for nominated nurses comprises the following activities:

- Sharing of information about the causes, consequences, and risks of joint contractures;
- Critical review of risk assessments used in the nursing home;
- Training in ways to consider residents' participation goals in the individual care planning through presentation of case vignettes and case reports;

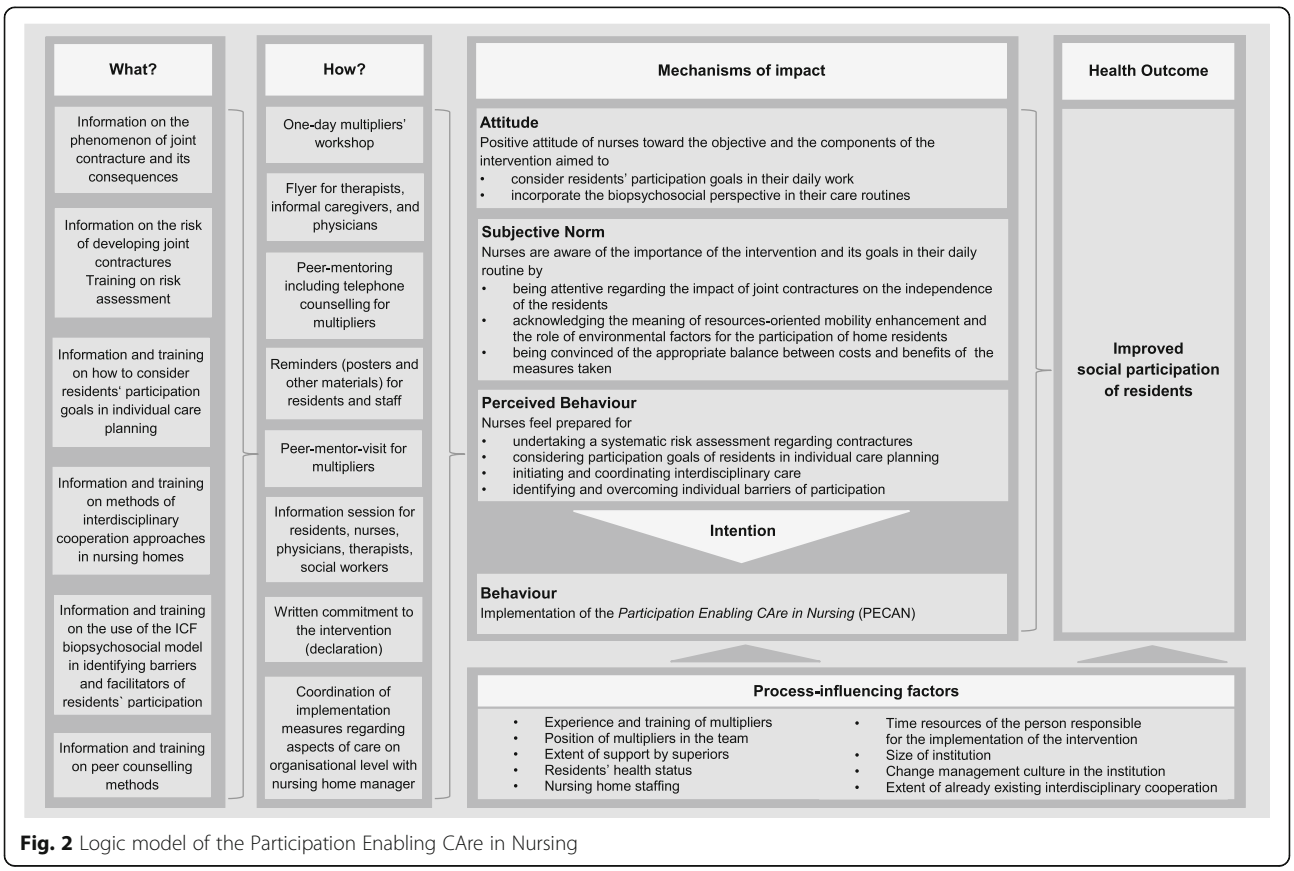

Fig. 2 Logic model of the Participation Enabling CAre in Nursing

- Presentation of information on methods of interdisciplinary collaboration;
- Training in the use of the ICF biopsychosocial model to identify barriers and facilitators of residents' participation;
- Provision of information on measures to prevent and treat joint contractures and their suitability for residents with different mobility restrictions;
- Training in peer counselling methods.

Information session

The researchers developed an information session for residents, informal caregivers, and staff of nursing homes to inform everyone about causes, risks, and consequences of joint contractures, to describe the model of the ICF and the PECAN intervention, and to introduce the implementation approach, the multipliers, and their tasks.

Peer-mentoring

The implementation process includes a mentoring approach, in which the multipliers receive counselling by a nurse of the research team (the mentor) on a regular basis to support role finding and planning of the implementation. The mentoring approach is derived from a peer assistance and review process that has already been proven successful in other circumstances [29]. At the beginning of the mentoring process, the multipliers receive counselling and support to determine implementation measures during a peer-mentor visit in the nursing home by an interdisciplinary team: an external peer experienced in change management in nursing homes, a therapist, and the mentor. During this visit, the multipliers critically review organizational procedures to identify barriers and facilitators of implementation using a checklist with predefined criteria. The required changes on an organizational level will be planned together with the head nurse, supported by the mentor. Moreover, the interdisciplinary team critically reviews individual care plans using a structured assessment tool to identify barriers and facilitators of PECAN and will plan changes in care with counsel by the external peer experts.

The multipliers will receive counselling by their mentor via phone calls every second week throughout the first two months of implementation. Thereafter, telephone calls will be held upon request, at least once a month. Multipliers are expected to train their colleagues in procedures of the PECAN intervention.

Supportive materials

A further component of the intervention, the use of posters and other written material, is intended to remind residents and staff. The written material comprises leaflets offering information about the intervention and contact details of the multipliers and the study team to be provided for external therapists and physicians, as well as informal caregivers.

Figure 3 presents the implementation approach of our intervention PECAN.

Discussion

We describe here the development of a theoretically and empirically informed complex nursing intervention aimed at improving social participation and quality of life in nursing home residents with joint contractures. The intervention is now ready for implementation within a pilot study.

Our intervention is based on findings from the literature and on the experiences of nursing home residents, managers of nursing homes, geriatricians, and nursing and rehabilitation scientists.

Whereas the graphical modelling and the group discussions with the nursing home residents revealed meaningful target points of the intervention, the systematic review did not contribute to the development. This review [25] revealed a lack of studies relevant for nursing home residents with joint contractures, and the few existing studies did not show sufficient effects of interventions. The findings from the interviews with nursing home residents underscored that immobility alone does not lead to restrictions in participation, but these restrictions are also influenced by a range of environmental and personal factors. Based on this information, we derived intervention goals that guided the development of the intervention components.

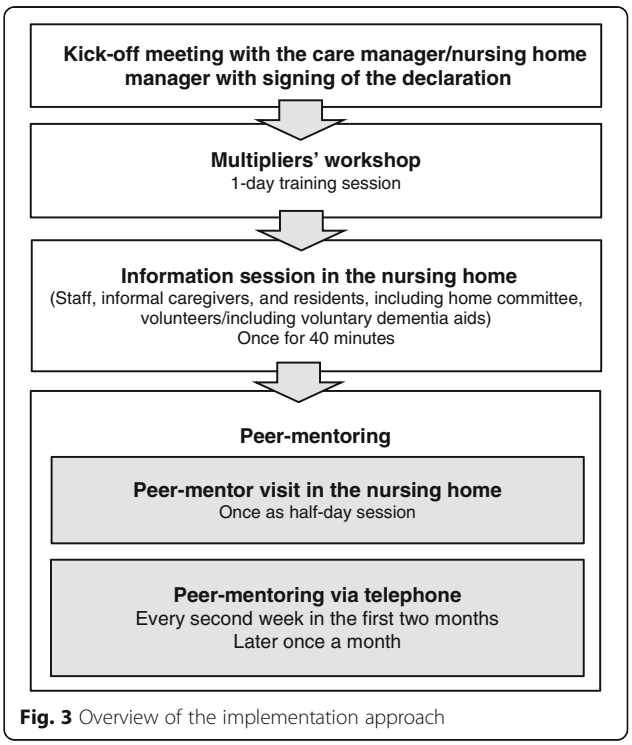

Fig. 3 Overview of the implementation approach

As a result of this modelling process, we developed a qualification scheme for nurses and an approach to support transfer into daily routine for the implementation of the intervention.

According to the biopsychosocial model of the ICF, participation restrictions are associated with impairment in body functions and structures and might be facilitated or hindered by environmental and personal factors. As such, the focus of our intervention is to reduce hindering, strengthen supportive environmental factors, and facilitate positive personal factors, such as the residents' motivation to maintain mobility and to engage in social activities within their current living situation [13]. Support of mobility is a key aspect of our intervention because of the relationship between immobility and joint contractures. Several studies suggest the positive effects of promoting physical activity on physical functioning in residents of nursing homes [30]. In this regard, our intervention is in line with other mobility programs like function-focused care [31, 32]. Our intervention uses the same strategies to promote physical activities that were successfully applied in the function-focused care concept, such as education, environmental assessment, goal setting, and mentoring. However, our intervention approach is novel, in that it expands its focus on participation and associated factors and therefore adds a range of possible interventions.

To implement the intervention, we chose a multiplier approach, which is a proven strategy for implementation of changes of nursing home care [28, 33–35]. This approach is accompanied by varying strategies to address all persons who are relevant to the improvement of residents' participation. Our assumptions about meaningful intervention components (as described in the logic model, Fig. 2) were driven by facilitators of implementation identified in previous research steps. This is comparable to other complex interventions in geriatric settings [36].

Our study uses the UK MRC framework [15] for development and evaluation of complex interventions, which has demonstrated its usefulness. Due to the weakness of the evidence that could have informed the intervention development process, we involved key stakeholders at different stages of intervention development to keep a broad and well-informed perspective.

The involvement of residents in the modelling process aimed at identifying participation priorities and barriers to participation and individual problem-solving strategies. However, the feedback from the residents added less information than expected and suggested that frail older people are likely to adapt to their physical disability and thus to their expectations on participation [37]. To overcome this unwanted phenomenon, strategies are needed enhancing older people's sense of self-worth and helping them understand the way how their social participation can be facilitated [38]. It has to be taken into account that residents with severe cognitive decline were not part of the group discussion as well as the other research steps did not focus on the specific needs of residents with severe cognitive decline. Hence, the intervention might not be applicable to this group of residents.

Consultation with experts proved to be a helpful approach to support the definition of intervention goals and collection of ideas about intervention components and possible implementation approaches. However, the information generated by the experts ultimately required further synthesizing efforts by the research team using iterative consensus rounds. In addition, facilitation of the process had to be stringent to keep participants on track, especially regarding the empirically generated intervention goals.

Because the UK MRC framework does not explicitly discriminate between what should be implemented and how it should it be implemented, the logic model [39, 40] helps to describe how the intervention might work and to differentiate between intervention content ("what") and implementation components ("how").

The intervention development was clearly theory-driven, using the ICF model in the graphic modelling process, in analysing the data on group discussions with residents, and in informing the intervention modelling process. The theory of planned behaviour worked well in elaborating the implementation components.

Conclusions

The PECAN intervention is ready for a pilot study investigating its impact and feasibility. A necessary adjunct to the pilot study will be a comprehensive process evaluation to identify the relevant elements of the intervention and to explore the barriers and facilitators of a successful implementation approach. Although the intervention was developed for nursing home residents with joint contractures, residents at risk of developing joint contracture might also benefit from the PECAN intervention. This question might be answered in a subsequent implementation study.

Our methodological approach might serve as a template for structured intervention development processes in areas where the evidence base is weak.

Abbreviations

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

Acknowledgments

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Availability of data and materials
A manual describing the implementation approach and all other materials are available on request from the authors. The datasets generated and analysed during this study are not publicly available, because only the professionals of nursing homes were interviewed so participants' anonymized data could be identifiable. In addition, we did not secure consent to share data from the residents and care managers.

Authors' contributions
GM, MM, and EG initially planned the development study. MM und KB wrote the study protocol. AS and GB conducted the group discussions with nursing home residents; AS, JH and MM analysed the data; GB conducted the group discussion with managers of nursing homes and analysed the data. RS conducted the graphic modelling. AS, SuS, MM, GM, and EG organized the expert workshop. SuS developed the intervention components and AS, HK, KB, and JH made substantial contributions to the logic model and the implementation procedure of the intervention. EM, SK, and MB advised the research group as members of the advisory board and critically appraised the planned intervention and implementation procedures. All authors interpreted the study data. SuS corresponded with the study authors and wrote the drafts of the manuscript with support from MM and GM. All the authors approved the final version of the manuscript and are accountable for all aspects of the work.

Ethics approval and consent to participate
This study was conducted according to the Declaration of Helsinki and Good Clinical Practice guidelines. The protocol of the study data used in the graphical models received approval from the research ethics committee of the Medical Faculty of the Ludwig-Maximilians-University Munich (ID: 530–12), and the protocol of the group discussions with nursing home residents gained approval from the ethics committee of the German Society of Nursing Science (DGP) (ID: 15–002). Written informed consent was obtained from participants of both studies. The trial was registered in the German clinical trials register, reference number DRKS00010037, registration date 12 February 2016.

Consent for publication
Not applicable.

Competing interests
All authors declare that they have no competing interests. GM is a member of the BMC Geriatrics editorial board, but was not involved in the review process.

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References

1. Gnass I, Bartoszek G, Thiesemann R, Meyer G. Joint contractures in older age. A systematic literature review. Z Gerontol Geriatr. 2010;43:147–57.
2. Clavet H, Hebert PC, Fergusson D, Doucette S, Trudel G. Joint contracture following prolonged stay in the intensive care unit. CMAJ. 2008;178:691–7.
3. Gerrits EG, Landman GW, Nijenhuis-Rosien L, Bilo HJ. Limited joint mobility syndrome in diabetes mellitus: a minireview. World J Diabetes. 2015;6:1108–12.
4. Hoang PD, Gandevia SC, Herbert RD. Prevalence of joint contractures and muscle weakness in people with multiple sclerosis. Disabil Rehabil. 2014;36:1588–93.
5. Souren LE, Franssen EH, Reisberg B. Contractures and loss of function in patients with Alzheimer's disease. J Am Geriatr Soc. 1995;43:650–5.
6. Fergusson D, Hutton B, Drodge A. The epidemiology of major joint contractures: a systematic review of the literature. Clin Orthop Relat Res. 2007;456:22–9.
7. Yip B, Stewart DA, Roberts MA. The prevalence of joint contractures in residents in NHS continuing care. Health Bull (Edinb). 1996;54:338–43.
8. Rabiner A, Roach KE, Spielholz NI, Judson L. Characteristics of nursing home residents with contractures. Physical & Occupational Therapy In Geriatrics. 1996;13:1–10.
9. Resnick B. Functional performance and exercise of older adults in long-term care settings. J Gerontol Nurs. 2000;26:7–16.
10. Fischer U, Müller 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;51:269–79.
11. Bartoszek G, Fischer U, Grill E, Müller M, Nadolny S, Meyer G. Impact of joint contracture on older persons in a geriatric setting. Z Gerontol Geriatr. 2015;48:1–8.
12. Fischer U, Müller 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. Rehabil Nurs. 2016;41:170–8.
13. WHO. International Classification of Functioning, Disability and Health (ICF). 2001. http://www.who.int/classifications/icf/en/
14. Müller M, Bartoszek G, Beutner K, Klingshirn H, Saal S, Stephan AJ, Strobl R, Grill E, Meyer G. 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 https://doi.org/10.3205/000217.
15. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;
16. Corry M, Clarke M, While AE, Lalor J. Developing complex interventions for nursing: a critical review of key guidelines. J Clin Nurs. 2013;22:2366–86.
17. Möhler R, Köpke S, Meyer G. Criteria for reporting the development and evaluation of complex interventions in healthcare: revised guideline (CReDECI 2). Trials. 2015;16:204.
18. Fischer U, Bartoszek G, Müller 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). Disabil Rehabil. 2014;36:2225–32.
19. Strobl R, Stucki G, Grill E, Müller M, Mansmann U. Graphical models illustrated complex associations between variables describing human functioning. J Clin Epidemiol. 2009;62:922–33.

