Aus dem Institut für Gesundheits- und Pflegewissenschaft

der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg

(Direktorin: Prof. Dr. Gabriele Meyer)

Teilhabeorientierte Gesundheitsversorgung von älteren Menschen mit Gelenkkontrakturen in Pflegeheimen

Habilitationsschrift

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von Dr. rer. medic. Susanne Saal

geboren am 24.09.1977 in Merseburg

Gutachter/Gutachterin: Prof. Dr. Falk Hoffmann, Prof. Dr. Kerstin Lüdtke

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Hintergrund: Chronische Gesundheitsbeeinträchtigungen haben diverse Implikationen auf Teilhabe an der Gesellschaft und unabhängige Lebensführung. Um derart individuelle Zielgrößen wie Teilhabe an der Gesellschaft positiv zu beeinflussen, braucht es sorgfältig an den Bedarfen der Adressaten ausgerichtete Interventionen, die die Mehrdimensionalität eines chronischen Gesundheitsproblems berücksichtigen. Diese Arbeit möchte unter Anwendung des Rahmenkonzepts des UK Medical Research Council (MRC) einen Beitrag zur Etablierung eines erprobten methodischen Vorgehens leisten.

Ziel: Ziel ist es, am Beispiel einer Interventionsentwicklung zur Verbesserung der Teilhabe an der Gesellschaft von Menschen mit Gelenkkontrakturen im Pflegeheim ein methodisches Vorgehen zur Entwicklung komplexer Interventionen zu erproben und kritisch zu reflektieren.

Methoden: Es wurde eine systematische Übersichtsarbeit, eine grafische Modellierung standardisierter Interviewdaten aus einer früheren Studie, Gruppendiskussionen mit Pflegeheimbewohnerinnen und -bewohnern, ein Expertenworkshop und eine Gruppendiskussion mit Pflegenden durchgeführt. Das Interventionsprotokoll wurde in einer Cluster-randomisierten Pilotstudie auf Machbarkeit sowie Akzeptanz überprüft.

Ergebnisse: Die systematische Übersichtsarbeit ergab kaum verwertbare Evidenz, so orientierte sich die Entwicklung konsequent an Interventionszielen, die durch Einbindung potentieller Nutzerinnen und Nutzer generiert wurden. Die PECAN-Intervention (Participation Enabling CAre in Nursing) wurde in einer Pilotstudie in sieben Pflegeheimen mit 265 teilnehmenden Bewohnerinnen und Bewohnern als machbar und akzeptabel eingeschätzt.

Schlussfolgerungen: Das entwickelte methodische Vorgehen hat sich bewährt und kann als Vorlage für die Interventionsentwicklung für Menschen mit chronischen Erkrankungen in der Langzeitpflege und mit entsprechenden Adaptionen auch in stationären Settings der Akutversorgung dienen. Es braucht weitere Empfehlungen zum methodischen Vorgehen der Interventionsentwicklung bei kaum vorhandener Evidenzbasis, in der Entwicklung von Programmtheorien zu hochindividualisierten Interventionen und zusätzlich zum MRC Rahmenkonzept weitere Konzepte, die die Implementierung stärker in den Fokus nehmen.

Background: Chronic health conditions have various implications on participation and independent living. In order to address such highly individual outcomes as participation, interventions are needed that carefully consider the needs of target populations and the multidimensional nature of the chronic health condition. This work uses the framework of the UK Medical Research Council (MRC) for complex interventions to contribute to a consolidated and proven methodological approach for intervention development processes.

Objective: The purpose of the study was to evaluate and critically reflect a methodological approach for intervention development processes, using as an example the development of a complex intervention to improve participation-centred healthcare of older people with joint contractures in nursing homes.

Methods: A systematic review of intervention studies, a graphic modelling approach of standardised interviews from a recent study, group discussions with nursing home residents, a workshop with experts in geriatric nursing and rehabilitation, and a group discussion with professionals in nursing homes were conducted. The feasibility and acceptance of the intervention protocol was evaluated in a cluster-randomised pilot study.

Results: The systematic review revealed a weak body of evidence. The development was closely aligned with the interventions' goals and involved both health professionals and residents. The PECAN-Intervention (Participation Enabling CAre in Nursing) was evaluated in a pilot study in seven nursing homes with 265 residents and was considered to be feasible and acceptable.

Conclusions: The developed methodological approach has been proven. It might serve as a template for structured intervention development processes for patients with chronic diseases in long-term care and, with modification, in hospital care. Further recommendations are needed regarding the methodological approach for intervention development processes when the evidence base is weak and in the development of program theories for highly individualized interventions. In addition to the MRC framework, further frameworks should be used to strengthen the focus on the implementation processes.

Inhaltsverzeichnis

Abkürzungsverzeichnis

PECAN	Participation Enabling CAre in Nursing
DASH	Disabilities of the Arm, Shoulder and Hand
CCT	kontrollierte Studie
CI	Konfidenzintervall
c-RCT	Cluster-randomisierte Studie
CFIR	Consolidated Framework for Implementation Research
CICI	Context and Implementation of Complex Interventions
DSS	Dementia Screening Scale
EKON	Expertinnen und Experten für kontraktursensible Pflege
EQ-5D-3L	EuroQol 5 Dimensions 3 Levels
i-PARIHS	Promoting Action on Research Implementation in Health Services
IADL	Instrumental activities of daily living
ICF	International Classification of Functioning, Disability and Health
ICTRP	International Clinical Trials Registry Platform
ICC	Intracluster-Korrelationskoeffizient
LMM	Lineares gemischtes Modell
MDK	Medizinische Dienst der Krankenkassen
RCT	randomisierte Studie
SD	Standardabweichung
TIDieR	Templates zur Interventionsbeschreibung und -replikation
UK MRC	United Kingdom Medical Research Council
VAS	Visuelle Analogskala
WOMAC	Western Ontario McMaster University Osteoarthritis Index Scales
WHO	World Health Organization

Tabellenverzeichnis

1 Einleitung

Diese Habilitationsschrift berichtet einen zentralen Ausschnitt eines umfassenderen Habilitationsthemas zur Verbesserung der Teilhabe von Menschen mit chronischen Erkrankungen. Ausgangspunkt ist eine unzureichende Teilhabeorientierung in der Versorgung von älteren Menschen mit Gelenkkontrakturen in Pflegeheimen. Das für diese Problemstellung entwickelte forschungslogische Vorgehen zur Entwicklung teilhabeorientierter Interventionen wurde dann auf die Interventionsentwicklung für Menschen nach Schlaganfall im stationären Setting übertragen. Diese Niederschrift fokussiert auf die Darstellung der Interventionsentwicklung für Menschen mit Gelenkkontrakturen, um auf die notwendigen Entwicklungsschritte in einem angemessenen Detaillierungsgrad eingehen zu können, verweist jedoch an den passenden Stellen auf die entsprechenden Arbeiten, die im Rahmen der Entwicklung teilhabeorientierter Interventionen für Menschen nach Schlaganfall durchgeführt wurden.

Hintergrund zur Versorgung von älteren Menschen mit Gelenkkontrakturen im Pflegeheim

Gelenkkontrakturen sind ein häufiges Phänomen bei Menschen in stationärer Langzeitpflege. Die Prävalenz variiert aufgrund unterschiedlicher Definitionen und schwer vergleichbarer Studienpopulationen zwischen 20 % und 75 % bei Menschen in Pflegeheimen (Harrington, Carrillo, Garfiled, Musumeci, & Scquires, 2018; Mollinger & Steffen, 1993; Resnick, 2000; Wagner et al., 2008; Yip, Stewart, & Roberts, 1996).

Es gibt Hinweise, dass das Ereignis eines Heimeinzugs selbst ein Bedingungsfaktor für die Entstehung von Gelenkkontrakturen sein könnte. Eine Untersuchung zeigte eine Zunahme von Gelenkkontrakturen nach Heimeintritt mit einer großen Varianz zwischen den beteiligten Pflegeeinrichtungen zwischen 5,4 % und 27 % neu erworbenen Gelenkkontrakturen (Wingenfeld et al., 2011).

2008 nahm der Medizinische Dienst der Krankenkassen (MDK) Maßnahmen zur Gelenkkontrakturprophylaxe in den Transparenzbericht zur Bewertung ambulanter und stationärer Pflegeeinrichtungen auf und entfachte damit einen wissenschaftlichen Diskurs über die Evidenz zu dieser Thematik. Es wurde deutlich, dass es bis zum damaligen Zeitpunkt keine einheitliche Definition von Gelenkkontrakturen gab, weder in Lehrbüchern (Bartoszek, Meyer, & Thiesemann, 2014) noch in Studien (Gnass, Bartoszek, Thiesemann, & Meyer, 2010). Noch gab es Informationen dazu, welche Einschränkungen Bewohner/-innen infolge von Gelenkkontrakturen konkret erleben und es gab auch keine Assessmentinstrumente, die diese Folgen hinreichend abbilden konnten (Bartoszek et al., 2014). Diese Debatte führte zur Entscheidung des MDK, Maßnahmen zur Gelenkkontrakturprophylaxe als Bewertungskriterium des Transparenzberichts zur Bewertung ambulanter und stationärer

Pflegeeinrichtungen wieder zu entfernen und bildete den Ausgangspunkt für eine Forschungskooperation von Arbeitsgruppen aus München und Witten, die sich systematisch mit den Auswirkungen von Gelenkkontrakturen der betroffenen Menschen auseinandersetzt.