20. Reinhardt JD, Fellinghauer BA, Strobl R, Stucki G. Dimension reduction in human functioning and disability outcomes research: graphical models versus principal components analysis. Disabil Rehabil. 2010;32:1000–10.
21. Becker S, Strobl R, Cieza A, Grill E, Harreus U, Tschiesner U. Graphical modeling can be used to illustrate associations between variables describing functioning in head and neck cancer patients. J Clin Epidemiol. 2011;64:885–92.
22. Karlsson G. Psychological qualitative research from a phenomenological perspective. Stockholm: Almquist & Wiskell International. 1995;
23. Kvale G. InterViews: an introduction to qualitative research interviewing. Thousand Oaks, California: Sage Publications; 1996.
24. Cieza A, Geyh S, Chatterji S, Kostanjsek N, Ustun B, Stucki G. ICF linking rules: an update based on lessons learned. J Rehabil Med. 2005;37:212–8.
25. Saal S, Beutner K, Bogunski J, Obermüller K, Müller M, Grill E, Meyer G. Interventions for the prevention and treatment of disability due to acquired joint contractures in older people: a systematic review. Age Ageing. 2017;46:373–82.
26. Higgins JPT, Green S. Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. 2011. http://training.cochrane.org/handbook.
27. Ajzen I. The theory of planned behavior. Organ Behav Hum Decis Process. 1991;50:179–211.
28. Köpke S, Mühlhauser I, Gerlach A, Haut A, Haastert B, Möhler R, Meyer G. Effect of a guideline-based multicomponent intervention on use of physical restraints in nursing homes: a randomized controlled trial. JAMA. 2012;307:2177–84.
29. Goldstein J. Easy to dance to: solving the problems of teacher evaluation with peer assistance and review. Am J Educ. 2007;113:479–508.
30. Wöhl C, Siebert H, Blättner B. Interventions for promoting physical activity in nursing homes : systematic review of the effectiveness of universal prevention [article in German]. Z Gerontol Geriatr. 2017;50:475–82.
31. Resnick B, Galik E. Using function-focused care to increase physical activity among older adults. Annu Rev Nurs Res. 2013;31:175–208.
32. Resnick B, Galik E, Boltz M. Function focused care approaches: literature review of progress and future possibilities. J Am Med Dir Assoc. 2013;14:313–8.
33. Richter C, Berg A, Fleischer S, Köpke S, Balzer K, Fick EM, Sönnichsen A, Löscher S, Vollmar HC, Haastert B, et al. Effect of person-centred care on antipsychotic drug use in nursing homes (EPCentCare): study protocol for a cluster-randomised controlled trial. Implement Sci. 2015;10:82.
34. Abraham J, Möhler R, Henkel A, Kupfer R, Icks A, Dintsios CM, Haastert B, Meyer G, Köpke S. Implementation of a multicomponent intervention to prevent physical restraints in nursing home residenTs (IMPRINT): study protocol for a cluster-randomised controlled trial. BMC Geriatr. 2015;15:86.
35. Plambech MZ, Lurie AI, Ipsen HL. Initial, successful implementation of sepsis guidelines in an emergency department. Dan Med J. 2012;59:A4545.
36. Ayton DR, Barker AL, Morello RT, Brand CA, Talevski J, Landgren FS, Melhem MM, Bian E, Brauer SG, Hill KD, et al. Barriers and enablers to the implementation of the 6-PACK falls prevention program: a pre-implementation study in hospitals participating in a cluster randomised controlled trial. PLoS One. 2017;12:e0171932.
37. Hedman M, Poder U, Mamhidir AG, Nilsson A, Kristofferzon ML, Haggstrom E. Life memories and the ability to act: the meaning of autonomy and participation for older people when living with chronic illness. Scand J Caring Sci. 2015;29:824–33.
38. Lis K, Reichert M, Cosack A, Billings J, Brown P. Evidence-based guidelines on health promotion for older. People. 2008. https://www.verwey-jonker.nl/doc/participatie/HPE-Guidelines_Online.pdf.
39. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. BMJ: Br Med J. 2015;350
40. Kellogg-Foundation WK: Logic Model Development Guide. Using Logic Models to Bring Together Planning, Evaluation, and Action. 2004. https://www.bttop.org/sites/default/files/public/W.K.%20Kellogg%20LogicModel.pdf.

Publikation II

Improved participation of older people with joint contractures living in nursing homes: feasibility of study procedures in a cluster-randomised pilot trial

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Kurzzusammenfassung

Die zweite Publikation ist Teil der Pilotierung der Intervention. In dieser Phase wurde die PECAN Intervention mit einer multizentrischen, pragmatischen Studie hinsichtlich ihrer Machbarkeit und Durchführbarkeit überprüft. Die Pilotstudie wurde zweiarmig mit einem Parallelgruppendesign durchgeführt. Ein wesentlicher Aspekt war dabei die Überprüfung der Durchführbarkeit der Studienprozeduren in Vorbereitung auf eine Hauptstudie sowie die Identifikation von Optimierungspotentialen.

Geteilte Erst-Autorenschaft, Eigenanteil: *Studienkoordination, Datenerhebung, Datenanalyse (Machbarkeit der Studienprozeduren, leitend), Interpretation der Daten, Manuskripterstellung.*

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Trials

RESEARCH Open Access

Improved participation of older people with joint contractures living in nursing homes: feasibility of study procedures in a cluster-randomised pilot trial

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Abstract

Background: Acquired joint contractures have a significant impact on functioning and quality of life in nursing home residents. There is very limited evidence on measures for prevention and treatment of disability due to joint contractures. We have developed the PECAN intervention (Participation Enabling CAre in Nursing) to improve social participation in nursing home residents. A cluster-randomised pilot trial was conducted to assess the feasibility of study procedures in preparation for a main trial according to the UK Medical Research Council (MRC) framework.

Methods: Nursing homes in two regions of Germany were randomly allocated either to the intervention or optimised standard care (control group). All residents with joint contractures aged > 65 years were eligible for the study. The residents' data were collected through structured face-to-face interviews by blinded assessors at baseline, after 3 and 6 months. The primary outcome was social participation, measured by a subscale of the PaArticular Scales. Secondary outcomes included activities and instrumental activities of daily living, health-related quality of life, falls and fall-related consequences. Data on the trial feasibility were collected via documentation forms.

Results: Seven out of 12 nursing homes agreed to participate and remained in the trial. Of 265 residents who fulfilled the inclusion criteria, 129 were randomised either to the intervention ($n = 64$) or control group ($n = 65$) and analysed. A total of 109 (85%) completed the trial after 6 months. The mean age was 85.7 years (SD 7.0), 80% were women. The severity of the residents' disability differed across the clusters. The completion rate was high (> 95%), apart from the Instrumental Activities of Daily Living Scale. Some items of the PaArticular Scales were not easily understood by residents. The frequency of falls did not differ between study groups.

Conclusion: Our data confirmed the feasibility of the overall study design. We also revealed the need to improve the procedures for the recruitment of residents and for data collection before implementation into a main trial. The next step will be an adequately powered main trial to assess the effectiveness and cost-effectiveness of the intervention.

Trial registration: German clinical trials register, ID: DRKS00010037. Registered on 12 February 2016.

Keywords: Joint contractures, Nursing homes, Participation, Complex intervention, Cluster-randomised pilot trial, Feasibility trial

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Background

Joint contractures are common among frail older people living in nursing homes [1]. Previous studies reported a prevalence of joint contractures ranging from 20 to 75% in nursing home residents [2–6]. Joint contractures are associated with restrictions in physiological joint mobility and may result in immobility [7, 8], limited capacity to perform activities of daily living (such as toileting and walking), decreased participation in social life, and increased need of nursing care [1, 3, 9, 10]. Restrictions in participation in social life are most relevant from the perspectives of both the affected individuals and the health professionals [10–12].

Despite the rising awareness of health professionals concerning joint contractures as a health problem in recent years, there is still a lack of effective measures for preventing and treating joint contractures and the associated disability [8, 13–15]. Therefore, we developed a theoretically and empirically informed complex nursing intervention, aimed at improving participation in nursing home residents with joint contractures, called the Participation Enabling CAre in Nursing intervention (PECAN) [16, 17].

In a next step, we pilot tested the PECAN intervention in a cluster-randomised controlled trial (c-RCT). We aimed to examine all of the study procedures and the feasibility of the intervention in preparation for a future definitive trial in accordance with the recommendations of the UK Medical Research Council (MRC) framework [18]. This paper presents the results of the feasibility of the study procedures in order to evaluate the design for a main trial, while the feasibility of the interventions' implementation, e.g. enablers and barriers for a successful implementation, will be reported elsewhere.

The specific objectives of this c-RCT were as follows:

1) To explore the recruitment and retention of nursing homes and residents
2) To examine the feasibility of blinding
3) To test the acceptability and eligibility of the selected outcome measures and data collection procedures
4) To assess the safety of the intervention regarding falls and fall-related fractures as unintended consequences, and
5) To explore how healthcare service utilisation data could be collected to prepare the health-economic evaluation for the main trial

Methods

Trial design

This multi-centre, pragmatic pilot study was designed as a two-armed, parallel-group c-RCT. A cluster was defined as one nursing home facility. A cluster design was indicated since the PECAN intervention aims to change professional behaviour in nursing staff within a specific facility.

Participants and setting

Nursing homes were recruited in two German regions (Southeastern Bavaria and Saxony-Anhalt) from a convenience sample (existing network of cooperating practice partners). Nursing homes were invited to participate in the study via mail and a subsequent telephone call. Upon request, an onsite visit was conducted. Nursing homes were eligible if they had reported providing care for at least 25 residents with joint contractures.

Recruitment of residents started immediately after consent of the respective nursing home director. Residents were eligible if they were aged 65 years or older and with contracture of at least one joint diagnosed either by a physician, an occupational or physical therapist, or a nurse. Exclusion criteria were: terminal stage of a disease (i.e. progressive disease, poor prognosis, reduced life expectancy). For data protection purposes, the evaluation of the residents' eligibility and the provision of written study information were carried out by the head nurse. Contact details of the resident or their legal representative (in case of the resident's cognitive impairment) were forwarded to the researchers once the respective resident declared their interest in study participation. Finally, the resident's or their legal representative's written informed consent was obtained by the researchers prior to the start of the study. Although the PECAN intervention was implemented in the entire nursing home, the number of included residents was limited to 25 per cluster for feasibility reasons.

Randomisation and blinding

Computer-generated randomisation lists were used for the allocation of clusters, stratified by region. The allocation of the clusters was performed by the external statistician, who informed the cluster representatives about the group assignment. To gather the maximum amount of information from the intervention group, more nursing homes were included in comparison to the control group [19]. All follow-up assessments were carried out by interviewers who were blinded regarding group allocation. Due to the characteristics of the intervention, it was not possible to blind nursing staff and residents. Data entry and statistical analysis was also carried out in a blinded manner.

PECAN intervention

The focus of the PECAN intervention is to reduce barriers, to strengthen supportive environmental factors as well as to enhance personal factors, such as the residents' motivation to maintain mobility and to engage in social activities within their current living situation.

The PECAN intervention uses a facilitation approach, which is a concerted, social process that focusses on evidence-informed practice change [20–23]. Since preliminary work revealed the absence of any robust evidence, the development of the PECAN intervention is based upon a close and iterative involvement of health professionals and residents [16].

The key aspect of the PECAN intervention to improve residents' participation is the implementation of the biopsychosocial perspective of the International Classification of Functioning, Disability and Health (ICF) of the World Health Organization (WHO) [24] into the nursing process and the nursing home's daily routines. This enables nurses to comprehensively assess residents' functioning (including activities and participation) and the facilitating and hindering of contextual factors. Barriers towards participation might be modified. Actual measures depend on the local context and may contain organisational changes and changes in individual care, such as adaption of offered leisure activities or alterations in offered physical or occupational therapy, or medical aids.

An overview of the implementation approach is displayed in Fig. 1. The implementation included the following core components:

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

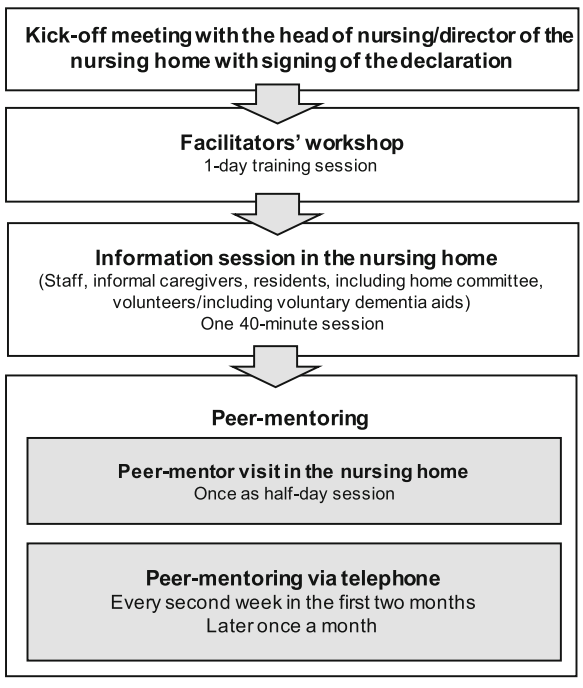

Fig. 1 Overview of the Participation Enabling CAre in Nursing (PECAN) implementation approach

In a first meeting with the nursing home director and the head nurse, the policy of the intervention was introduced and discussed, and a declaration was signed to formally emphasise the institutional commitment.

2) *Facilitators' workshop*

Facilitation is a process that depends upon the facilitator, someone who acts and enables others to implement a change in practice [20]. Nurses who were nominated as facilitators for the intervention in the nursing homes were invited to a 1-day workshop held by the researchers. During the workshop, the facilitators were trained to identify barriers against residents' participation based on the ICF biopsychosocial model, to consider residents' participation goals in individual care planning, to implement measures for preventing and treating joint contractures and to educate their peers with regard to the intervention.

3) *Information session*

An in-house information session lasting 40 min was held by the researchers to inform residents, family members and nursing home staff about the causes, risks and consequences of joint contractures, the PECAN intervention and its implementation approach

4) *Peer-mentoring*

The implementation approach included regular mentoring conducted by a trained nurse from the research team (the mentor) in order to support the facilitators' role development and the planning of the implementation. At the beginning, the facilitators were visited in the nursing home by an interdisciplinary team of peer-mentors made up of the mentor, an external peer experienced in change management in nursing homes, and an occupational or physical therapist. During this visit, organisational procedures were evaluated using a checklist to identify implementation barriers and enablers. Individual care plans were critically reviewed, and changes in care were planned with support from the external peer expert.

The facilitators were supported by their mentor via telephone calls every second week throughout the first 2 months of implementation, and at least once a month thereafter.

5) *Supportive materials*

Posters and other written material informed and reminded staff, residents and their families as well as the external occupational or physical therapists and physicians.

The written material comprised leaflets with information about the intervention and contact details of the facilitators and the research team. Further details of the intervention and its development are described elsewhere [16].

Optimised standard care

In Germany, nursing homes are run by welfare organisations, communities or private operators and are financed by the German statutory long-term care insurance with additional payment from residents. According to legal requirements, 50% of nursing staff has to have 3 years of vocational training in nursing. Nursing homes usually also employ social care assistants and sometimes social workers. General practitioners, physical therapists and occupational therapists are usually not employed by the nursing home but visit the nursing homes. Technical aids are reimbursed by the German statutory long-term care insurance with additional payment by residents, whereas physiotherapy, occupational therapy and speech and language therapy are covered by the German statutory healthcare insurance with additional payment by residents. The nursing homes in the control group received an in-house information session lasting 40 min that was offered to the residents, their families and the nursing home staff. The content covered causes, risks, and consequences of joint contractures, and general information about the study.

Data collection procedures

Interviewers were trained in structured, half-day training sessions conducted by members of the research team (HK, SuS). Data collection was carried out by structured face-to-face interviews with residents and staff. Data on the characteristics of the nursing homes were collected at baseline in an interview with the head nurse. Residents' data were collected at baseline and at follow-up after 3 and 6 months by means of interviews and data extraction from the residents' records.

If residents were not able to communicate (e.g. because of cognitive impairment), the interview was conducted with a proxy, i.e. a nurse in charge, using the same questionnaire items as in the residents' interview.

Characteristics of nursing homes and residents

Socio-demographic and clinical data were extracted from the residents' records. To describe the functional and cognitive status of each resident, the level of care dependency was extracted from the residents' records. The level of care dependency is regularly assessed by expert raters from the medical service of the German statutory health insurance system using structured questionnaires and was rated as 0 = low, 1 = considerable, 2 = severe and 3 = most severe [25].

Cognitive status was determined by means of the Dementia Screening Scale (DSS) at baseline. The DSS is a valid seven-item proxy-rating tool for health professionals, comprising the two domains of memory and orientation [26]. The maximum score is 16 points (highest impairment) with a cut-off of 4 for cognitive impairment (moderate to severe dementia) [26]. In the case of cognitive impairment, a proxy version of the residents' interview was carried out. For follow-up interviews, the DSS was repeated if the nursing staff pointed to a possible cognitive decline within the last 3 months.

Participation and activities (PaArticular Scales)

The PaArticular Scales, a newly developed, condition-specific and patient-centred outcome assessment based on the ICF, were assessed at baseline and after 3 and 6 months. Using two independent subscales, activity limitations (24 items, e.g. standing, grasping, dressing, eating) and participation restrictions (11 items, e.g. community life, sports, crafts, socialising) in older individuals with joint contractures can be rated as follows: none, mild or moderate, severe, or complete problems and transformed into an interval-scaled score from 0 (no problems) to 100 (complete problems) [27]. The primary outcome was measured by the participation subscale, whereas the activity subscale was a secondary outcome.

Instrumental Activities of Daily Living (Lawton IADL Scale)

The Lawton Instrumental Activities of Daily Living Scale (IADL Scale) is a geriatric assessment tool used to rate independent living skills in eight domains of functioning (e.g. food preparation) [28]. Each domain is represented by different items, which should resemble a resident's highest functional level. The summary score ranges from 0 (low function) to 8 (high function). The IADL Scale was developed for older adults living independently in the community or who are in a hospital and is not recommended for use with institutionalised older adults [29]. However, in German nursing homes, in principle, there is the opportunity for residents to perform most of the instrumental activities of daily living that the IADL assesses. Hence, we included this scale to verify the activities subscale of the PaArticular Scales at baseline and after 6 months.

Health-related quality of life (EQ-5D-3 L)

The EQ-5D-3 L is a standardised, generic health-related quality of life questionnaire. The questionnaire consists of a descriptive three-level system based on five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and includes a self-rated Visual Analogue Scale (VAS), which records self-perceived health status on a scale ranging from 0 (worst imaginable health status) to 100 (best imaginable health

status) [30]. The valuation of the health status is self-rated from the resident's point of view or is proxy-rated (version 2) by the nursing staff. Within this cluster-randomised pilot trial, the health status measured with the EQ-5D-3 L at baseline and 6-month follow-up was used to prepare the health-economic evaluation for the main trial.

Safety measures

Since falls might be a potential adverse event that could be attributed to the intervention, data on falls and fall-related consequences (e.g. fall-related fractures, hospital admission) were collected during the preceding 4 weeks and 6 months, at baseline and follow-up using the residents' records.

Trial feasibility

Trial feasibility was evaluated using different measures. Since understanding the motivation of the nursing homes in taking part in the studies is helpful when interpreting the findings or developing tailored recruitment procedures [31], reasons for study participation (or non-participation) were evaluated by asking the head nurse. The flow of recruitment of nursing homes and residents was documented using recruitment protocols.

Retention of nursing homes and residents was documented, including reasons for early study termination. To examine whether blinding could be maintained, interviewers were asked to rate whether the visited nursing homes were allocated to the intervention or control group after each measurement point.

The acceptability and eligibility of the outcome measures were assessed by monitoring interview duration, comprehensibility of questions, and missing information (including reasons) using documentation forms after each measurement point.

Comparison of proxy- versus self-reported activities and participation

The level of agreement between self-reported participation and activities (PaArticular Scales) and the rating by nurses in charge was assessed at the 3-month follow-up in a subsample of residents without cognitive impairment. The respective interviews were conducted with residents and nurses on the same day and by the same interviewer.

Health-economic evaluation

Cost parameters were collected and calculated on implementation-related intervention components. Data collection procedures for outcome-related components were tested for data reliability in preparation of the health-economic evaluation in the main trial. The methodology for cost calculation followed the recommendations for the health-economic evaluations based on currently available data [32, 33]. Implementation-related resources are displayed in Additional file 1: Table S2 and were quantified using standardised protocols. Cost parameters were documented alongside the trial.

Data on utilisation of healthcare services were extracted from residents' records or inquired about from the nursing home staff. Data were collected on the utilisation of medical and technical aids as well as on physical and occupational therapy.

Sample size

Since this pilot c-RCT aims to assess the feasibility and acceptability rather than the effectiveness of the intervention, we did not conduct a sample size calculation [34, 35]. All analyses must, therefore, be regarded as exploratory. Based on pragmatic considerations, we planned to include a total of 150 participating residents. We assumed that an average cluster size of 25 participants is feasible, resulting in six clusters.

Statistical analysis

Descriptive statistics were used to calculate baseline characteristics, health service utilisation, safety, and trial feasibility data. Categorical variables were summarised using absolute and relative frequencies. Continuous data were summarised using mean and standard deviation (SD). All data were stratified for the intervention and the control group. For the description of nursing homes' characteristics, data were additionally stratified on the cluster level.

The mean differences between the intervention group and the control group starting with baseline and up to 6 months are presented along with 95% confidence intervals (CI).

The association of the primary endpoint and intervention was analysed by means of linear mixed models. The models used a mixed-effects term for varying intercepts by clusters, and for residents nested within clusters and adjusted for age and gender.

All statistical analyses were performed using R version 3.3.2 [36].

Results

Recruitment

Recruitment took place in February and March of 2016. Twelve nursing homes were approached, and seven agreed to participate in the study. Reasons for non-participation were lack of time ($n = 3$), no interest in the study subject ($n = 1$), and not fulfilling required self-reported joint contracture prevalence ($n = 1$). Reasons for participation (multiple reasons were possible) were professional development and further education ($n = 5$), perceiving the topic as important and interesting ($n = 3$), improving the quality of care ($n = 3$), a previous

commitment to support the study ($n = 1$), collaboration with other nursing homes ($n = 1$), and anticipating legal regulations ($n = 1$).

Among the seven participating nursing homes, a total of 265 residents met the inclusion criteria. Of these, 129 (49%) residents consented to participate. Reasons for the residents' non-participation were poor health status ($n = 62$), personal reasons ($n = 12$), and death before inclusion ($n = 1$). A total of 61 residents gave no reason for their denial. Figure 2 displays the flow of the study.

Baseline characteristics of nursing homes and residents

The seven nursing homes provided between 40 and 171 long-term care beds. The nursing staff to resident ratio for skilled nurses was 0.19 in total and varied from 0.16 to 0.28. The overall prevalence of joint contractures was 28% with a wide range of 19 to 96%. The nursing home characteristics are displayed in Table 1.

A total of 129 residents participated in the study (range: 9 to 24 per nursing home). The mean age was 85.7 years (SD = 7.0), 80% were women, and 40% were rated as severely care dependent. The level of care dependency varied between the clusters, especially for considerable (range: 4 to 70% per cluster) and most severe (range: 0 to 62% per cluster) care dependency. The mean DSS was 5.1 (SD 4.5). Half of the residents were assessed as cognitively impaired, and, therefore, 65 interviews were conducted with proxies. Cognitive status declined during the 6 months of the intervention, and a change from self-rated interview to nurse-led interview was necessary in six cases. The study groups differed in terms of the localisation of joint contractures (both extremities $n = 36$, 57% in the intervention group versus $n = 45$, 69% in the control group) and the proportion of proxy-

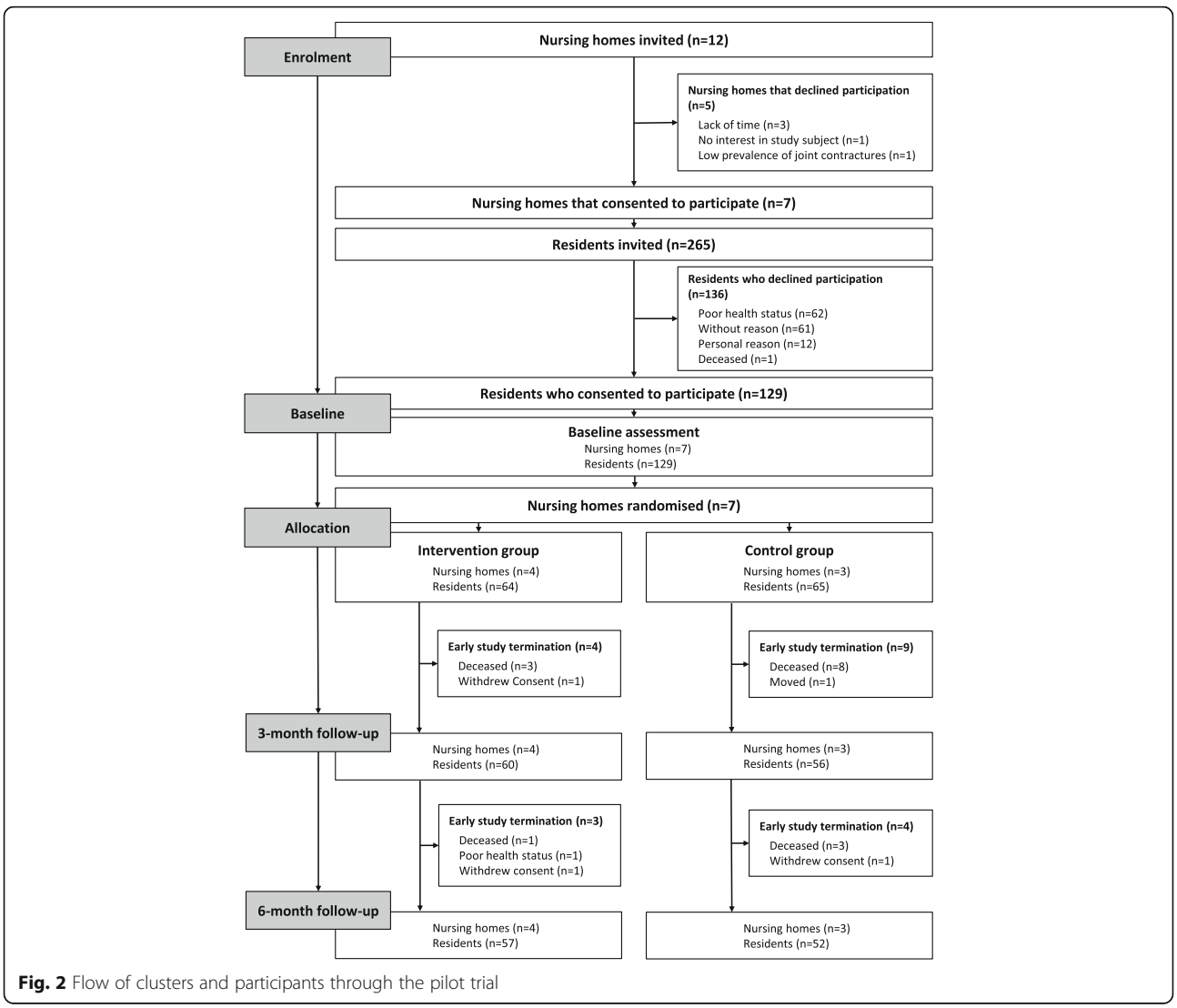

Fig. 2 Flow of clusters and participants through the pilot trial

Table 1 Characteristics of nursing homes at baseline

	Intervention group				Control group			Total
	C1	C2	C3	C4	C5	C6	C7	
Study participants, *n*	9	20	11	24	24	23	18	129
Long-term care beds, *n*	40	107	171	165	48	128	115	774
Nursing home wards, *n*	3	4	4	6	2	4	6	29
Residents per nursing ward	13	27	43	28	24	32	18	27
Estimated prevalence of joint contractures	0.40	0.96	0.19	0.21	0.50	0.31	0.60	0.28
Nursing staff to resident ratio for skilled nurses and assistants	0.49	0.30	0.35	0.38	0.32	0.34	0.30	0.35
Nursing staff to resident ratio for skilled nurses	0.28	0.16	0.19	0.20	0.17	0.16	0.16	0.19

reported assessments ($n = 28$, 44% in the intervention group versus $n = 37$, 57% in the control group). The residents' characteristics are displayed in Table 2.

Maintenance of blinding

The study protocol could not be followed as planned as some follow-up interviews were conducted by a-priori non-blinded raters. Assessments were conducted by blinded researchers for 81 residents (70%) at the 3-month follow-up and for 74 residents (68%) at the 6-month follow-up. Three additional events of un-blinding assessors towards the cluster allocation occurred; two cases were due to unintentional disclosure of the cluster allocation by the nursing staff during the assessment visit and one case was due to unintentional disclosure of the cluster allocation by the research team. Interviewers who were asked about their perception of the grouping allocation of the clusters they visited rated the correct group allocation to 40% at the 3-month follow-up and to 70% at the 6-month follow-up.