Das Phänomen der Gelenkkontrakturen ist beispielhaft für ein chronisches Gesundheitsproblem. An der Versorgung von Menschen mit Gelenkkontrakturen in Pflegeheimen sind sowohl Pflegende, Therapeutinnen und Therapeuten, Hausärztinnen und Hausärzte, Mitarbeitende von Sanitätshäusern und bestenfalls auch Angehörige beteiligt. Entsprechend der biopsychosozialen Perspektive der World Health Organization (WHO, 2001) geht es in der Versorgung nicht nur darum, Gelenkkontrakturen bei bestehenden physischen und psychischen Vorerkrankungen zu vermeiden, sondern Aktivitäts- und Teilhabeeinschränkungen auch bei bestehenden Gelenkerkrankungen so gering wie möglich zu halten. Dabei spielen Umweltfaktoren wie der Einsatz von Hilfsmitteln oder die Anpassung der direkten Lebensumgebung eine nicht zu unterschätzende Rolle.

Die Berücksichtigung einer solchen Mehrdimensionalität eines Gesundheitsproblems bzw. einer Versorgungssituation ist für die Entwicklung wirksamer Interventionen von großer Bedeutung (Craig et al., 2008). Um eine bestimmte Zielgröße bei einem komplexen Gesundheitsproblem zu adressieren, ist es somit häufig notwendig, mehr als einen Interventionsbestandteil einzusetzen, um das Ziel zu erreichen. Die bisher vorrangig etablierten singulären Interventionen trugen nur unzureichend der Komplexität der Versorgungssituation chronischer Erkrankungen Rechnung. Aus diesem Grund entstanden im vergangenen Jahrzehnt eine Reihe methodischer Rahmenkonzepte, die bei der Interventionsentwicklung die Vielschichtigkeit der Versorgungssituation stärker berücksichtigten (Corry, Clarke, While, & Lalor, 2013). Interventionen, die sich aus mehreren Komponenten zusammensetzen, die einer Zielerreichung dienen, sich wechselseitig verstärken und voneinander abhängig sind, werden auch als komplexe Interventionen bezeichnet (Craig et al., 2013). Das Rahmenkonzept des UK Medical Research Council (MRC) zur Entwicklung komplexer Interventionen stellt dabei aktuell ein Referenzmodell da und wurde bisher am häufigsten in Studien zur Entwicklung von Multikomponenteninterventionen eingesetzt (Corry et al., 2013).

Zum Beginn der hier vorliegenden Forschungsarbeit gab es keine Studien, die Interventionen für Menschen in Pflegeheimen methodisch entsprechend der Komplexität der vorliegenden Versorgungssituation umsetzten. Die Versorgungsforschung braucht jedoch dringend erprobte methodische Verfahren, um Interventionen für komplexe Versorgungssituationen zu etablieren, da die Zyklen solcher Interventionsentwicklung und -etablierung sehr lange dauern und durch wiederholte Anpassung Zeit verloren geht.

Damit Umsetzungslösungen für die theoretischen Empfehlungen des MRC in spezifischen Settings weiter zur Methodenverfeinerung in der Entwicklung komplexer Interventionen beitragen können, braucht es eine detaillierte Beschreibung von Entwicklungszyklen in den jeweiligen Settings.

2 Zielstellung

Daher widmet sich die vorliegende Habilitationsschrift der methodisch-kritischen Umsetzung der Empfehlungen des UK MRC Rahmenkonzeptes zur Entwicklung komplexer Interventionen am Beispiel der Interventionsentwicklung zur Verbesserung der Teilhabe bei Menschen mit Gelenkkontrakturen im Setting Pflegeheim.

Das MRC Rahmenkonzept gibt einen Handlungskorridor zur Entwicklung komplexer Interventionen, der einen deutlichen Umsetzungsspielraum je Ziel, Setting und Zielgruppen eröffnet. Da bisher konkrete Methodenkonzepte für die stationäre Langzeitpflege fehlen, ist es nicht nur das Ziel, eine Intervention zur Verbesserung der sozialen Teilhabe von Menschen mit Gelenkkontrakturen im Pflegeheim zu entwickeln, sondern auch ein methodisches Verfahren für die Entwicklungsschritte Modellierung und Pilotierung einer Intervention (Abbildung 1) zu erproben, um zu den methodischen Standards für die Interventionsentwicklung für Menschen in stationären Settings beizutragen.

3 Methodischer Rahmen zur Entwicklung komplexer Interventionen

Das MRC Rahmenkonzept zur Entwicklung komplexer Interventionen beschreibt Schritte einer sorgsamen Interventionsentwicklung von der Beschreibung des Versorgungsproblems, über die Interventionsentwicklung bis hin zur Implementierung der auf Wirksamkeit geprüften Intervention. Die Konzeptphasen sind als zirkulär zu verstehen, so dass Ergebnisse einer nachgelagerten Entwicklungsphase durchaus eine vorhergegangene Entwicklungsphase informieren kann und dadurch eine kontinuierliche Korrektur des Entwicklungsprozesses möglich ist.
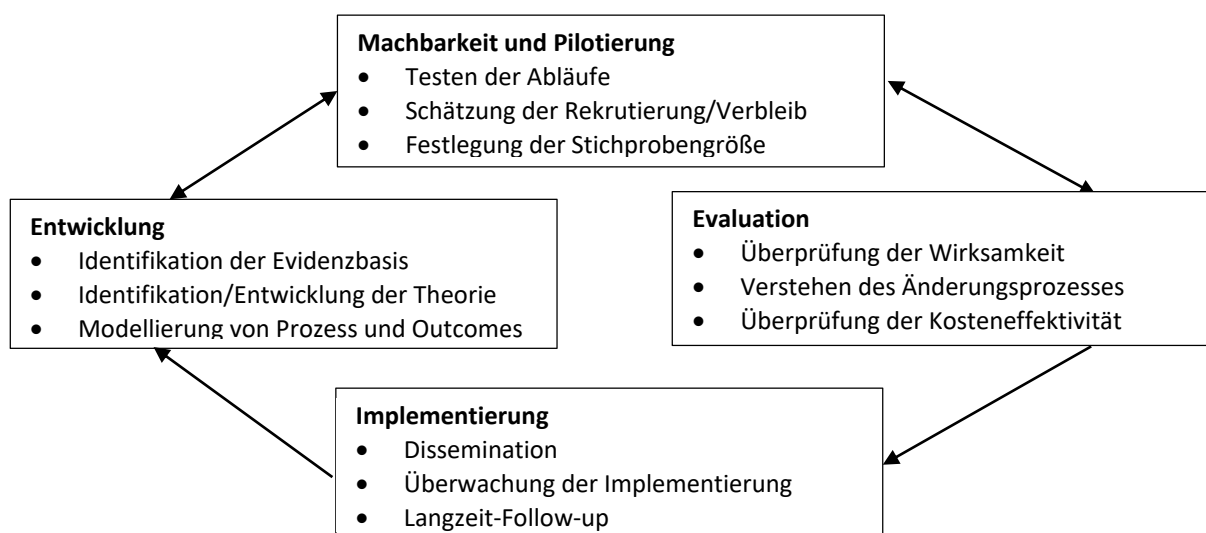
Abbildung 1 – Schlüsselelemente des Entwicklungs- und Evaluationsprozesses des MRC Rahmenkonzeptes, Übersetzung aus Craig et al. (2008)

In dieser Arbeit werden anhand von vier aufeinander aufbauenden Veröffentlichungen die Phasen der Entwicklung und Pilotierung einer Intervention für Menschen mit Gelenkkontrakturen näher beschrieben, die methodischen Herausforderungen dieser Phasen kritisch diskutiert und an den jeweiligen Stellen des methodischen Vorgehens auf die Übertragung der Interventionsentwicklung für Menschen nach Schlaganfall in stationären Settings anhand von weiteren drei Arbeiten verwiesen.