Table 2 Characteristics of nursing home residents at baseline

	Intervention group ($n = 64$)	Control group ($n = 65$)	Total ($n = 129$)
Age, years, mean (SD)	86.1 (6.3)	85.2 (7.7)	85.7 (7.0)
Women, *n* (%)	49 (76.6)	54 (83.1)	103 (79.8)
Localisation of joint contracture, *n* (%)			
Upper extremity	11 (17.5)	7 (10.9)	18 (14.2)
Lower extremity	16 (25.4)	13 (20.3)	29 (22.8)
Both	36 (57.1)	45 (68.8)	81 (63)
Levels of care dependency [a], *n* (%)			
None	1 (1.6)	0 (0)	1 (0.8)
Low	0 (0)	2 (3.1)	2 (1.6)
Considerable	23 (35.9)	18 (27.7)	41 (31.8)
Severe	24 (37.5)	27 (41.5)	51 (39.5)
Most severe	16 (25.0)	18 (27.7)	34 (26.4)
DSS, mean (SD)	4.69 (5.0)	5.46 (4.3)	5.09 (4.6)
Type of interview, *n* (%)			
Self-rated	35 (55.6)	28 (43.1)	63 (49.2)
Proxy-rated	28 (44.4)	37 (56.9)	65 (50.8)

Missing values: localisation of joint contracture ($n = 1$); Dementia Screening Scale (DSS) ($n = 2$); type of interview ($n = 1$);
[a]For the description of the functional and cognitive status, we used levels of care dependency as assessed by expert raters from the medical service of the German statutory health insurance system

Retention

All seven nursing homes completed the trial. Fifteen residents died during follow-up (12%), one resident moved, one became too frail to continue (poor health status), and three withdrew their consent. Overall, 109 (84%) residents completed the trial (Fig. 2).

Outcome measures

The effect of the PECAN intervention on participation, activities, self-perceived health status and IADL, including the number of missing values for all measurements, are presented in Table 3. The results of the participation subscale and activities subscale of the PaArticular Scales and EQ-5D-3 L indicate a slight decrease in activities, participation and self-perceived health status over 6 months, although the data imply an increase in the residents' instrumental activities. There were no significant differences between the intervention group and the control group with regard to participation.

Acceptability and eligibility of the outcome measures

The interviewers' documentation forms indicated that some items of the PaArticular Scales, especially of the subscale activities (maintaining a body position, maintaining a standing position, transferring oneself while sitting, transferring oneself while lying), were difficult for the residents to understand due to similar or overlapping contents. Additional file 1: Table S1 shows how the answers to the participation scale are distributed. The item 'assisting people who need assistance in different areas of daily life' was most frequently rated as 'complete problem', whereas the item 'practising your religion' was most frequently rated as 'no problem'.

At the 3-month follow-up, 14 self-reported residents' assessments were compared to proxy assessments on the

Table 3 Impact of the Participation Enabling CAre in Nursing (PECAN) intervention on participation, activity, health status, and instrumental activities of daily living

	Intervention group ($n = 57$)			Control group ($n = 52$)			Group difference[a]	LMM[b]
	Baseline Mean (SD)	6 months Mean (SD)	Difference Mean t_2-t_0 (SD)	Baseline Mean (SD)	6 months Mean (SD)	Difference Mean t_2-t_0 (SD)	Mean (95% CI)	Coefficient (95% CI)
Participation scale	46.2 (26.3)	43.0 (35.6)	− 2.9 (23.5)	43.9 (16.8)	41.3 (24.7)	− 2.4 (21.8)	0.5 (− 8.4; 9.3)	− 2.5 (− 5.5, 0.6)
Activity scale	56.5 (20.1)	54.4 (24.6)	− 2.439 (12.5)	57.5 (14.7)	51.8 (20.8)	− 5.7 (11.4)	− 3.2 (− 7.8; 1.4)	− 2.4 (− 9.8, 5.0)
VAS EQ-5D-3 L	52.9 (18.4)	51.8 (18.1)	− 2.1 (20.4)	53.9 (22.4)	54.8 (28.2)	0.7 (25.9)	2.8 (− 6.3; 11.9)	–
Lawton IADL Scale	1.5 (1.6)	2.6 (2.5)	0.6 (1.5)	1.2 (1.8)	2.2 (2.4)	0.7 (1.5)	0.1 (− 0.6; 0.7)	–

$n = 109$; t_0 = baseline, t_2 = 6-month follow-up
Missing values: Participation scale t_2 ($n = 5$); Activity scale t_2 ($n = 3$); Visual Analogue Scale of the European Quality of Life 5 Dimensions 3 Level Version (VAS EQ-5D-3 L) t_0 ($n = 1$), t_2 ($n = 4$); and Lawton Instrumental Activities of Daily Living (IADL) Scale t_0 ($n = 18$), t_2 ($n = 1$)
Ranges: Participation scale and Activity scale 0 (no problems) to 100 (complete problems); Lawton IADL Scale 0 (low function) to 8 (high function); VAS EQ-5D-3 L 0 (worst imaginable health status) to 100 (best imaginable health status)
[a]Difference between mean-intervention (t_2-t_0) versus mean-control (t_2-t_0)
[b]Linear mixed model (LMM) with a mixed-effect term for varying intercepts by clusters, and for residents that are nested within clusters, adjusted for age and gender

PaArticular Scales. Figures 3 and 4 provide a graphical illustration of the agreement between the ratings. Figure 3 indicates a correlation between residents' and nurses' rating on activities. Figure 4 fails to show any correlation between residents' and nurses' rating on participation.

The Lawton IADL Scale showed the highest proportion of missing values with a total number of 18 (16%). In particular, the item preparing food revealed with 15 residents (12%) the most missing values at baseline. Some residents indicated that, for example, preparing food was taken care of by the nursing home irrespective of their personal abilities, and thus, it was not relevant for them.

The EQ-5D-3 L was generally evaluated as feasible, and only a few residents needed further explanation in assessing their self-perceived health status by the VAS.

On average, the assessments took 35 min for the self-reported version and 15 min for the proxy-reported version.

Safety

Falls and fall-related fractures during the study period are displayed in Table 4. There was no relevant difference between the intervention group and the control group concerning the frequency of falls and fall-related fractures. The number of falls remained stable throughout the follow-up.

Health-economic evaluation

The total costs of the implementation-related intervention components were € 12,163.50, of which the greater part (€

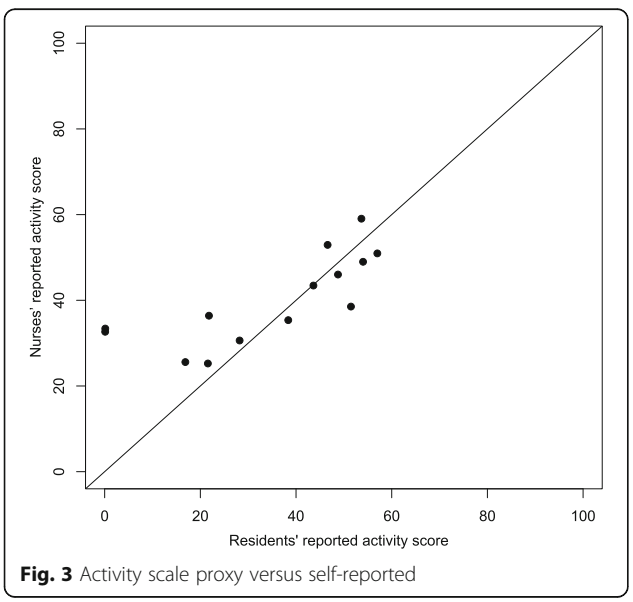

Fig. 3 Activity scale proxy versus self-reported

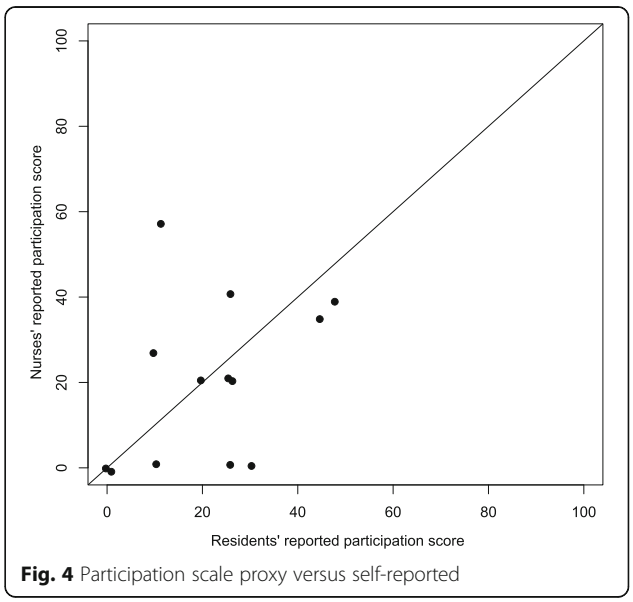

Fig. 4 Participation scale proxy versus self-reported

Table 4 Falls and fall-related fractures during the study

	Intervention group ($n = 57$)			Control group ($n = 52$)		
	Baseline	3 months	6 months	Baseline	3 months	6 months
Residents with falls within the last 4 weeks, *n* (%)	7 (12)	7 (12)	8 (14)	2 (4)	6 (12)	5 (10)
Mean falls per resident within the last 4 weeks	1.57	1.86	1.25	1.00	1.83	1.00
Residents with falls within the last 6[a] or 3[b] months, *n* (%)	13[a] (23)	12[b] (21)	14[b] (25)	19[a] (37)	9[b] (18)	11[b] (21)
Mean falls per resident within the last 6 months	2.23	3.25	1.93	2.63	2.11	1.55
Residents with fall-related fracture, *n* (%)	2 (4)	0 (0)	0 (0)	2 (4)	1 (2)	0 (0)

$n = 109$; t_0 = baseline, t_1 = 3-month follow-up, t_2 = 6-month follow-up
Missing values: mean falls per resident within the last 4 weeks t_0 ($n = 1$); residents with falls within the last 6 t_0 ($n = 1$) or 3 t_1 ($n = 1$) months; and residents with fall-related fracture t_0 ($n = 1$), t_1 ($n = 1$)
[a]At baseline falls within the last 6 months were recorded
[b]At the 3-month follow-up and the 6-month follow-up falls within the last 3 months were recorded

9396.20) was staff costs (Additional file 1: Table S2). The cost of the intervention per nursing home varied depending on the number and qualification of facilitators. The costs of the intervention per resident were € 109.58.

Utilisation of healthcare services

The following mobility aids were used by the residents at baseline: manual wheelchairs (intervention group, $n = 23$; control group, $n = 20$), electric wheelchairs (intervention group, $n = 2$; control group, $n = 1$), multi-functional wheelchairs (intervention group, $n = 11$; control group, $n = 6$), walkers (intervention group, $n = 28$; control group, $n = 26$) and walking sticks (intervention group, $n = 3$; control group, $n = 7$). At the 6-month follow-up, four manual wheelchairs (intervention group, $n = 2$; control group, $n = 2$), two multi-functional wheelchairs (intervention group, $n = 1$; control group, $n = 1$), a walker (intervention group) and a walking stick (intervention group) had been newly provided to the residents. Furthermore, two manual wheelchairs (intervention group, $n = 1$; control group, $n = 1$) and a walker (control group) could be disposed of completely.

Minutes and field notes from the interviewers indicated that medically prescribed technical and medical aids were usually not sufficiently documented in the residents' records and information had to be obtained personally from nursing staff interviews.

Information about the provision of physical (PT) and occupational therapy (OT) was available in most of the cases (i.e. at each measurement point, less than 5% of the data were not available). In the case of PT treatment, the exact number of treatment units was available only in less than half of the cases.

Sample size estimation for the definitive trial

Experience in the recruitment of individuals indicates that an inclusion of 15 residents per cluster is feasible. Thus, the sample size calculation was based on the assumption of a fixed cluster size of 15 residents and a free number of clusters. Using pilot data, the ICC was estimated at 0.38. This resulted in an inflation factor of $(1 - (15–1) \times 0.38) = 6.32$. The variance observed in this pilot trial was about 200, the effect difference for the participation subscale between control and intervention group was assumed to be 10, or sometimes 12. We experienced that the PECAN intervention addressed both participation and activities and decided to use the Participation Scale and the Activities Scale as two primary endpoints simultaneously in the main trial. Since two endpoints are assessed simultaneously, a Bonferroni adjustment is performed by setting the significance level of a single test at $0.05/2 = 0.025$. The size of one group in the main trial will be $n = 241$ (38×6.32) if the test is two-sided at a significance level of 0.025 and with a power of 80%. This results in a total of 16 clusters per study group ($241/15 = 16.1$). In anticipation of early study withdrawals, 15% more participants will be included, resulting in 30 clusters with a cluster size of 18 individuals and two clusters with 19 individuals; the total study size will be 578 individuals.

Discussion

We aimed to determine the feasibility of all the study procedures in a pilot c-RCT, since it is well known that large, multi-centre, pragmatic trials are challenging, particularly in sensitive and under-explored fields of research, such as in nursing homes [37–40].

Our pilot c-RCT confirmed the feasibility of the overall study design. However, it also revealed the need to improve the procedures for the recruitment of residents and for data collection.

In contrast to other research groups who conducted trials in nursing homes [41–44], we did not experience any reluctance to participate in the study. We adopted strategies that are known to positively influence the decision-making in nursing homes with regard to participating in a study [41]. We made it clear that our intervention comes with minimum risk and possibly provides more benefits for the participants. Secondly, we emphasised the non-invasive study approach, which

excluded additional costs for the nursing home staff and which we tried to keep minimally burdensome [41]. Based on recent studies involving nursing homes, we knew about the benefit of a structured, stepwise approach with timely provision of precise study information with appropriate wording for a successful enrolment [45, 46].

Some studies indicate that enrolment of nursing home residents is challenging [37–40]. Due to data protection regulations, it is not allowed to share contact data of residents with researchers without the resident's agreement. Therefore, it was not feasible to approach eligible nursing home residents directly. Instead, the head nurses enlisted the residents. This procedure resulted in appropriate recruitment rates, since 49% of approached residents agreed to participate. However, inclusion criteria were applied differently across clusters despite the provision of a list of inclusion criteria and a personal introduction by the head nurses. In some clusters, residents with cognitive impairment were not approached. The reluctance to make decisions about research participation on behalf of residents without the capacity to consent has been known in other studies [47]. In other clusters, residents with a higher level of care dependency were predominately enrolled (cluster variation between 0% and 62% within the most severe level of care dependency).

This pilot study gave valuable information on how the enrolment procedures can be optimised. Thus, we are going to better specify the inclusion criteria for our main trial and will focus on residents with current joint contractures in major joints that are affecting their daily life and who are at least able to be mobilised into a sitting position. In accordance with the recommendations of Gismondi, additional training for the head nurse might also reduce the heterogeneous approach of the head nurses during the recruitment procedures [41]. Furthermore, in the main trial, a researcher will review the recruitment list of residents regarding the standardised application of the inclusion criteria prior to the consenting process [41]. In Table 5, we have adapted the recommendations for enrolment in nursing homes, taking our enrolment experiences into consideration [41].

The proportion of residents with joint contractures derived from the recruitment protocols varied vastly between the participating nursing homes, ranging from 19 to 93%. Basically, this is in line with findings from other studies where different definitions were used and hardly comparable populations were studied [2–6]. Against the background of a standardised definition of the inclusion and exclusion criteria, these findings in our pilot trial are surprising and cannot be explained by the characteristics in the nursing homes' populations alone. We hypothesise that several components led to that phenomenon: first, a lack of awareness of joint contractures and their consequences, as well as a lack of standardised procedures for identifying joint contractures in German nursing home residents might have led to deviations from our standard procedures for inclusion and exclusion. Second, our intentionally selected broad definition of joint contractures led to the inclusion of both residents with joint contractures in small joints (e.g. joints of the fingers) and residents with joint contractures in major joints (e.g. knee or hip) and also to the inclusion of residents with multiple joint contractures (upper and lower extremities).

Blinding the interviewers was a crucial point, particularly since it was not possible to blind the participants or the staff towards the allocation [48]. Even though promotional material was handed out to nursing homes in the intervention group, it was feasible to keep the interviewers blinded. Furthermore, it proved successful to involve only one or two members of the nursing staff

Table 5 Adapted version of recommendations for enrolment of nursing homes according to Gismondi et al. [41]

1. Use all available state government resources, as well as professional and personal referrals, to identify and select nursing homes
2. Long-term care institutions should be explored and recruited at the planning stage of the clinical trial so that all the necessary Institutional Review Board requirements can be met in a timely fashion
3. First contact with nursing home management should be initiated by the project coordinator or leading team member in charge, not by a research assistant
4. Provide timely, precise study information with appropriate wording for the first nursing home contact
5. For more effective recruitment efforts, involve the primary care physicians (PCPs) in the nursing home as early in the process as possible. This not only helps in the identification of appropriate candidates but also encourages enrolment when the PCP agrees that the study is worthwhile
6. Enrolling residents should performed consecutively in one nursing ward after another instead of approaching all nursing wards simultaneously in order to keep the burden for the nursing staff as low as possible
7. Perform detailed patient record reviews prior to the consenting process
8. Provide adequate training sessions and incentives to assure the cooperation of the nursing home staff
9. Establish objective methods for the determination of mental competency as part of the protocol, and enlist the assistance of the nursing home social service staff
10. Anticipate the need for two research team members to be present during the consenting process
11. Reduce or eliminate any extra burden on the nursing home staff generated by the study
13. Anticipate that state public health regulations pertaining to long-term care facilities might impede on your study procedures
14. Collect data according to proposed, funded, and actual recruitment requirements to estimate project-specific staff time and costs

Extended recommendations emerging from our study are shown in italics. One recommendation from Gismondi et al. 2005 about focussing on nursing homes with large bed capacities to keep the number of sites manageable was skipped since it seemed to contradict the premise to develop interventions suitable for nursing homes with both small and large bed capacities

when arranging the interviewers' assessment so that the risk of unmasking the group allocation is reduced. However, blinding up to the 6-month follow-up was not maintained in all clusters.

For the main effectiveness trial, we will ensure a sufficient number of interviewers to maintain the blinding, based on the experiences during the pilot c-RCT.

All seven clusters completed the trial, although the nursing homes faced several organisational problems during the study, e.g. staff turnover and staff shortages. In contrast to other studies [47], there were no differences between the intervention and control groups regarding retention. Our offer to implement PECAN after study completion might have motivated the control group to remain in the trial. Although we included both large and small nursing homes, none of the clusters reached the predefined target sample size per cluster. Therefore, sample size calculation for the main trial must take this issue into consideration.

The time used for conducting the interviews with residents and nurses seems to be acceptable. Missing data occurred in less than 5% of all assessments. This suggests appropriateness and comprehensibility of the assessment instruments with the exception of the IADL Scale (16% missing values within the baseline assessment). Although we experienced that preparing food and doing laundry were tasks that nursing home residents could generally do, only in a few cases did residents actually perform those tasks. In most cases, residents used the services offered by the nursing home. Since the items did not address the everyday life in nursing homes, we cannot recommend the IADL Scale for use in nursing home settings. The intended comparison between the subscale activities of the PaArticular Scales and the IADL was not feasible because of the high number of missing values in the IADL data. Difficulties in understanding how to complete the VAS of the EQ-5D-3 L were known from another study with nursing home residents [47] and might be improved by adding an intuitive graphical design. The PaArticular Scales were used for the first time in a c-RCT and proved to be feasible in general. Some modifications are needed since some items turned out to be less self-explanatory for the residents. More appropriate nursing-home-specific examples have to be added to the study manual.

The model of the WHO's ICF provides clear definitions of activities and participation. "Activity is the execution of a task or action by an individual", whereas "Participation is involvement in a life situation" [24]. In the ICF's taxonomy, the distinction between activities and participation is less clear, in fact, it uses a common list of categories for activities and participation and provides three different solutions for the assignment of categories to either concept [49]. Considering this, together with the findings of our pilot study with only little change in both subscales, it would be reasonable to consider changes in both subscales as a positive effect of the intervention and, therefore, to define combined endpoints for the main trial.

Surprisingly, a considerable proportion of residents reported having "no problems" with most of the items of the participation subscale (Additional file 1: Table S1). This needs further explanation. According to the ICF model, activity limitations or participation restrictions have to be rated against the background of the lived experience of the individual. This means that activities or participation that are not realised in the living situation of the individual at all have to be rated as not a problem, irrespective of the objective capability. In addition, the PaArticular Scales were developed using pooled data from patients in geriatric rehabilitation facilities and nursing home residents [27]. To verify the psychometric properties of the scales in a more homogenous population, such as the trial participants in nursing homes, a further Rasch analysis using the trial data has to be carried out. This might result in a more sensitive version of the scales so that it may be possible to detect even small changes in activities and participation as a result of the developed intervention.

Another reason for only small changes in both subscales might be limitations in spreading the intervention: The intervention was delivered as planned to the facilitators, but insufficiently to the nurses, the interprofessional team and subsequently to the residents. Since this paper focusses on the feasibility of the study procedures, the findings on the feasibility of the intervention and the conclusions for improving the implementation strategy will be reported elsewhere in detail. In brief: the qualitative interviews with the facilitators, therapists, social workers, and relatives revealed a lack of involvement by the different agents regarding the overall implementation strategy. The interviewers gave possible explanations for this, mentioning, for instance, major barriers for implementing interventions, such as a lack of impact on organisational conditions and routines including unclear responsibilities, a strict separation of working areas and no established culture of contact and exchange, as well as a lack of time and staff competence.

Considering the high number of participants with cognitive impairment, instruments are needed that are appropriate for self- and proxy-reported interviews. However, differences between self- and proxy-reported outcomes are common phenomena [50–52]. Since participation is a highly individual concept, we already expected a lower agreement between the residents' and the nurses' rating compared to the activities scale.

Contrary to comparisons on self- and proxy-rated participation [52] and health status [50] involving next of kin, we found no tendency towards a certain direction

for a lower proxy-rating. For half of the included participants, it was not feasible to involve next of kin for an interview in the nursing homes. Therefore, an assessment with the best-informed nurse is the only way to include residents with cognitive impairment in the trial. The small number of participants in our comparison ($n = 14$) allows no robust conclusion about the relation between self- and proxy-reported data. A further investigation with an adequate sample size is needed.

In terms of safety measures, i.e. the number and severity of falls, we did not document any difference between the study groups; therefore, the intervention did not seem to increase the risk of falling.

The health-economic data collection of implementation-related data generally proved to be feasible. All necessary information on prescribed technical aids and the delivery of physiotherapy and occupational therapy was not regularly documented in the residents' records. An additional interview with nurses might be performed in the main study.

Even though our intervention consists of several components, the costs of the intervention are mainly staff costs, due to the non-productive time of the facilitators during the workshops and visits. The overall costs are lower than other similar complex intervention programs that implemented the intervention without using a facilitator [46]. However, the cost advantages of using a facilitator have to be interpreted in the context of the findings of the process evaluation, i.e. regarding the reach of the implementation approach (in preparation for publication). In addition, it should be noted that the cost findings are only preliminary. However, the health-economic evaluation approach has proved feasible and a full economic evaluation including cost utility analysis will be conducted in the main trial.

Conclusions

Our pilot c-RCT revealed important information on how to optimise residents' recruitment, and on blinding and data collection procedures for our planned main trial. In particular, the inclusion of nursing home residents is challenging and requires a large amount of time and detailed guidance from the study team. In the planning stage of c-RCTs in nursing homes, a tailored strategy to maintain blinding and appropriate resources of research staff are needed.

Additional file

Additional file 1: Table S1. Problems in participation of residents with joint contractures during the study. **Table S2.** Resource use due to implementation of the intervention. (PDF 438 kb)

Abbreviations

CI: Confidence intervals; c-RCT: Cluster-randomised controlled trial; DSS: Dementia Screening Scale; IADL: Instrumental Activities of Daily Living; ICF: International Classification of Functioning, Disability and Health of the World Health Organization; LMM: Linear mixed model; MRC: Medical Research Council; OT: Occupational therapy; PECAN: Participation Enabling CAre in Nursing; PT: Physical therapy; SD: Standard deviation; UK: United Kingdom; VAS: Visual Analogue Scale; WHO: World Health Organization

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Authors' contributions

GM, MM and EG designed the overall project (JointConImprove) and received the funding. GM and MM supervised the study. SuS, HK and KB coordinated all study processes. SuS, HK and KB contributed to the acquisition of the data. RS was responsible for data management and statistical analysis. HK led the analysis related to trial feasibility and was supported by SuS and KB. All of the authors contributed to the interpretation of data. SuS and HK corresponded with the study authors and wrote the manuscript drafts with support by GM and MM. All of the authors read and approved the final manuscript.

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Availability of data and materials

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

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-University Munich (ID: 760–15). All of the participants gave their consent prior to data collection.

Consent for publication

All participants gave consent for the publication of anonymised data.

Competing interests

The authors declare that they have no competing interests.

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References

1. Fergusson D, Hutton B, Drodge A. The epidemiology of major joint contractures: a systematic review of the literature. Clin Orthop Relat Res. 2007. https://doi.org/10.1097/BLO.0b013e3180308456.
2. Wagner LM, Capezuti E, Brush BL, Clevenger C, Boltz M, Renz S. Contractures in frail nursing home residents. Geriatr Nurs. 2008. https://doi.org/10.1016/j.gerinurse.2007.09.002.
3. Resnick B. Functional performance and exercise of older adults in long-term care settings. J Gerontol Nurs. 2000;26(3):7–16.
4. Yip B, Stewart DF, Roberts MA. The prevalence of joint contractures in residents in NHS continuing care. Health Bull (Edinb). 1996;54(4):338–43.
5. Mollinger LA, Steffen TM. Knee flexion contractures in institutionalized elderly: prevalence, severity, stability, and related variables. Phys Ther. 1993;73(7):437–44.
6. Harrington C, Carrillo H, Garfield R, Musumeci M, Squires E. Nursing facilities, staffing, residents and facility deficiencies, 2009 through 2016. (2018). http://files.kff.org/attachment/REPORT-Nursing-Facilities-Staffing-Residents-and-Facility-Deficiencies-2009-2016. Accessed 27 Apr 2018.
7. Gnass I, Bartoszek G, Thiesemann R, Meyer G. Joint contractures in older age. A systematic literature review. Z Gerontol Geriatr. 2010. https://doi.org/10.1007/s00391-009-0089-6.
8. Katalinic OM, Harvey LA, Herbert RD, Moseley AM, Lannin NA, Schurr K. Stretch for the treatment and prevention of contractures. Cochrane Database of Syst Rev. 2010;(9):CD007455. https://doi.org/10.1002/14651858.CD007455.pub2.
9. Rabiner A, Roach KE, Spielholz NI, Judson L. Characteristics of nursing home residents with contractures. Phys Occup Ther Geriatr. 1996;13(4):1–10.
10. Fischer U, Müller 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. 2014;51(3):269–79.
11. Bartoszek G, Fischer U, Grill E, Müller M, Nadolny S, Meyer G. Impact of joint contracture on older persons in a geriatric setting. Z Gerontol Geriatr. 2015. https://doi.org/10.1007/s00391-015-0895-y.
12. Fischer U, Müller 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. Rehabil Nurs. 2016. https://doi.org/10.1002/rnj.190.
13. Fox P, Richardson J, McInnes B, Tait D, Bedard M. Effectiveness of a bed positioning program for treating older adults with knee contractures who are institutionalized. Phys Ther. 2000;80(4):363–72.
14. Lannin NA, Cusick A, McCluskey A, Herbert RD. Effects of splinting on wrist contracture after stroke: a randomized controlled trial. Stroke. 2007;38(1):111–6.
15. Saal S, Beutner K, Bogunski J, Obermüller K, Müller M, Grill E, Meyer G. Interventions for the prevention and treatment of disability due to acquired joint contractures in older people: a systematic review. Age Ageing. 2017. https://doi.org/10.1093/ageing/afx026.
16. Saal S, Meyer G, Beutner K, Klingshirn H, Strobl R, Grill E, Mann E, Köpke S, Bleijlevens MHC, Bartoszek G, et al. Development of a complex intervention to improve participation of nursing home residents with joint contractures: a mixed-method study. BMC Geriatr. 2018. https://doi.org/10.1186/s12877-018-0745-z.
17. Müller M, Bartoszek G, Beutner K, Klingshirn H, Saal S, Stephan AJ, Strobl R, Grill E, Meyer G. 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. https://doi.org/10.3205/000217.
18. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008. https://doi.org/10.1136/bmj.a1655.
19. Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL, Bond CM. Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. PLoS One. 2016. https://doi.org/10.1371/journal.pone.0150205.
20. Berta W, Cranley L, Dearing JW, Dogherty EJ, Squires JE, Estabrooks CA. Why (we think) facilitation works: insights from organizational learning theory. Implement Sci. 2017. https://doi.org/10.1186/s13012-015-0323-0.
21. Dogherty EJ, Harrison M, Graham I, Keeping-Burke L. Examining the use of facilitation within guideline dissemination and implementation studies in nursing. Int J Evid-Based Healthcare. 2014. https://doi.org/10.1097/XEB.0000000000000008.
22. Persson LA, Nga NT, Malqvist M, Thi Phuong Hoa D, Eriksson L, Wallin L, Selling K, Huy TQ, Duc DM, Tiep TV, Thi Thu Thuy V, Ewald U. Effect of facilitation of local maternal and newborn stakeholder groups on neonatal mortality: cluster randomised controlled trial. PLoS Med. 2013. https://doi.org/10.1371/journal.pmed.1001445.
23. Baskerville NB, Liddy C, Hogg W. Systematic review and meta-analysis of practice facilitation within primary care settings. Ann Fam Med. 2012. https://doi.org/10.1370/afm.1312.
24. WHO. International Classification of Functioning, Disability and Health (ICF). (2001). http://www.who.int/classifications/icf/en/. Accessed 27 Apr 2018.
25. Dalichau G, Grüner H, Müller-Alten L, editors. SGB XI – Pflegeversicherung. München: C.H. Beck; 2002.
26. Köhler L, Weyerer S, Schaufele M. Proxy screening tools improve the recognition of dementia in old-age homes: results of a validation study. Age Ageing. 2007. https://doi.org/10.1093/ageing/afm108.
27. Müller M, Oberhauser C, Fischer U, Bartoszek G, Saal S, Strobl R, Meyer G, Grill E. 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. Int J Nurs Stud. 2016. https://doi.org/10.1016/j.ijnurstu.2016.04.002.
28. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. Gerontologist. 1969;9(3):179–86.
29. Graf C. The Lawton Instrumental Activities of Daily Living (IADL) Scale. (2013). https://consultgeri.org/try-this/general-assessment/issue-23.pdf. Accessed 30 Apr 2017.
30. EuroQol Group. EuroQol—a new facility for the measurement of health-related quality of life. Health Policy. 1990;16(3):199–208.
31. 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. https://doi.org/10.1186/1745-6215-14-15.
32. Krauth C, Hessel F, Hansmeier T, Wasem J, Seitz R, Schweikert B. Empirical standard costs for health economic evaluation in Germany—a proposal by the working group methods in health economic evaluation. Gesundheitswesen. 2005. https://doi.org/10.1055/s-2005-858698.
33. Icks A, Chernyak N, Bestehorn K, Bruggenjurgen B, Bruns J, Damm O, Dintsios CM, Dreinhofer K, Gandjour A, Gerber A, et al. Methods of health economic evaluation for health services research. Gesundheitswesen. 2010. https://doi.org/10.1055/s-0030-1262859.
34. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract. 2004. https://doi.org/10.1111/j.2002.384.doc.x.
35. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol. 2010. https://doi.org/10.1186/1471-2288-10-67.
36. R Core Team. A language and environment for statistical computing. (2016). https://www.R-project.org/. Accessed 7 Mar 2017.
37. Davies K, Collerton JC, Jagger C, Bond J, Barker SA, Edwards J, Hughes J, Hunt JM, Robinson L. Engaging the oldest old in research: lessons from the Newcastle 85+ study. BMC Geriatr. 2010. https://doi.org/10.1186/1471-2318-10-64.
38. Zermansky AG, Alldred DP, Petty DR, Raynor DK. Striving to recruit: the difficulties of conducting clinical research on elderly care home residents. J R Soc Med. 2007. https://doi.org/10.1177/014107680710000608.
39. Hall S, Longhurst S, Higginson IJ. Challenges to conducting research with older people living in nursing homes. BMC Geriatr. 2009. https://doi.org/10.1186/1471-2318-9-38.
40. Shepherd V, Nuttall J, Hood K, Butler CC. Setting up a clinical trial in care homes: challenges encountered and recommendations for future research practice. BMC Res Notes. 2015. https://doi.org/10.1186/s13104-015-1276-8.
41. Gismondi PM, Hamer DH, Leka LS, Dallal G, Fiatarone Singh MA, Meydani SN. Strategies, time, and costs associated with the recruitment and enrollment of nursing home residents for a micronutrient supplementation clinical trial. J Gerontol A Biol Sci Med Sci. 2005;60(11):1469–74.
42. Blekken LE, Nakrem S, Gjeilo KH, Norton C, Morkved S, Vinsnes AG. Feasibility, acceptability, and adherence of two educational programs for care staff concerning nursing home patients' fecal incontinence: a pilot