4 Problembeschreibung

Die Problembeschreibung wird im MRC Rahmenkonzept (Craig et al., 2008, 2019) nicht explizit als Phase der Interventionsentwicklung beschrieben. Dennoch kann eine Intervention nur dann erfolgreich entwickelt werden, wenn das zu adressierende Problem in all seinen bedeutsamen Facetten bekannt ist. Einen wichtigen Beitrag zur vorliegenden Interventionsentwicklung bildeten Vorarbeiten zur ausführlichen Problembeschreibung einer Arbeitsgruppe aus München und Witten. Die Arbeitsgruppe beschrieb die Auswirkungen von Gelenkkontrakturen auf den Alltag der Pflegeheimbewohner/-innen in mehreren Untersuchungen näher und schuf damit den Ausgangspunkt der in dieser Habilitationsschrift präsentierten Forschungsarbeiten. Die Arbeitsgruppen aus München und Witten befragten 149 Menschen mit Gelenkkontrakturen ab 65 Jahren in elf Pflegeheimen und drei geriatrischen Rehabilitationskliniken standardisiert (Bartoszek, Fischer, Grill, et al., 2015), führten 43 problemzentrierte Interviews mit Menschen mit Gelenkkontrakturen ab 65 Jahren (Fischer et al., 2014a) und eine onlinebasierte Expertenbefragung mit 80 Personen aus der Gesundheitsversorgung durch (Fischer et al., 2014). Die Ergebnisse zeigten, dass sowohl Menschen mit Gelenkkontrakturen als

auch Expertinnen und Experten der Gesundheitsversorgung eine große Vielfalt an Auswirkungen auf die Funktionsfähigkeit und soziale Teilhabe beschrieben. Dabei wurden insbesondere die Einschränkungen der individuellen Mobilität mit Gelenkkontrakturen assoziiert. Eine standardisierte Befragung von 150 Patienten aus drei akutgeriatrischen Krankenhäusern rund um München bestätigte, dass die meisten Probleme infolge von Gelenkkontrakturen im Bereich der Mobilität liegen, die offenbar mit den ebenfalls sehr häufig geäußerten Teilhabeeinschränkungen und der notwendigen Unterstützung durch andere in Beziehung stehen (Fischer et al., 2014b).

Aufgrund der Ätiologie von Gelenkkontrakturen bei älteren, zum Teil multimorbiden Menschen ist davon auszugehen, dass die Verhinderung der Entstehung von Gelenkkontrakturen bei dieser Zielgruppe nur begrenzt möglich ist. Die Befunde zur Vielfältigkeit der Einschränkungen für ältere Menschen in Pflegeheimen infolge von Gelenkkontrakturen sowie deren umfangreiche Auswirkungen auf die soziale Teilhabe führten zur leitenden Forschungsfragestellung, wie die Teilhabe von Menschen mit Gelenkkontrakturen in Pflegeheimen verbessert werden kann. Das schließt Maßnahmen der Prävention von Gelenkkontrakturen ebenso mit ein wie Maßnahmen für Verbesserung der Teilhabe bei bestehenden Gelenkkontrakturen.

Diese Fragestellung leitete den im folgenden beschriebenen Entwicklungsprozess. Die Phase der Entwicklung komplexer Interventionen nach dem UK MRC Rahmenkonzept umfasst die Identifikation bereits bestehender Evidenz (Abschnitt 5), die Entwicklung einer Theorie (Abschnitt 6) sowie die Modellierung des Prozesses (Abschnitt 7.1) und der Outcomes (Abschnitt7.3) (Craig et al., 2013).

5   Identifikation bereits bestehender Evidenz

Dazugehörige Veröffentlichungen:

⇒   Anlage 1: 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. 2017; Age Ageing; 46(3): 373-382.

Um *research waste* zu vermeiden, sollte vor Beginn einer Interventionsentwicklung immer die aktuell bestehende Evidenz systematisch gesichtet werden (Ioannidis et al., 2014). So wird ersichtlich, ob und welche Interventionen bereits existieren, die das Versorgungs- bzw. Gesundheitsproblem bereits adressieren und was zu deren Wirksamkeit bereits bekannt ist. Ist dazu keine systematische Evidenz vorhanden, sollte diese in diesem Schritt erstellt werden (Craig et al., 2013; Ioannidis et al., 2014).

Zur Versorgung von Menschen mit Gelenkkontrakturen in Pflegeheimen gibt es wenig Evidenz. Die bisher vorhandenen Reviews zeigten, dass sich die bestehenden Studien zur Versorgung von Menschen mit Gelenkkontrakturen vorrangig auf Outcomes der Körperfunktionen und besonders auf das Bewegungsausmaß des Gelenkes (range of motion) konzentrierten (Katalinic, Harvey, & Herbert, 2011; Prabhu, Swaminathan, & Harvey, 2013; Scheffell & Hantikaine, 2011). Die eingeschlossenen Studien fokussierten dabei beinah ausschließlich auf die Therapie von Gelenkkontrakturen. Aus Vorarbeiten war jedoch bekannt (Bartoszek, Fischer, Grill, et al., 2015; Fischer et al., 2014a), dass das Ausmaß des Bewegungsumfangs für Menschen mit Gelenkkontrakturen weit weniger relevant ist als die sich daraus ergebenden Einschränkungen auf die Aktivitäten und Teilhabe. Eine weitere Limitierung der bestehenden Evidenz war, dass die systematischen Übersichtsarbeiten Studien zusammenfassten, die sowohl jüngere als auch ältere Erwachsene adressierten und die Gruppe der älteren Menschen nicht getrennt betrachteten. Es ist jedoch davon auszugehen, dass ältere Menschen auf Interventionen wie zum Beispiel Dehnungsübungen körperlich anders reagieren als jüngere Menschen. Aus diesem Grund war es notwendig, eine eigene systematische Übersichtsarbeit durchzuführen, die Studien mit älteren Menschen untersuchte und alle relevanten Outcomes, von Körperfunktionen bis hin zu Aktivitäten und Teilhabe, erfasst.

Die systematische Übersichtsarbeit verglich die Wirksamkeit von Interventionen für Prävention und Behandlung von Behinderung infolge von Gelenkkontrakturen bei älteren Menschen mit anderen Interventionen bzw. der Regelversorgung (Saal et al., 2017).

5.1 Methoden der systematischen Übersichtsarbeit

5.1.1 Recherche

Es wurden die medizinischen Datenbanken Cochrane Library, PubMed, EMBASE, PEDro, CINAHL, das Studienregister International Clinical Trials Registry Platform (ICTRP), Literaturverzeichnisse identifizierter Studien und Tagungsbände einschlägiger Tagungen systematisch gesichtet. Zusätzlich erfolgte eine Vorwärtssuche zu den eingeschlossenen Studien in Google Scholar, Web of Science sowie Scopus und es wurden persönlich bekannte Experten im Forschungsfeld kontaktiert, um in Durchführung befindliche und nichtpublizierte Studien zu identifizieren. Unter anderem wurden folgende Suchbegriffe bei der Datenbankrecherche miteinander verknüpft: *contracture* [MeSH], *joint contracture*, *social participation*, *aged* [MeSH], *randomized controlled trial*, *controlled clinical trial*. Die Recherche fand zwischen November 2014 und Februar 2015 statt und wurde im August 2016 aktualisiert. Es wurden kontrollierte und randomisierte kontrollierte Studien eingeschlossen, wenn in englischer oder deutscher Sprache publiziert waren, die interessierende Intervention gegen eine

andere Intervention oder gegen die Regelversorgung verglichen wurde und die Studienpopulation ein Alter von ≥ 65 Jahren hatte.

5.1.2 Bewertung der Studienqualität

Die kritische Bewertung der Studienqualität folgte dem Cochrane Handbook for Systematic Reviews of Interventions, Version 5.1.0 (Higgins & Green, 2011). Zwei Forschende führten unabhängig voneinander den Studieneinschluss, die Bewertung der Studienqualität und die Datenextraktion durch und Konsens im Falle von Uneinigkeit wurde durch eine dritte Person herbeigeführt. Die ausführliche Suchstrategie und alle Einschluss- und Ausschlusskriterien sind im Supplement der Publikation in der Anlage 1 beschrieben.

5.1.3 Datenextraktion und -synthese

Die Datenextraktion wurde durch zwei Forschende unabhängig voneinander durchgeführt. Informationen zu den Studieninterventionen wurden mit Hilfe eines Templates zur Interventionsbeschreibung und -replikation (TIDieR) extrahiert. Wie erwartet waren die eingeschlossenen Studien sehr heterogen bezüglich der Studiensettings, der Interventionen und Outcomes, so dass entsprechend der Empfehlungen des York Centre for Reviews and Dissemination (CRD, 2009) eine narrative Synthese durchgeführt wurde. Zur Visualisierung wurde die Methode des Harvest Plots verwendet.

5.2 Ergebnisse der systematischen Übersichtsarbeit

Die Abbildung 2 beschreibt den Suchverlauf. Siebzehn Studien mit insgesamt 992 Studienteilnehmenden entsprachen den Einschlusskriterien: sechzehn randomisierte kontrollierte Studien (RCT) und eine kontrollierte Studie (CCT). Vier davon fanden in Pflegeheimen statt und 13 in der häuslichen Versorgung. Die Stichprobengrößen der Studien variierten zwischen acht und 208 Teilnehmenden im Alter zwischen 58 und 86 Jahren. In einer Studie lag das mittlere Alter der Kontrollgruppe mit 58 Jahren unter der festgelegten Altersgrenze von 65 Jahren. Da jedoch die Interventionsgruppe ein mittleres Alter von 66 Jahren hatte, wurde entschieden, die Studie ebenfalls einzuschließen. Die Beschreibung der Studienmerkmale sind in der Publikation in der Anlage 1 zusammengefasst.