study preceding a cluster-randomized controlled trial. Implement Sci. 2015. https://doi.org/10.1186/s13012-015-0263-8.
43. Garcia C, Kelley CM, Dyck MJ. Nursing home recruitment: trials, tribulations, and successes. Appl Nurs Res. 2013. https://doi.org/10.1016/j.apnr.2013.01.001.
44. Zwijsen SA, Smalbrugge M, Eefsting JA, Gerritsen DL, Hertogh CM, Pot AM. Grip on challenging behavior: process evaluation of the implementation of a care program. Trials. 2014. https://doi.org/10.1186/1745-6215-15-302.
45. Abraham J, Möhler R, Henkel A, Kupfer R, Icks A, Dintsios CM, Haastert B, Meyer G, Köpke S. Implementation of a Multicomponent intervention to Prevent Physical Restraints In Nursing home residenTs (IMPRINT): study protocol for a cluster-randomised controlled trial. BMC Geriatr. 2015. https://doi.org/10.1186/s12877-015-0086-0.
46. Köpke S, Mühlhauser I, Gerlach A, Haut A, Haastert B, Möhler R, Meyer G. Effect of a guideline-based multicomponent intervention on use of physical restraints in nursing homes: a randomized controlled trial. JAMA. 2012. https://doi.org/10.1001/jama.2012.4517.
47. Wylie G, Menz HB, McFarlane S, Ogston S, Sullivan F, Williams B, Young Z, Morris J. Podiatry intervention versus usual care to prevent falls in care homes: pilot randomised controlled trial (the PIRFECT study). BMC Geriatr. 2017. https://doi.org/10.1186/s12877-017-0541-1.
48. Low LF, Brodaty H, Goodenough B, Spitzer P, Bell JP, Fleming R, Casey AN, Liu Z, Chenoweth L. The Sydney Multisite Intervention of LaughterBosses and ElderClowns (SMILE) study: cluster randomised trial of humour therapy in nursing homes. BMJ Open. 2013. https://doi.org/10.1136/bmjopen-2012-002072.
49. WHO. How to use the ICF: a practical manual for using the International Classification of Functioning, Disability and Health (ICF). Exposure draft for comment. (2013). http://www.who.int/classifications/drafticfpracticalmanual.pdf. Accessed 13 Apr 2018.
50. Vuorisalmi M, Sarkeala T, Hervonen A, Jylha M. Among nonagenarians, congruence between self-rated and proxy-rated health was low but both predicted mortality. J Clin Epidemiol. 2012. https://doi.org/10.1016/j.jclinepi.2011.11.001.
51. Koch AD, Vogel A, Becker T, Salize HJ, Voss E, Werner A, Arnold K, Schutzwohl M. Proxy and self-reported Quality of Life in adults with intellectual disabilities: impact of psychiatric symptoms, problem behaviour, psychotropic medication and unmet needs. Res Dev Disabil. 2015. https://doi.org/10.1016/j.ridd.2015.07.022.
52. Poulin V, Desrosiers J. Participation after stroke: comparing proxies' and patients' perceptions. J Rehabil Med. 2008. https://doi.org/10.2340/16501977-0115.

Publisher's Note

Publikation III

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

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Kurzzusammenfassung

Die dritte Publikation schließt die Pilotierung der Intervention mit einer Prozessevaluation ab. Mit einem Mixed-Methods-Ansatz wurde die Umsetzbarkeit der Intervention im Setting Pflegeheim evaluiert und Förderfaktoren und Barrieren für eine erfolgreiche Implementierung identifiziert. Es ergeben sich Empfehlungen für die Optimierung der Implementierungsstrategie.

Erst-Autorenschaft, Eigenanteil: *Konzeptualisierung der Prozessevaluation, Datenerhebung (Gruppendiskussion und qualitative Interviews), Datenanalyse (leitend), Interpretation der Daten, Manuskripterstellung (leitend).*

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RESEARCH ARTICLE Open Access

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

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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 regions of Germany 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 nurses. 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.

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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.

Trial registration: German clinical trials register, DRKS00010037. Registered 12 February 2016.

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

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 of functioning such as mobility, self-care, sensory function and pain, domestic life and community, social and civic life [9]. Limitations in activities (i.e., "the execution of a task or action") and restrictions in participation (i.e., "the involvement in a life situation") are the most relevant problems for the affected individuals [9–13]. 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 complexity of the phenomenon of joint contracture. Despite the multiple causes of joint contractures, currently used interventions for prevention and treatment are mainly single interventions [14–16], which are not effective in multimorbid, older people 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 healthcare professionals are involved in the care of individuals with joint contractures, for example nurses, physical and occupational therapists and physicians. The involvement of informal caregivers is also crucial [12]. A successful intervention for nursing home residents with joint contractures has to consider the interaction between joint contractures, the individuals' daily life and the influence of environmental and personal factors, and should also address all healthcare 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.

Particularly in a pilot trial, the key function of a process evaluation is to understand the feasibility and acceptability of the implementation strategy and the proposed evaluation design [20]. 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 [21].

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 [21]. In summary, the PECAN pilot trial was planned as a multicentre 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 suffering from 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 regions of Germany. 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 3 and 6 months. The primary outcome was defined as the residents' participation and measured with the PaArticular Scales [22]. The secondary outcomes were defined as residents' activities, instrumental activities of daily 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 [23].

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 [24]. 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 [24]. 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 [25] for reporting our implementation and the Template for Intervention Description and Replication (TIDieR) checklist [26] for reporting our intervention.

The PECAN intervention

Based on the biopsychosocial model of the ICF [8], the core idea of the PECAN intervention is to facilitate a participation-oriented understanding of care in nursing homes, to allow improved analysis of the residents' situation and to guide the nursing home staff in their decision-making. The individually tailored 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 for performing activities and for participation [8, 17].

Process of change

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) [27], which is a proven theory to predict or explain the behaviour of healthcare professionals [28, 29]. 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, Figure A1.

Implementation strategy

The key aspect of the PECAN implementation strategy is the facilitation approach [30]. Facilitation is the active part of the implementation, carried out by trained facilitators, who guide individuals or organisations through a challenging change process [30, 31]. As change agents, facilitators are 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 throughout all the nursing homes. In the second step, the facilitators are responsible for the integration of the PECAN intervention into the daily practice by involving, counselling or educating the nursing team, physicians, therapists, social workers and relatives. During this process the facilitators were supported by experienced peer-mentors, who were members of the research team [17].

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

Researcher-guided implementation steps

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.

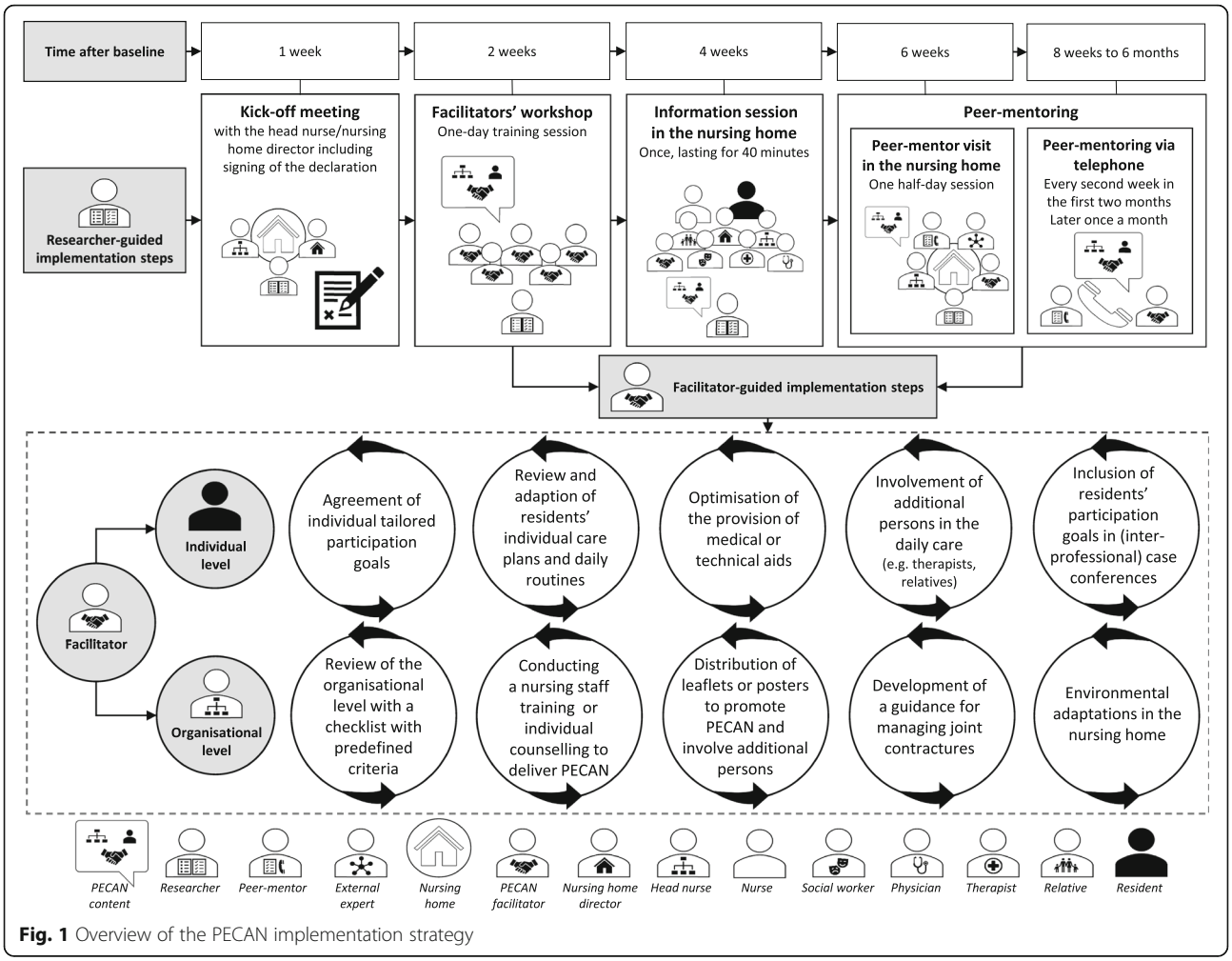

Fig. 1 Overview of the PECAN implementation strategy

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 3 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 [32] to involve all team members in the implementation process and to improve interprofessional collaborations.

Information session A single *information session* lasting 40 min was held by a member of the research team in each nursing home for the residents, relatives, nursing staff and other interested healthcare 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. Based on this review, the facilitators developed a tailored action plan for the

implementation of PECAN in their nursing home. During the implementation process, the peer-mentor supported the facilitators in transforming their plans into action. Changes at the organisational level were realised in collaboration with the *peer-mentor*, the head nurse and the facilitator. Following the visit, *peer-mentoring* was conducted via phone calls from their mentors every second week in the first 2 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.

Facilitator-guided implementation steps

To achieve the intervention goals, an individually tailored approach is used including both the individual (i.e., resident) and the organisational (i.e., nursing home) level.

Individual level The residents' activities and participation were addressed by defining individual participation goals and their care plans and daily routines were accordingly reviewed and adapted. Measures to meet the participation goals on the individual level contained, for example, the use of a biographical approach to identify the residents' potential motivation for activities and participation, the inclusion of residents' participation goals in (interprofessional) case conferences, the optimisation of the provision of medical or technical aids and the involvement of additional persons in the daily care by peer counselling and by using project leaflets for external therapists, physicians or relatives when it is necessary to reach residents' participation goals.

Organisational level The review and change process to integrate the perspective of the ICF was guided by using a checklist with predefined criteria. In consultation with the head nurse the facilitators promoted changes on the organisational level to disseminate the PECAN principles. This included nursing team training sessions, individual counselling, the distribution of leaflets and posters, the de-novo-development of a guidance for managing joint contractures according the core aspects of the PECAN intervention or the adaptation of an existing guidance, environmental adaptations in the nursing home, 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].

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 3 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 of

- the facilitators, responsible for the implementation of PECAN,
- the nurses, who were introduced to the intervention by the facilitators,
- additional persons, who were closely engaged in the care of residents with joint contractures, i.e., therapists, social workers and relatives,
- and 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 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 [21].

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 focussed on the components "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 adopts intervention content into daily nursing care), and "the context" (i.e., anything external to the intervention) which might be an interacting component [24]. An overview of the components and data collection methods of the process evaluation for the PECAN intervention adapted from Grant et al. [24] is presented in Table 1.

Characteristics 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.

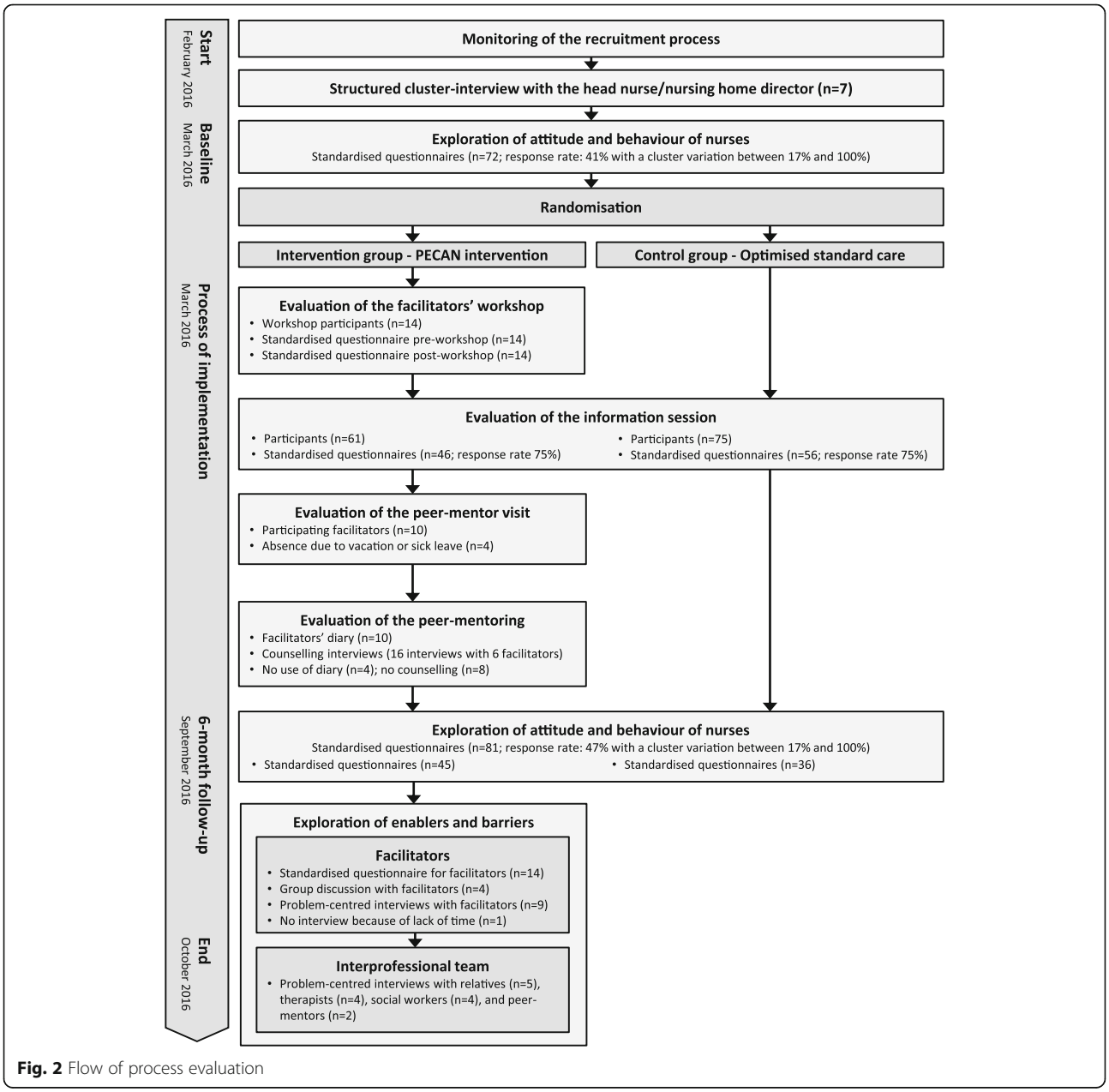

Fig. 2 Flow of process evaluation

Table 1 Components and methods of the process evaluation for the PECAN intervention adapted from Grant et al. (2013) [24]

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

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 content 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 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 [33] and problem-centred interviews [34]. 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 [35].

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 [36]. Audio records of the group discussion and the interviews were "abridged transcribed" [33] 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 [37]. 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 [8, 38]. The data analysis was supported by MAXQDA Version 12 [39]. 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

Characteristics of nursing homes – the context

Seven nursing homes ($n = 4$ intervention groups, $n = 3$ control groups) in two regions of Germany 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 an environment that promotes physical activity with therapeutic gardens or walking circuits. The characteristics of the nursing homes are presented in Table 2.

Process of implementation

Results on the degree of implementation of the PECAN intervention are presented in Table 3. Results on enablers and barriers of the PECAN implementation strategy from the problem-centred interviews are summarised in Table 4.

Out of the 57 persons invited to the problem-centred interviews, 28 persons took part, 13 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 a few external stakeholders (therapists and relatives) responded to the invitation distributed by the head nurse.

The head nurse or nursing home director of each nursing home signed the declaration to ensure their 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 1 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 $n = 3$). Whereas in clusters 2, 3 and 4

Table 2 Characteristics of nursing homes (adapted from Saal et al. 2019) [21]

	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
Participants levels of care dependency[a]								
None	0	0	1	0	0	0	0	1
Low	0	0	0	0	0	0	2	2
Considerable	5	14	3	1	10	1	7	41
Severe	4	6	6	8	11	9	7	51
Most severe	0	0	1	15	3	13	2	34
Ownership [b]	*private*	*private*	*church-owned*	*church-owned*	*non-profit*	*non-profit*	*private*	
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 [c]	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 [d]	*regularly*	*occasionally*	*regularly*	*regularly*	*regularly*	*occasionally*	*regularly*	
Local environment [e]								
Park areas	*yes*	*yes*	*yes*	*yes*	*no*	*yes*	*yes*	
Stores (e.g. supermarket, drugstore)	*no*	*yes*	*yes*	*yes*	*no*	*yes*	*yes*	
Churches	*no*	*no*	*yes*	*yes*	*no*	*yes*	*yes*	
Coffee bars	*no*	*yes*	*yes*	*yes*	*no*	*yes*	*yes*	
Environment promoting physical activity[f]	*no*	*no*	*yes*	*yes*	*yes*	*yes*	*yes*	
Degree of urbanisation [g]	*rural*	*urban*	*urban*	*suburban*	*suburban*	*urban*	*suburban*	

[a]Levels of care dependency as assessed by expert raters from the medical service of the German statutory health insurance system
[b]Categorisation of ownership = non-profit, private, state-owned, or church-owned
[c]Prevalence estimated by the head nurse
[d]Categorisation of the conduction of interprofessional case conferences = regularly, occasionally, or never
[e]Defined as close to the nursing home within walking distance for the residents
[f]Defined as movement-promoting architectural features in or outside the nursing home e.g. therapeutic garden, barrier-free walking circuits, handrails, wheelchair accessibility
[g]Defined by degree of urbanisation acc. to the statistical office of the European office (Eurostat) = urban, suburban, or rural

all the facilitators were engaged in daily nursing care on their ward, one of the facilitators in cluster 1 was the deputy nursing home director.

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 1, 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.

Findings from the problem-centred interviews present a more detailed picture: The theoretical part of the workshop, in which the existing evidence on the development and prevention of joint contractures was conveyed, was found to be not really instructive, on the other hand the practical elements of the workshop were judged as particularly relevant for daily care.

Facilitator (F3, C2) about the theoretical part of the workshop:

> *I had thought that maybe I would learn something new, [...] but that was not the case.*

Facilitator (F1, C1) about the practical part of 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.*

The *information session* was conducted in all clusters according to protocol. A total of 136 participants from

Table 3 Implementation of the PECAN intervention

	Cluster 1	Cluster 2	Cluster 3	Cluster 4
Kick-off meeting				
Meeting conducted according to protocol	✓	✓	✓	✓
Declaration signed	✓	✓	✓	✓
Facilitators' workshop				
Agenda and content according to protocol	✓	✓	✓	✓
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	✓	✓	✓	✓
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 according to protocol	✓	✓	✓	✓
Number of facilitators participating	2/2	2/2	2/4	4/6
Participation of the head nurse	✓	✓	✓	✓
Support by an external peer-expert	✓	✓	–	✓
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 (20–20)	5 (5–5)	19 (17–20)	5 (1–10)

seven nursing homes (intervention group $n = 61$; 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. The statement by a relative points out why in some nursing homes external participants rarely receive information about the events taking place in the nursing home.

Relative (R2, C3) about the poster with the announcement for the *information session*:

> *[…] there's a bulletin board a little further back in the hall, but there are a thousand notes. I don't really take notice of it.*

Table 4 Enablers and barriers of the PECAN implementation strategy

Categories	Enablers	Barriers
Overall strategy	• Stepwise training of facilitators (i.e., facilitators' workshop, peer-mentor visit, peer-mentoring via telephone) (F)	• Lack of systematic involvement of all the different stakeholders (i.e., management, social workers, relatives, and therapists) (F, R, T, SW)
	• Clear defined PECAN content (F)	• Available time period too short to complete implementation (F)
	• Personal contact initiated by the management or the facilitators to provide the different stakeholders with information on PECAN (T, F)	• Difficulties in the implementation for residents with severe physical and cognitive impairment (F)
Facilitators' workshop	• Practical elements (e.g., training on the use of technical and medical aids) (M)	• Unbalanced ratio between theory and practice (i.e., more active participation during workshop required) (F, RT)
Information session	• Use of plain language when addressing the different participant groups (RT)	• Lack of systematic involvement of the nursing staff (e.g., no presentation within the nursing team) (F)
	• Diverse groups of participants could be reached and informed about PECAN in one session (F, SW)	• Invitation to the session (i.e., poster at the entrance area) did not reached all potential participants (F, T, R, SW, RT)
Peer-mentoring	• The peer-mentor visit was highlighted as a useful introduction to the implementation of PECAN (F)	• Facilitators were usually not directly available via e-mail or telephone (e.g., appointments via the head nurse were necessary) (F, PM)
	• Continuous availability of the peer-mentors via telephone (F)	
	• Standardised procedure of peer-mentoring via telephone (F, PM) - Routines for communication and regular appointments (F, PM) - Specific objectives based on the last counselling (PM)	
Supportive materials	• Supportive materials tailored for the target population (F, T, SW) - 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) - Article regarding PECAN published in nursing home journal (SW)	• 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) - 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)

From the perspective of the facilitators, the session should have reached more nurses.

Facilitator (F13, C4) about the participation of nurses in the information session:

> *There [should have been] many more employees, perhaps this should have taken place at a different time.*

Regardless of their participation in the information session, it became apparent that the content of the session was not detailed enough for the nurses. In the problem-centred interviews, some facilitators therefore suggested a short training session for all the nurses.

Facilitator (F12, C4) about the training of nursing staff:

> *[...] the head nurse could already decide that [...] I can indeed explain what we have discussed - what the purpose of the intervention is - but to conduct a compulsory training session is a different matter [...]. For one or two hours.*

Peer-mentoring (*peer-mentor visit, peer-mentoring by telephone, supportive material)* was offered to all the nursing homes. Due to sick leave and vacation occurrences, four out of 14 facilitators were unable to participate during the *peer-mentor visit*. Overall, the *peer-*

mentor visit was highlighted by the facilitators as a useful introduction to implementing PECAN.

Facilitator (F11, C4) about the *peer-mentor visit*:

> *It was especially interesting [...] at that time we introduced our residents, you [the researchers] also got to know our residents. That was really, really great.*

During the visit the facilitators used a structured assessment tool to review organisational procedures and to develop tailored action plans to implement PECAN into their nursing home. In addition, case conferences were conducted at each visit, and individual care plans were developed for two residents to improve their participation. Support was given by the peer-mentor (all clusters) and an external peer expert (cluster 1, 2 and 4).

The action plans were realised with support of the peer-mentor during the following weeks. 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 min with a range from 10 to 85 min (Table 3).

The main counselling 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. The standardised procedure of counselling with routines for communication and regular appointments was emphasised by both facilitators and peer-mentors as being supportive.

Facilitator (F1, C1) about the peer-mentor:

> *The mentoring by one of 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.*

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 problem-centred interviews highlighted the impact to provide supplementary materials to support the implementation.

Facilitators (F13, C4):

> *Yes, your information material was an advantage, we could hang up the posters. Well, someone always took a look at it.*

Facilitator (F8, C3):

> *A special supplement for the documentation is missing.*

The facilitators adopted various measures to implement the PECAN intervention in their nursing homes. 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. The documentation from the peer counselling and the problem-centred interviews provided better information about what was happening in the nursing homes.

For example on the individual level, in cluster 2 the review of medical aids resulted in the necessity to replace a walker with a more suitable one. Another resident in cluster 2, has been using a wheelchair since moving into the nursing home, although the nurses believed he would be still able to walk short distances. Therapists and nurses agreed to encourage the resident to become more involved in transfers and use a walker in his room.

At the organisational level, cluster 1 organised an interprofessional in-house workshop to optimise the provision of medical or technical aids. The workshop was conducted 6 weeks after the visit in cooperation with the medical supply store. In addition to the nursing staff and the advisor from the medical supply store, external therapists and the *peer-mentor* took part to support the training. In cluster 4, the facilitators introduced the PECAN intervention to their nursing team, using the

posters and material sets for nursing team training in team meetings, and integrated the intervention in the daily handovers and case conferences.

Attitude and behaviour of nurses

The response of nursing staff to the PECAN intervention after 6 months is presented in Table 5.

All in all, some of the nurses disagreed ("strongly disagree" and "disagree") that they felt well informed about PECAN (13/45, 29%), that comprehensive *supportive materials* were provided (13/45, 29%) and that the facilitators provided counselling whenever it was needed (12/45, 27%). After 6 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%). Particularly in cluster 2, the majority of the nurses felt poorly informed about the PECAN intervention (11/12, 92%) and were dissatisfied with the implementation (5/8, 42%). The interview with the peer-mentor revealed that especially in cluster 2 the facilitators had no support from the nursing home director, which made it impossible for them to realise their role and to involve the nursing staff in initiating changes. In contrast, a facilitator from cluster 3 describes his role as being only supportive to counselling colleagues and instigating changes.

Peer-Mentor (P1) about cluster 2:

> *[...] it was not at all possible […] to realise the role as facilitator, i.e. the facilitator had the task after the training [...] of passing on the [contents of the intervention] to the colleagues. This was not successful at all in the larger institution. The support of the nursing home director was lacking.*

Facilitator (F8, C3):

> *In the role [as facilitator] I was able to assert myself better. I could say "Come, let's go to the resident and then you show me how you do it".*

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 1; Table A2). For example, in the intervention group, two thirds of the nurses (30/45, 67%) agreed ("strongly agree" and "agree") with 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,

Table 5 Response of the nursing staff to the PECAN intervention after 6 months

Do you agree with the following statements?	Cluster 1 ($n = 10$)		Cluster 2 ($n = 12$)		Cluster 3 ($n = 6$)		Cluster 4 ($n = 17$)		Total ($n = 45$)	
	n	(%)	n	(%)	n	(%)	n	(%)	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)

43%) or at the 6-month follow-up in the control group (17/36, 47%).