Vier Studien berichteten Ergebnisse zu Schienen, neun zu Dehnungsübungen und jeweils eine Studie untersuchte Ultraschall, passive Bewegungstherapie, ein Lagerungsprogramm und ein Gruppenübungsprogramm. Die methodische Qualität der Studien variiert und ist im Supplement der Publikation in der Anlage 1 dargestellt.

Dreizehn Studien untersuchten die Gelenkbeweglichkeit (Christiansen, 2008; Cristopoliski, Barela, Leite, Fowler, & Rodacki, 2009; Falconer, Hayes, & Chang, 1992; Feland, Myrer, Schulthies, Fellingham,

& Measom, 2001; Fox, Richardson, McInnes, Tait, & Bedard, 2000; Gajdosik, Vander Linden, McNair, Williams, & Riggin, 2005; Jongs, Harvey, Gwinn, & Lucas, 2012; Kerrigan, Xenopoulos-Oddsson, Sullivan, Lelas, & Riley, 2003; Light, Nuzik, Personius, & Barstrom, 1984; Reid & McNair, 2011; Steffen & Mollinger, 1995; J. R. Watt et al., 2011; J.R. Watt et al., 2011a), drei Spastizität (Hobbelen, Tan, Verhey, Koopmans, & de Bie, 2012; McPherson, Becker, & Franszczak, 1985; Sheehan, Winzeler-Mercay, & Mudie, 2006) und Schmerz (Falconer et al., 1992; Fox et al., 2000; Hobbelen et al., 2012), fünf untersuchten Durchführungsaspekte wie Gehgeschwindigkeit (Christiansen, 2008; Cristopoliski et al., 2009; Gajdosik et al., 2005; J. R. Watt et al., 2011; J.R. Watt et al., 2011a) und zwei verwendeten Fragebögen zur Selbsteinschätzung der Aktivitäten des täglichen Lebens (Jongs et al., 2012; Kudo et al., 2013). Keine der Studien untersuchte unerwünschte Wirkungen, obwohl diese ein wesentlicher Aspekt der Wirksamkeitsprüfung sind (Golder, Loke, Wright, & Norman, 2016; Honvo et al., 2019).
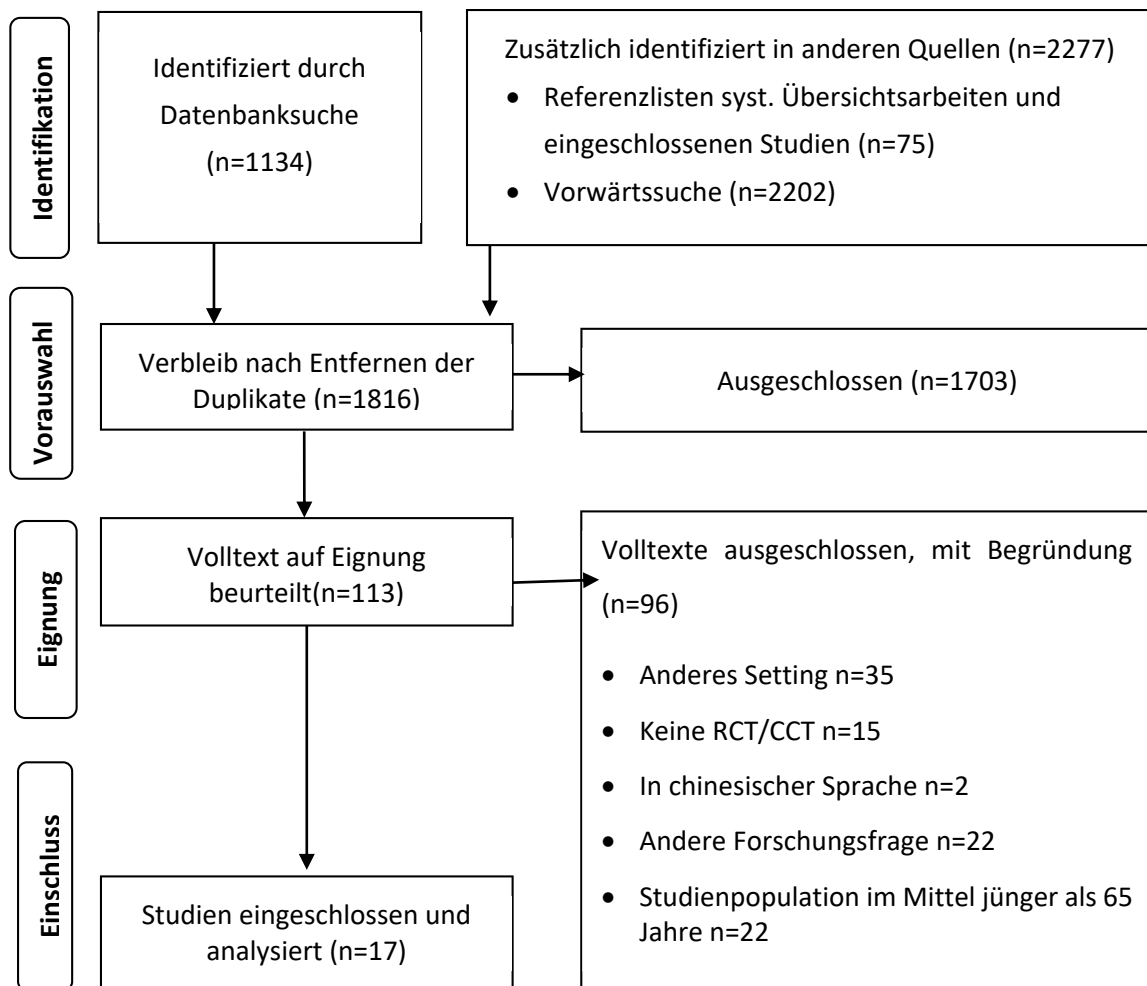
Abbildung 2 – Flussdiagramm zum Studieneinschluss der systematischen Übersichtsarbeit (übersetzt aus Saal et al. 2017)

Fünf der sieben Studien, die aktive Dehnungsprogramme bei gesunden älteren Menschen untersuchten, berichteten statistisch signifikante Effekte auf die Gelenkbeweglichkeit zugunsten der Dehnungsinterventionen (Christiansen, 2008; Cristopoliski et al., 2009; Feland et al., 2001; Gajdosik et

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al., 2005; Reid & McNair, 2011). Nur eine von vier Studien, die die Wirksamkeit von Schienen untersuchten, berichtete signifikante Verbesserungen der passiven Gelenkbeweglichkeit (Jongs et al., 2012). Eine Studie, die ein Gruppenübungsprogramm untersuchte, beobachtete signifikante Verbesserungen in den Aktivitäten des täglichen Lebens (Kudo et al., 2013). Keine Effekte zeigten sich für ein aktives Dehnungsübungsprogramm für gebrechliche ältere Menschen (Light et al., 1984; J. R. Watt et al., 2011), Ultraschall (Falconer et al., 1992), passive Bewegungstherapie (Hobbelen et al., 2012) und ein Lagerungsprogramm (Fox et al., 2000). Die untersuchten Studien betrachteten selten Outcomes wie Schmerz, Lebensqualität, Einschränkungen der Aktivitäten und der Partizipation. Insgesamt ist die Qualität der Evidenz als gering einzuschätzen und stellt somit keine verlässliche Basis zur weiteren Interventionsentwicklung dar. Ein Überblick zu den Effekten der Studieninterventionen gibt die Abbildung 3.
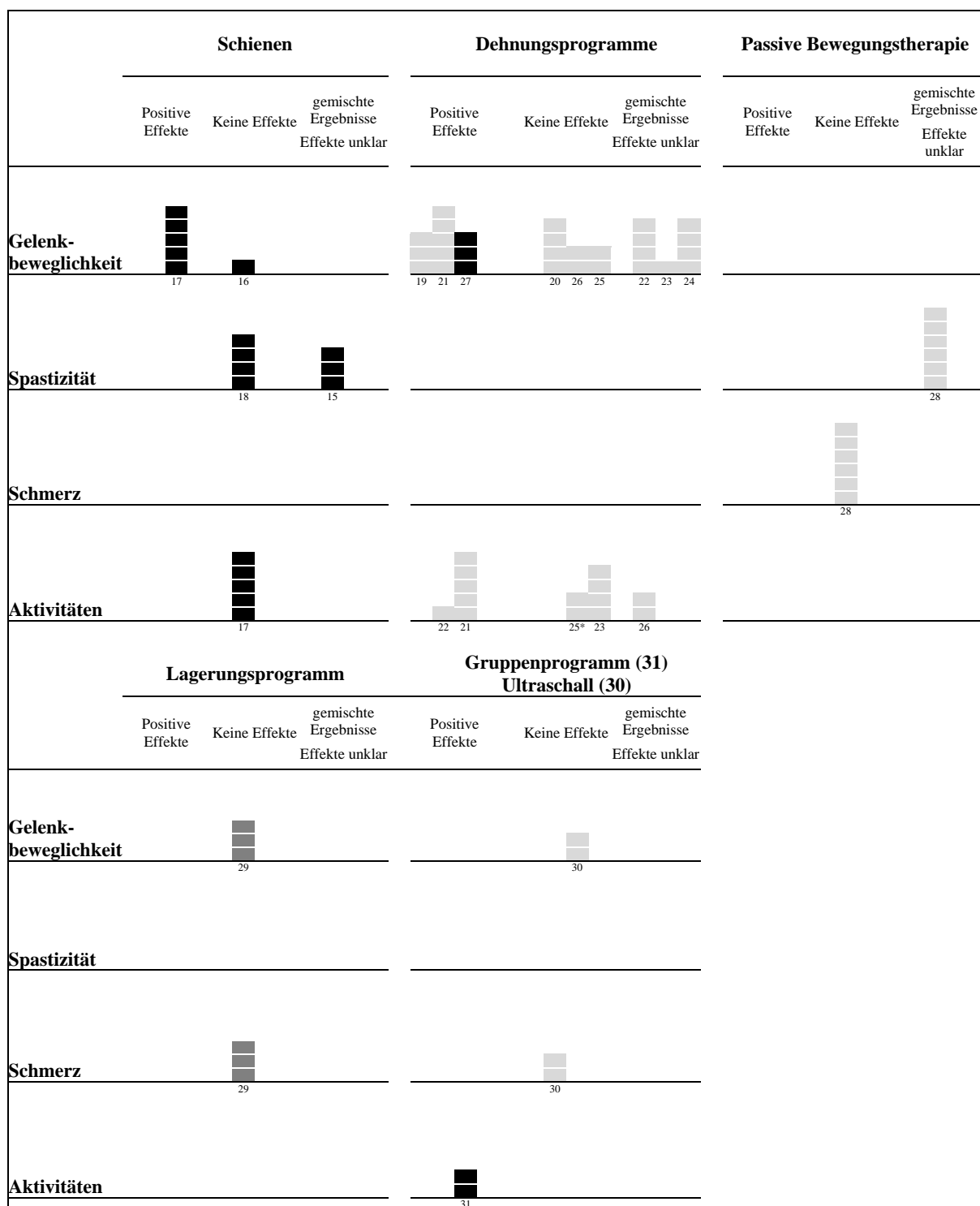
Die methodische Qualität des Studiendesigns wird durch die Höhe der Säulen visualisiert (je höher die Säule, desto besser die methodische Qualität anhand der risk of bias Zusammenfassung. Die Zahlen unter den Säulen entsprechen den Referenznummern. The Farbe der Säulen weisen auf die Art der Kontrollintervention hin (hellgrau – Intervention versus keine Intervention/Scheinintervention, dunkelgrau – zusätzlich zur Regelversorgung; schwarz – versus eine andere Intervention).

Abbildung 3 - Harvest plots zur Zusammenfassung der Effekte der Studieninterventionen (übersetzt aus Saal et al. 2017)

Exkurs 1 – Identifikation bestehender Evidenz für Verbesserung der Teilhabe von Menschen nach einem Schlaganfall im Übergang von stationärer in poststationäre Versorgung

Im Rahmen der Habilitation wurde wie bereits eingangs erwähnt, das methodische Verfahren zur Entwicklung komplexer Intervention auf eine zweite Zielgruppe übertragen, die der Menschen nach einem Schlaganfall im Übergang von der stationären in die poststationäre Versorgung. Das Versorgungsgeschehen im Sektorenübergang wird sowohl durch die potentielle Vielzahl sowie Heterogenität der Symptomatik nach einem Schlaganfall bestimmt als auch durch die Vielfalt an möglichen Zielstellungen im Rahmen der Überleitung sowie der damit zusammenhängenden Akteure. Vorarbeiten zeigten Versorgungsbrüche im Übergang von stationärer zu poststationärer Versorgung von Schlaganfallbetroffenen (Saal et al., 2015; Zein & Saal, 2017). In Anlehnung an das Vorgehen zur Entwicklung einer teilhabeverbessernden Intervention für Menschen in stationärer Langzeitpflege, wurde auch für die Zielgruppe der Schlaganfallpatientinnen und -patienten im Übergang von stationärer in die ambulante Versorgung das Problem im Vorfeld näher beschrieben. Dazu wurden problemzentrierte Fokusgruppen- und Einzelinterviews mit stationär und ambulant tätigen Ärzten, Therapeuten und Pflegenden durchgeführt und Patientinnen und Patienten standardisiert befragt (Saal, Kirchner-Heklau, et al., 2019). Auch wurden 14 Experten- und drei Gruppeninterviews (n = 18) durchgeführt. Als Einflussfaktoren der Überleitung wurden u. a. Aspekte der Kommunikation, der sozialen Unterstützung und des Rollenverständnisses der Patienten identifiziert. Die standardisierte Patientenbefragung (n = 110) zeigte eine Umsetzung von Empfehlungen fachärztlicher Konsultationen von 37 % und von ambulanten Therapien bis zu 86 %.

Ergänzend dazu wurde systematisch die Evidenz aufgearbeitet, um potentielle Interventionen zu identifizieren, die die Kontinuität notwendiger Gesundheitsleistungen verbessern (Saal, Kirchner-Heklau, et al., 2019). Aufgrund der zu erwartenden Vielzahl an unterschiedlichen Interventionen wurde in einem ersten Schritt ein Scoping-Review durchgeführt. Der Scoping Review identifizierte sieben systematische Übersichtsarbeiten, 21 randomisierte und fünf kontrollierte Studien zu edukativen Maßnahmen, Information und Beratung, Early Supported Discharge, stroke liaison services, interprofessionellen Teamkonferenzen und Versorgungspfaden. Zur Verbesserung der Überleitung nach Hause ist es notwendig, über die Fallebene der Patienten hinaus, Abläufe innerhalb und zwischen den versorgenden Einrichtungen zu berücksichtigen. Die im Scoping-Review identifizierten Interventionen adressierten jedoch in der Regel nur eine Ebene, die Fallebene (u. a. Patientenedukation, Beratung) oder die Organisationsebene (Teamkonferenzen und Versorgungs- pfade). Eine Intervention zur Verbesserung der Kontinuität der Versorgung, die den

Rahmenbedingungen des deutschen Gesundheitssystems gerecht wird und beide Handlungsebenen gleichermaßen adressiert, liegt bisher nicht vor.

6 Identifikation und Entwicklung einer Theorie

Dazugehörige Veröffentlichungen:

$\Rightarrow$ Anlage 2: 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 Geriatrics 2018; 18 (1): 61.

Wenn wie in dem vorliegenden Fall eine sehr schwache Evidenz zu geeigneten Strategien vorliegt, nimmt eine systematische Auseinandersetzung mit dem theoretischen Verständnis der angestrebten Veränderungsprozesse eine zentrale Bedeutung in der Interventionsentwicklung ein (Craig et al., 2013). Dazu können bestehende Evidenz und Theorien herangezogen werden oder falls notwendig neu geforscht werden (Moore et al., 2015). Bereits in den Vorstudien wurden die standardisierten (Bartoszek, Fischer, Grill, et al., 2015; Fischer et al., 2014b) und qualitativen Interviews (Fischer et al., 2014a) vor dem Hintergrund des biopsychosozialen Modells der International Classification of Functioning, Disability and Health (ICF) der World Health Organization (WHO) analysiert, um einen größtmöglichen Teilhabebezug der Ergebnisse herzustellen. Da sich das biopsychosoziale Modell der ICF als strukturierendes Element in der Problemanalyse bewährt hat, wurde es als theoretischer Ansatz zur Erklärung der Interventionswirkweise fortgeführt.