Enablers and barriers at the nursing home level

Enablers and barriers of implementation at the nursing home level are summarised in Table 6.

Implementation at the nursing home level is influenced by the personal characteristics of the different stakeholders and by the organisational and structural conditions of the nursing homes. Moreover, there are differences between the included clusters and between the perceptions of the stakeholders. For example, the facilitators experienced the social relationship, which includes the open-mindedness of staff towards the PECAN intervention, in different ways.

Facilitator (F1, C1):

> *It's hard... to really convince these die-hard nurses to actively participate, to implement, to think, to observe. That is difficult [...], and they must really want it.*

Facilitator (F12, C4):

> *Now something is happening here and I felt it was positive that we were practically involved. Half [of the nursing staff] could also have said "Oh, I don't feel like it" [...] or "I'm not interested in that here".*

As a fundamental precondition for a successful implementation, the clear commitment of the entire nursing home is required. This covers an active leadership in supporting the changes, open-mindedness to the changes, and clear responsibilities. These quotes from two facilitators illustrate how commitment can be experienced and, in contrast, how implementation stagnates if there is no commitment by the nursing home.

Facilitator (F9, C4):

> *We were always exempted from work for the meetings. For discussions, we got extra time. [...] It was a very, very close collaboration.*

Table 6 Enablers and barriers of implementation at the nursing home level

Categories	Enablers	Barriers
Personal factors	• Social relationships (F) - Respect and social support of facilitators by the nursing team (F)	• 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	• 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 with social workers, therapists and physicians) (F)	• 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)
	• 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

Facilitator (F6, C3):

I missed the togetherness [...]. I had talked to the head nurse after our workshop [...], but I had the impression 'yes, that's nice you were here' [...]. I missed the commitment and the interest.

Moreover, a successful implementation is motivated by respecting the expertise of the different stakeholders, as emphasized in the following quote.

Facilitator (F1, C1):

And I also have to say, the whole solidarity between us all, nurses, physical therapists, physicians, occupational therapists, this is now a really good collaboration, it works, you complement each other, you get tips.

A lack of impact on organisational conditions and routines was identified as a major barrier for the implementation. This includes unclear responsibilities and a lack of interprofessional collaboration which was impeded by the strict separation of working areas and the lack of an established culture of change. The subsequent quote by a therapist addresses the problem of the documentation.

Therapist (T3, C2):

[...] 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.

A barrier that was reported as important across all clusters and from different stakeholders was a lack of time and staff competence, as illustrated by the subsequent quotes:

Social worker (S2, C2):

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.

Facilitator (F6, C3):

The major problem is of course the staff shortage, this is still known in many nursing homes [...] the time of course [...] whether management or staff, everyone has to do his work, is a bit stressed [...]

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 passed on properly to the nurses, healthcare professionals, relatives and, subsequently, to the residents.

During the implementation process, differences between the nursing homes became apparent. While in cluster 1 all the nursing staff surveyed were satisfied with the implementation of the intervention, the nurses in cluster 2 were not satisfied with the implementation. Cluster 1 is a comparably small nursing home in which the support of the management was assured, since one of the two facilitators held the position of the deputy nursing home director. Moreover, the facilitators in cluster 1 invested a lot of time in the implementation and also made intensive use of *peer-mentoring*. In contrast, cluster 2 had limited support from the nursing home management due to personnel changes, which eventually led to termination of the implementation at the nursing home level.

In 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 [40–43]. 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 [30]. Our results confirmed the stepwise training of facilitators as an appropriate implementation strategy to empower facilitators. Nevertheless, in our pilot study empowerment of a facilitator alone was not sufficient to change practice. Here, our results are in line with Aasmul et al., indicating that a successful implementation did not depend on the facilitator alone [40]. It turned out that the facilitators can only act successfully when they can rely on a working environment that is supportive to inducing changes. This includes the existing time resources and the colleagues' open-mindedness for training and counselling. Considering the low participation of the nurses in the information session and their lack of information regarding the PECAN intervention, it is apparent that further implementation strategies are needed to ensure the reach of

the intervention. As a complementary strategy we used critical review and adaption of existing guidance for managing joint contractures to initiate the change in practice. However, we failed to support the facilitator in translating the guidance into nursing home practice using the existing quality management infrastructure. A nursing staff training support by the nursing home quality management would have probably increased the acceptance of the PECAN intervention.

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 [44]. 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 during case conferences, which are an established approach to improve the care of nursing home residents [45–47]. In our study, case conferences have also proven to be a useful strategy for the adoption of tailored intervention measures and for implementation processes in practice, particularly since the concept of the case conference had already been established in the nursing homes. The participation of the *peer-mentor* in a case conference would have been another useful measure to ensure a better implementation of the PECAN intervention. The use of routine communication mechanisms to ensure staff commitment is a proven measure to provide practice change [48]. Moreover, peer counselling methods [32] to advise and coach nurses during implementation were an important module of the *facilitators' workshop*, which needs more practical training and discussion in an extra session. The *peer-mentoring* via *telephone* was mainly considered as an enabler for initiating changes, 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 [40, 41, 43]. 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 [40, 42]. 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. [49], 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 than scheduled in a pilot study.

Although there was a clear commitment of the entire nursing home, that was ensured by the adoption of a declaration to the PECAN intervention on the one hand, on the other hand there was a lack of staff commitment in organisation and practice change. During the implementation process, it became apparent in some clusters that the nursing management and the nursing staff had different priorities, that responsibilities were unclear, and that time slots for unscheduled tasks were not provided. While commitment is a precondition for change, change requires more effort than merely commitment. Several reasons might explain this paradox. First, despite detailed information on the PECAN implementation, nursing home managers seemed to underestimate the support needed by the facilitators. It is likely that more specific information about the responsibilities of the nursing home management might have increased the commitment. Second, staff turnover and sick leave limited the support by the nursing home management, especially in cluster 2. Therefore, the involvement of the quality management - not only as a deputy for the nursing home manager, but also as the existing infrastructure for inducing change – might have increased the practice change.

As in other studies [49, 50], we experienced that an active leadership component is important for initiating necessary organisational changes. In cluster 2, the nurses were dissatisfied with the implementation. This might have been caused by lack of support from the management, or because the vacancy of the head nurse was not filled over a longer period of time, which made the change process almost impossible. To increase the 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 [51]. 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. [52], 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 [50, 53]. 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 [53], 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 [40, 54, 55]. 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 [56]. 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) [27]. 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 [57]. 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 [58]. 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. [24] 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 [59]. Although we have tried to reduce the occurrence of socially desirable responses by ensuring a maximum of anonymity, it cannot be fully ruled out [60]. 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 [40, 61], in our study the use of a diary was insufficient to analyse the commitment of the facilitators to change culture and practice, 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 [62], methods with no additional documentation effort like a "diary interview" [63] would be more appropriate for the data collection in the main trial.

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 essential 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 in most clusters, 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 the use of existing structures of quality management and communication to ensure staff commitment, 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 get an 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.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s12877-020-01655-z.

Additional file 1: Figure A1. Logic model of the Participation Enabling CAre in Nursing intervention; **Table A1.** Self-assessed preparedness for the role as facilitator after the workshop; **Table A2.** Nursing care of residents with joint contractures.

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

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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, JH and SuS. 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.

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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.

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 written informed consent prior to data collection.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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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. Phys Ther. 1993; 73(7):437–44 discussion 444-436.
3. Resnick B. Functional performance and exercise of older adults in long-term care settings. J Gerontol Nurs. 2000;26(3):7–16.
4. Wagner LM, Capezuti E, Brush BL, Clevenger C, Boltz M, Renz S. Contractures in frail nursing home residents. Geriatr Nurs. 2008;29(4):259–66.
5. Yip B, Stewart DA, Roberts MA. The prevalence of joint contractures in residents in NHS continuing care. Health Bull. 1996;54(4):338–43.
6. Fergusson D, Hutton B, Drodge A. The epidemiology of major joint contractures: a systematic review of the literature. Clin Orthop Relat Res. 2007;456:22–9.
7. Rabiner A, Roach KE, Spielholz NI, Judson L. Characteristics of nursing home residents with contractures. Phys Occup Ther Geriatr. 1996;13(4):1–10.
8. World Health Organization. International classification of functioning, disability and health (ICF). Geneva: WHO; 2001.
9. Fischer U, Bartoszek G, Müller 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). Disabil Rehabil. 2014;36(26):2225–32.

10. Bartoszek G, Fischer U, von Clarenau SC, Grill E, Mau W, Meyer G, Strobl R, Thiesemann R, Nadolny S, Müller M. 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. Arch Gerontol Geriatr. 2015;61(1):61–6.
11. Fischer U, Müller 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, Müller 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. Rehabil Nurs. 2016;41(3):170–8.
13. Heise M, Müller 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.
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(9):CD007455. https://doi.org/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. 2007;38(1):111–6.
16. Saal S, Beutner K, Bogunski J, Obermüller K, Müller M, Grill E, Meyer G. Interventions for the prevention and treatment of disability due to acquired joint contractures in older people: a systematic review. Age Ageing. 2017;46(3):373-82.
17. Saal S, Meyer G, Beutner K, Klingshirn H, Strobl R, Grill E, Mann E, Köpke S, Bleijlevens MHC, Bartoszek G, Stephan AJ, Hirt J, Müller M. 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.
18. Müller M, Bartoszek G, Beutner K, Klingshirn H, Saal S, Stephan AJ, Strobl R, Grill E, Meyer G. 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.
19. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Medical Research Council G: developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.
20. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D, et al. Process evaluation of complex interventions: Medical Research Council guidance. Bmj. 2015;350:h1258.
21. Saal S, Klingshirn H, Beutner K, Strobl R, Grill E, Müller M, Meyer G. 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.
22. Müller M, Oberhauser C, Fischer U, Bartoszek G, Saal S, Strobl R, Meyer G, Grill E. 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. Int J Nurs Stud. 2016;59:107–17.
23. 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.
24. 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.
25. Pinnock H, Barwick M, Carpenter CR, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, et al. Standards for reporting implementation studies (StaRI) statement. BMJ. 2017;356:i6795.
26. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687.
27. Ajzen I. The theory of planned behavior. Organ Behav Hum Dec. 1991;50(2):179–211.
28. Eccles MP, Grimshaw JM, MacLennan G, Bonetti D, Glidewell L, Pitts NB, Steen N, Thomas R, Walker A, Johnston M. Explaining clinical behaviors using multiple theoretical models. Implement Sci. 2012;7:99.
29. 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.
30. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. Implement Sci. 2016;11:33.
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.
32. Herwig-Lempp J. Resource-oriented Teamwork: a systemic approach to collegial consultation. Göttingen: Vandenhoeck & Ruprecht; 2013.
33. Krueger RA, Casey MA. Focus groups: a practical guide for applied research. 5th ed. Thousand Oaks: SAGE Publications; 2015.
34. Kvale S. Interviews : an introduction to qualitative research interviewing. Thousand Oaks: Sage Publications; 1996.
35. 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.
36. Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. Qual Health Res. 2005;15(9):1277–88.
37. Denzin NK. The research act: a theoretical introduction to sociological methods. Chicago: Aldine; 1970.
38. Muller R, Geyh S. Lessons learned from different approaches towards classifying personal factors. Disabil Rehabil. 2015;37(5):430–8.
39. MAXQDA: Software for qualitative data analysis. Berlin: VERBI Software - Consult - Sozialforschung GmbH 1989-2016.
40. 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.
41. Abraham J, Möhler R, Henkel A, Kupfer R, Icks A, Dintsios CM, Haastert B, Meyer G, Köpke S. Implementation of a multicomponent intervention to prevent physical restraints in nursing home residents (IMPRINT): study protocol for a cluster-randomised controlled trial. BMC Geriatr. 2015;15:86.
42. 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. Z Gerontol Geriatr. 2016;49(3):209–15.
43. 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.
44. 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.
45. Halcomb EJ, Shepherd BM, Griffiths R. Perceptions of multidisciplinary case conferencing in residential aged care facilities. Aust Health Rev. 2009;33(4):566–71.
46. Kim H, Park YH, Jung YI, Choi H, Lee S, Kim GS, Yang DW, Paik MC, Lee TJ. 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.
47. Reuther S, Dichter MN, Buscher I, Vollmar HC, Holle D, Bartholomeyczik S, Halek M. 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.
48. Godfrey M, Young J, Shannon R, Skingley A, Woolley R, Arrojo F, Brooker D, Manley K, Surr C. The Person, Interactions and Environment Programme to improve care of people with dementia in hospital: a multisite study. Southampton (UK): NIHR Journals Library; 2018.
49. Colon-Emeric C, Toles M, Cary MP Jr, Batchelor-Murphy M, Yap T, Song Y, Hall R, Anderson A, Burd A, Anderson RA. Sustaining complex interventions in long-term care: a qualitative study of direct care staff and managers. Implement Sci. 2016;11:94.
50. 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.
51. Anderson RA, Issel LM, McDaniel RR Jr. Nursing homes as complex adaptive systems: relationship between management practice and resident outcomes. Nurs Res. 2003;52(1):12–21.
52. 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.
53. Low LF, Fletcher J, Goodenough B, Jeon YH, Etherton-Beer C, MacAndrew M, Beattie E. 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.
54. 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.

55. 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.
56. Sarafis P, Rousaki E, Tsounis A, Malliarou M, Lahana L, Bamidis P, Niakas D, Papastavrou E. The impact of occupational stress on nurses' caring behaviors and their health related quality of life. BMC Nurs. 2016;15:56.
57. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, Proctor EK, Kirchner JE. A refined compilation of implementation strategies: results from the expert recommendations for implementing change (ERIC) project. Implement Sci. 2015;10:21.
58. Beauchamp MK, Lee A, Ward RF, Harrison SM, Bain PA, Goldstein RS, Brooks D, Bean JF, Jette AM. Do exercise interventions improve participation in life roles in older adults? A systematic review and meta-analysis. Phys Ther. 2017;97(10):964–74.
59. Garcia C, Kelley CM, Dyck MJ. Nursing home recruitment: trials, tribulations, and successes. Appl Nurs Res. 2013;26(3):136–8.
60. van de Mortel TF. Faking it: social desirability response bias in self-report research. Aust J Adv Nurs. 2008;25(4):40–8.
61. 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.
62. Hall S, Longhurst S, Higginson IJ. Challenges to conducting research with older people living in nursing homes. BMC Geriatr. 2009;9:38.
63. Elliott H. The use of Diaries in Sociological Research on Health Experience. Sociol Res Online. 1997;2(2):38–48.

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Implementierung einer komplexen Intervention zur Verbesserung der Teilhabe von älteren Menschen mit Gelenkkontrakturen in Pflegeheimen – eine Prozessevaluation

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Herrsching, 29.03.2021 — Hanna Klingshirn

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