Basis der Interventionsentwicklung waren aufgrund der unzureichenden Evidenzlage die die systematische Übersichtsarbeit ergeben hat, ausschließlich die Probleme, die die Menschen mit Gelenkkontrakturen in Interviews der Vorarbeiten geschildert hatten sowie die Hauptzielstellung der Verbesserung der Teilhabe. Im Fokus dieses Arbeitsschrittes stand die Identifikation potentieller Interventionsziele, die als Teilziele der Verbesserung der Teilhabe dienen (Abbildung 4).
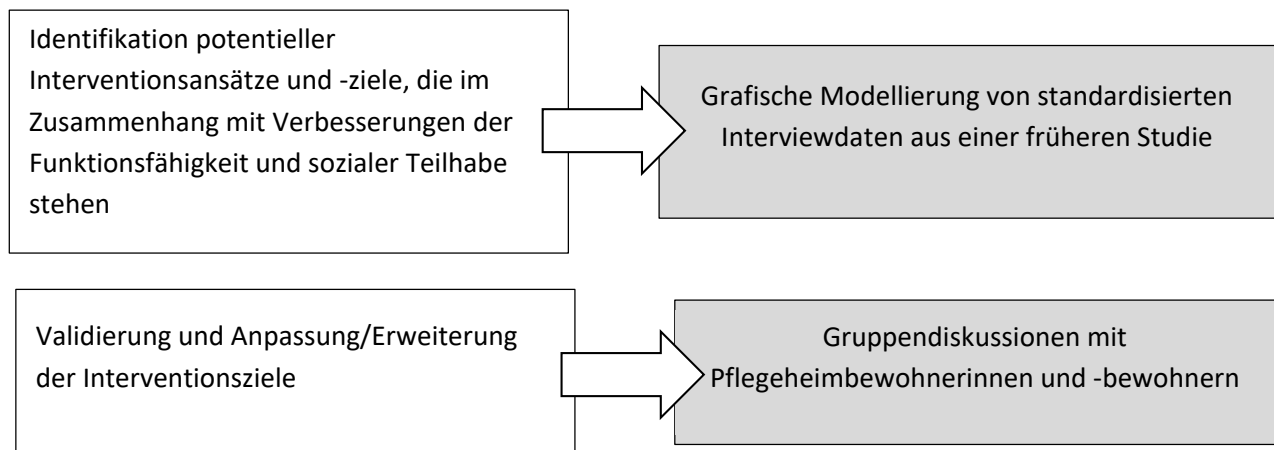
Abbildung 4 – Methodisches Vorgehen zur Identifikation von Interventionszielen (übersetzt aus Saal et al. 2018)

6.1 Grafische Modellierung von standardisierten Interviewdaten aus einer früheren Studie

Eine grafische Modellierung von Daten aus einer Vorstudie (Fischer et al., 2014b) hatte das Ziel, Hinweise auf potentielle Interventionsziele zu gewinnen. Eine grafische Modellierung ist ein Verfahren, das mögliche Abhängigkeiten zwischen verschiedenen Variablen in einer netzartigen Struktur visualisiert (Becker et al., 2011; Strobl, Stucki, Grill, Müller, & Mansmann, 2009). Es wurde davon ausgegangen, dass Variablen, die mit besonders vielen anderen Variablen vernetzt sind, als relevante Ansatzpunkte der Intervention dienen können. Der verwendete Datensatz umfasste Befragungsdaten von 294 Teilnehmerinnen und Teilnehmern mit mindestens einer Gelenkkontraktur aus drei geriatrischen Abteilungen von Krankenhäusern in und um München und aus 11 Pflegeheimen sowie drei geriatrischen Rehabilitationseinrichtungen in und um Witten, Nordrhein-Westfalen.

6.2 Gruppendiskussionen mit Pflegeheimbewohnerinnen und -bewohnern

In einem zweiten Schritt wurden leitfadengestützte Gruppendiskussionen mit Pflegeheimbewohner-innen und -bewohnern in München und Witten zwischen März und Juni 2015 durchgeführt. Konkretes Ziel des Interviews war es, Barrieren und Förderfaktoren für Aktivitäten und Teilhabe zu identifizieren und die Interventionsziele zu validieren, die sich aus der grafischen Modellierung ergeben haben. Die Auswertung erfolgte deduktiv entlang der Kategorien der ICF. Näheres zum methodischen Vorgehen beschreibt die Publikation in der Anlage 2.

6.3 Ergebnisse aus der grafischen Modellierung und der Gruppendiskussionen

Die grafische Modellierung ergab, dass Einschränkungen in der Fortbewegung, Gehen in Gebäuden, Gedächtnisfunktionen und Hand- und Armgebrauch am häufigsten mit anderen Variablen assoziiert sind und deshalb vielversprechende Interventionsansätze sein können. In sieben Gruppendiskussionen mit insgesamt 33 Pflegeheimbewohnerinnen und -bewohnern (88 % weiblich; mittleres Alter 85 Jahre) wurden Einschränkungen in den ICF-Kategorien *Mobilität und Selbstversorgung* in der Domäne *Umweltfaktoren* am häufigsten von den Interviewten als Barrieren der Aktivitäten und Teilhabe berichtet. Damit bestätigte sich, dass die Mobilität und der Arm- und Handgebrauch zur Selbstversorgung zentrale Aspekte der Verbesserung der Teilhabe sind. Ausführliche Ergebnisse sind in der Publikation in der Anlage 2 dargestellt.

7 Modellierung des (Implementierungs-)Prozesses und der Outcomes

Dazugehörige Veröffentlichungen:

⇒ Anlage 2: 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. 2018; BMC Geriatrics; 18:61.

7.1 Methoden der Modellierung des (Implementierungs-) Prozesses

Die Modellierung des (Implementierungs-) Prozesses beinhaltet sowohl die Erstellung der Interventionsinhalte und deren Abstimmung aufeinander als auch die Entwicklung einer Strategie, wie diese Inhalte in die Pflegeheime transferiert werden sollen (Implementierung). Die Teilschritte dieser Arbeitsphase sind in der Abbildung 5 zusammenfassend dargestellt.

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┌─────────────────────────────────┐          ┌─────────────────────────────────┐
│ Zusammenstellen der             │          │ Strukturierter zweitägiger      │
│ Interventionskomponenten zu den │  ═══▷    │ Expertenworkshop                │
│ Interventionszielen             │          │                                 │
└─────────────────────────────────┘          └─────────────────────────────────┘

┌─────────────────────────────────────────────────────────────────────────────┐
│              Entwicklung eines initialen Interventionsprotokolls             │
└─────────────────────────────────────────────────────────────────────────────┘

┌─────────────────────────────────┐          ┌─────────────────────────────────┐
│                                 │  ═══▷    │ Schriftliches Feedback der      │
│                                 │          │ Workshopteilnehmenden           │
│ Kritischer Review- und          │          └─────────────────────────────────┘
│ Konsensusprozess                │          ┌─────────────────────────────────┐
│                                 │  ═══▷    │ Gruppendiskussion mit Pflegenden│
│                                 │          │                                 │
└─────────────────────────────────┘          └─────────────────────────────────┘

┌─────────────────────────────────────────────────────────────────────────────┐
│        Finalisierung des Interventionsprotokolls für eine Pilotstudie        │
└─────────────────────────────────────────────────────────────────────────────┘
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Abbildung 5 – Methodisches Vorgehen in der Modellierung des (Implementierungs-) Prozesses (übersetzt aus Saal et al. 2018)

7.1.1 Expertenworkshop und schriftliches Feedback von Workshopteilnehmenden

Ein zweitägiger strukturierter Workshop mit acht Teilnehmenden (zwei Personen mit geriatrischer Expertise, drei Personen mit pflegewissenschaftlicher Expertise und drei Personen mit rehabilitationswissenschaftlicher Expertise) wurde durchgeführt. Zu Beginn wurden die Teilnehmenden mit den bereits vorliegenden Ergebnissen der Problembeschreibung, der Evidenzrecherche und den potentiellen Interventionszielen vertraut gemacht. Anschließend wurden in Kleinarbeitsgruppen zu den jeweiligen Interventionszielen mögliche Interventionsinhalte erarbeitet (u. a. mögliche Assessmentinstrumente, Maßnahmen zur Reduzierung von Umweltbarrieren, Maßnahmen zur Verbesserung der interprofessionellen Zusammenarbeit, Strategien zur Berücksichtigung personbezogener Faktoren) sowie Implementierungsstrategien vorgeschlagen (u. a. Einsatz und Schulung von Multiplikatoren, Schulung der Pflegenden, Strategien zur Einbindung der Heimleitung, Mitarbeiterinnen und Mitarbeitern des Sozialen Dienstes, Therapeutinnen und Therapeuten sowie Angehörigen).

Im Anschluss an den Expertenworkshop priorisierte das Forscherteam die Vorschläge zu Interventionsinhalten unter Berücksichtigung der zu erwartenden Umsetzbarkeit in den Pflegeheimen und erarbeitete auf Grundlage der Expertenvorschläge ein Implementierungskonzept. Fünf Teilnehmende des Expertenworkshops validierten das Interventionsprotokoll und das dazugehörige Implementierungskonzept im Rahmen eines schriftlichen Feedbackverfahrens.

7.1.2 Gruppendiskussion mit Mitarbeiterinnen und Mitarbeitern in Pflegeheimen

Das Interventionsprotokoll und das dazugehörige Implementierungskonzept wurden anhand der Rückmeldungen aus dem schriftlichen Feedback angepasst und mit Mitarbeiterinnen und Mitarbeitern in Pflegeheimen im Rahmen eines Feedbackgesprächs in der Gruppe diskutiert. Eine nähere Charakterisierung der Teilnehmenden ist in Anlage 2 näher dargestellt. Die Teilnehmenden beurteilten das Implementierungskonzept als machbar und umfassend und schätzten die Interventionsinhalte als bedeutsam und konsistent ein. Zusätzlich wiesen sie auf die Bedeutung einer intensiven Kooperation mit den Betreuungsassistentinnen und -assistenten des Sozialen Teams hin. Sie hoben hervor, dass für eine erfolgreiche Implementierung zwischen den einzelnen Schritten ausreichend Zeit eingeplant werden sollte, um den Multiplikatoren Zeit zu geben, zusätzlich zu ihren regulären Aufgaben ihre neue Rolle als Changemanager zu übernehmen. Das Interventionsprotokoll und das Implementierungskonzept wurden anhand der Rückmeldung der Pflegenden wiederholt angepasst und in einem logischen Modell gemeinsam mit den Grundannahmen zu den erwartenden Veränderungen durch die Interventionsimplementierung visualisiert.

7.2 Ergebnisse zur Modellierung des (Implementierungs-) Prozesses – die PECAN-Intervention

Das logische Modell in der Abbildung 6 fasst die Grundannahmen zur Wirkweise der Intervention Participation Enabling CAre in Nursing (PECAN) zusammen.

The PECAN Intervention ist ein multifaktorielles Programm zur Verbesserung der Pflege von Bewohnerinnen und Bewohnern mit Gelenkkontrakturen. Der Fokus der PECAN Intervention liegt auf der Reduzierung von Teilhabebarrieren und der Förderung teilhabebegünstigender personbezogener und Umweltaspekte bei Bewohnerinnen und Bewohnern von Pflegeheimen. Das soll erreicht werden, indem Pflegende befähigt werden, die biopsychosoziale Sichtweise der ICF im täglichen Pflegehandeln umzusetzen.

Die Implementierungskomponenten sind in der Anlage 2 näher beschrieben. Den Implementierungsablauf fasst Abbildung 7 zusammen.

Health Outcome

Improved social participation of residents

Mechanisms of impact

Attitude
Positive attitude of nurses toward the objective and the components of the intervention aimed to
- consider residents' participation goals in their daily work
- incorporate the biopsychosocial perspective in their care routines

Subjective Norm
Nurses are aware of the importance of the intervention and its goals in their daily routine by
- being attentive regarding the impact of joint contractures on the independence of the residents
- acknowledging the meaning of resources-oriented mobility enhancement and the role of environmental factors for the participation of home residents
- being convinced of the appropriate balance between costs and benefits of the measures taken

Perceived Behaviour
Nurses feel prepared for
- undertaking a systematic risk assessment regarding contractures
- considering participation goals of residents in individual care planning
- initiating and coordinating interdisciplinary care
- identifying and overcoming individual barriers of participation

Intention

Behaviour
Implementation of the *Participation Enabling CAre in Nursing* (PECAN)

Process-influencing factors
- Experience and training of multipliers
- Position of multipliers in the team
- Extent of support by superiors
- Residents' health status
- Nursing home staffing
- Time resources of the person responsible for the implementation of the intervention
- Size of institution
- Change management culture in the institution
- Extent of already existing interdisciplinary cooperation

How?
- One-day multipliers' workshop
- Flyer for therapists, informal caregivers, and physicians
- Peer-mentoring including telephone counselling for multipliers
- Reminders (posters and other materials) for residents and staff
- Peer-mentor-visit for multipliers
- Information session for residents, nurses, physicians, therapists, social workers
- Written commitment to the intervention (declaration)
- Coordination of implementation measures regarding aspects of care on organisational level with nursing home manager

What?
- Information on the phenomenon of joint contracture and its consequences
- Information on the risk of developing joint contractures; Training on risk assessment
- Information and training on how to consider residents' participation goals in individual care planning
- Information and training on methods of interdisciplinary cooperation approaches in nursing homes
- Information and training on the use of the ICF biopsychosocial model in identifying barriers and facilitators of residents' participation
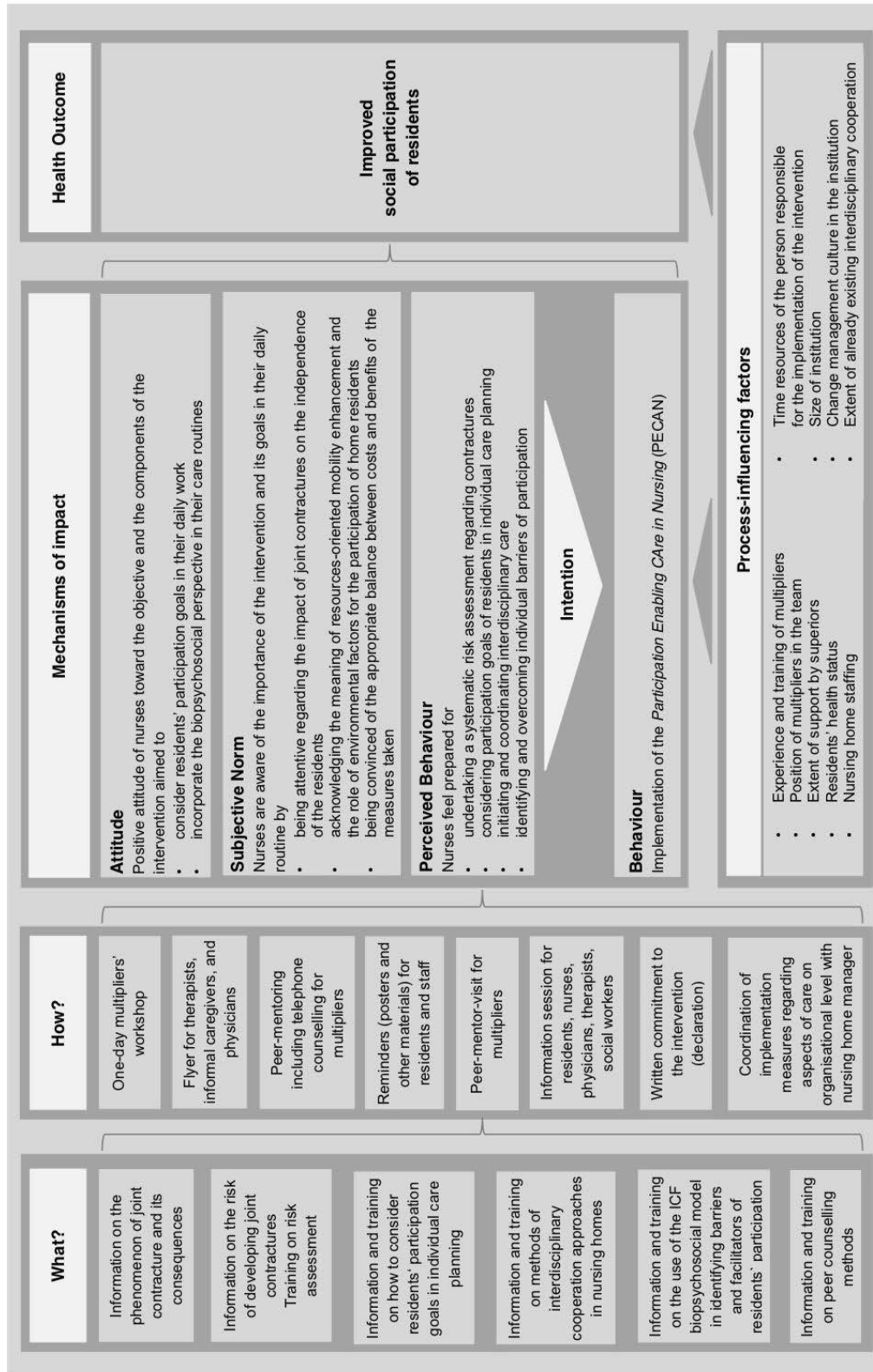- Information and training on peer counselling methods

Abbildung 6 - Logisches Modell der PECAN-Intervention (aus Saal et al. 2018)
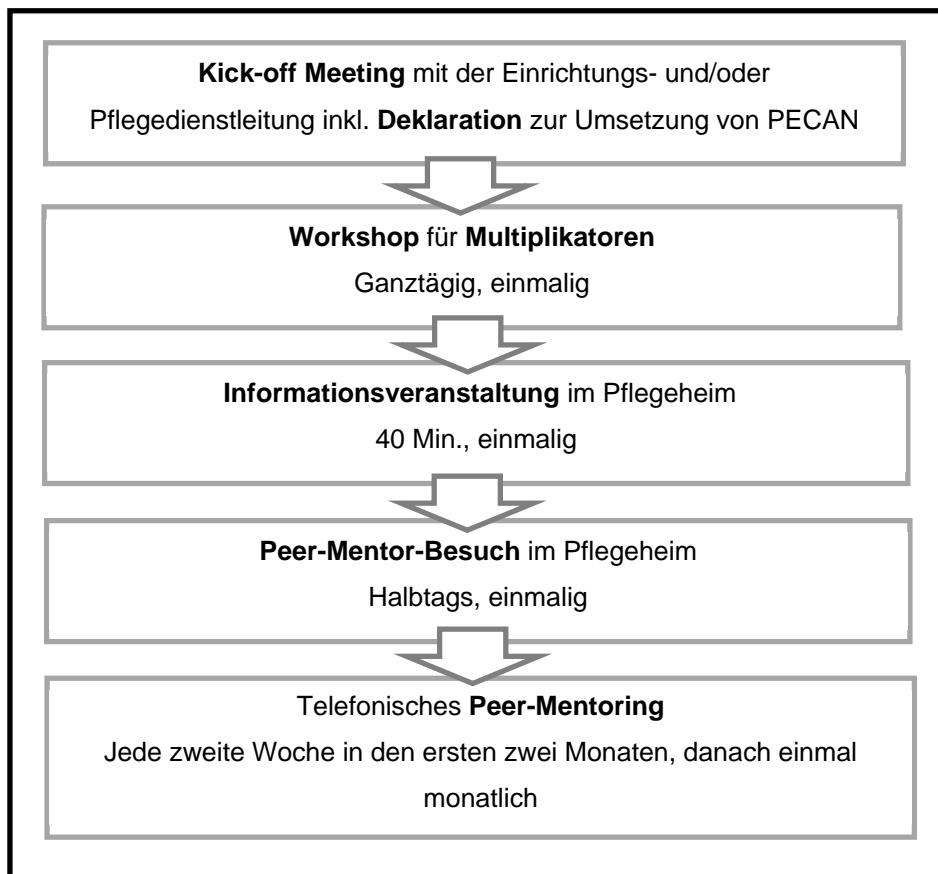
Abbildung 7 – Implementierungsablauf der PECAN Intervention

7.3 Modellierung der Outcomes

Die am häufigsten verwendete Zielgröße, um die Wirksamkeit von Interventionen bei Menschen mit Gelenkkontrakturen zu messen, ist das Bewegungsausmaß (Saal et al., 2017). Obwohl Evidenz vorliegt, dass für Betroffene mit Gelenkkontrakturen die sich aus der Bewegungseinschränkung ergebenden Aktivitäts- und Teilhabeeinschränkungen weitaus relevanter sind und diese durch eine Reihe von Umweltfaktoren beeinflusst werden können (Bartoszek, Fischer, Grill, et al., 2015; Fischer et al., 2014a; Fischer et al., 2014b), dominieren in Wirksamkeitsstudien immer noch funktionsorientierte Zielgrößen.

In einer systematischen Übersichtsarbeit im Rahmen der Problembeschreibung zeigte sich, dass zwar in den 60 identifizierten Studien 24 standardisierte Instrumente eingesetzt wurden die auch Items zur Erfassung von Aktivitäten und Teilhabe erfassen (Bartoszek et al., 2016), dennoch richten sich die standardisierten Instrumente sehr häufig auf bestimmte Erkrankungen (WOMAC, Western Ontario McMaster University Osteoarthritis Index Scales) (Bellamy, Buchanan, Goldsmith, Campbell, & Stitt, 1988) oder auf bestimmte Körperabschnitte (DASH, Disabilities of the Arm, Shoulder and Hand) (Hudak, Amadio, & Bombardier, 1996). Ein Instrument, das Teilhabe infolge von Gelenkkontrakturen

unabhängig der Genese der Gelenkkontrakturen für Menschen in Pflegeheimen erhebt, lag zum gegebenen Zeitpunkt nicht vor.

Ein solches Instrument wurde unabhängig von der Interventionsmodellierung aus einem ICF-basierten Standard-Set zur Beschreibung der Auswirkungen von Gelenkkontrakturen auf die Teilhabe von Menschen in geriatrischen Settings entwickelt und validiert (Bartoszek, Fischer, von Clarenau, et al., 2015; Müller et al., 2016).

Das neu entwickelte Instrument PaArticular Scales setzt sich aus einer Skala für Aktivitäten (24 Items) mit und einer Skala für Teilhabe (11 Items) zusammen mit einer transformierten Intervallskala von 0 (keine Probleme) bis 100 (größtmögliche Probleme) und weist eine hohe interne Konsistenz auf (Cronbach's alpha 0,96 für die Aktivitätenskala und 0,92 für die Teilhabeskala) (Müller et al., 2016).

8 Pilotierung der PECAN Intervention

> **Dazugehörige Veröffentlichungen:**
>
> ⇒ Anlage 3: 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. 2019; Trials; 20 (1): 411.
> ⇒ Anlage 4: 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. 2020; BMC Geriatrics, 20(1):270.

Wenn eine Intervention einer umfangreichen Wirksamkeitsüberprüfung unterzogen wird, sollte gewährleistet sein, dass die geplanten Untersuchungsmethoden umsetzbar und akzeptiert sind. Als häufig problematisch werden dabei Aspekte der Rekrutierbarkeit der teilnehmenden Zentren und Individuen und deren Verbleib in der Studie berichtet (Bower, Wilson, & Mathers, 2007; McDonald et al., 2006). Auch sollte sichergestellt sein, dass sowohl die Interventionsinhalte als auch die Implementierungsstrategie akzeptiert und machbar sind (Craig et al., 2019).

Eine der eigentlichen Wirksamkeitsstudie vorgeschaltete Pilotstudie leistet hierzu einen wesentlichen Beitrag und verhindert, dass die Aussagekraft von Ergebnissen zur Wirksamkeit im weiteren Verlauf durch methodische Unzulänglichkeiten des Studiendesigns oder der Interventionsimplementierung

beeinträchtigt wird. Eine Pilotstudie kann zudem dazu beitragen, zu verstehen, wie die Interventions-komponenten miteinander agieren, hilft unerwünschte Wirkungen zu identifizieren und stellt eine wesentliche Datenquelle für die Fallzahlkalkulation der Wirksamkeitsstudie dar (Blatch-Jones, Pek, Kirkpatrick, & Ashton-Key, 2018; Hallingberg et al., 2018).

Pilotstudien sind in Abgrenzung zu Machbarkeitsstudien als eine kleinere Version der Hauptstudie zu verstehen, mit dem Ziel, zu testen, ob die Komponenten der Hauptstudie zusammen funktionieren (NIHR, 2018). Eine Pilotstudie fokussiert dabei auf die Prozesse der Hauptstudie und gleicht ihr daher im Aufbau.

8.1 Methoden der Pilotierung der PECAN Intervention

8.1.1 Studiendesign und Zielstellung

Es wurde eine multizentrische Cluster-randomisierte zweiarmige Pilotstudie durchgeführt, die zum einen das Ziel hatte, die Machbarkeit des Studiendesigns und der Erhebungsabläufe zu überprüfen. Dafür wurden die teilnehmenden Pflegeheime (Cluster) per Zufallsverfahren der PECAN Intervention oder optimierter Standardversorgung (eine einmalige Informationsveranstaltung zu allgemeinen Versorgungsaspekten von Menschen mit Gelenkkontrakturen zusätzlich zur Standardversorgung) zugewiesen. Im Fokus der Evaluation stand die Überprüfung

- die Überprüfung der Machbarkeit der Rekrutierung,
- die Überprüfung des Verbleibs der teilnehmenden Cluster und Individuen,
- die Überprüfung der Verblindung,
- die Testung der gewählten Erhebungsinstrumente und Datenerhebungsverfahren die die Testung der Erfassung der Leistungsinanspruchnahme in Vorbereitung einer später geplanten gesundheitsökonomischen Evaluation auf Machbarkeit und
- die Sicherheit der Intervention hinsichtlich Stürze und sturzbedingte Frakturen.

Ein weiteres Ziel der Pilotierung war es, die Machbarkeit und Akzeptanz des Implementierungskon-zeptes zu überprüfen. Dazu wurden entsprechend der Empfehlungen für Prozessevaluationsstudien quantitative und qualitative Methoden miteinander kombiniert. Quantitative Erhebungen fokussier-ten darauf, in wie weit die Implementierung den Vorgaben des Studienprotokolls entsprach und qualitative Methoden identifizierten Barrieren und Förderfaktoren der Implementierung (Moore et al., 2015). Der Aufbau der Prozessevaluation zur Implementierung der Intervention folgte dem Rahmenkonzept für Prozessevaluationen in Cluster-randomisierten Studien nach Grant et. al. 2013 (Grant, Treweek, Dreischulte, Foy, & Guthrie, 2013). Da für eine erfolgreiche Umsetzung der PECAN-

Intervention direkt bei den Bewohnerinnen und Bewohnern eine vollständige Implementierung in die Einrichtung und den Pflegenden voraussetzt, fokussiert die Prozessevaluation der Pilotstudie auf die Implementierungsprozesse auf Heimebene.

Die PECAN-Implementierung nutzte als zentrale Strategie den Einsatz von *facilitators,* einer Funktionsbezeichnung aus dem Rahmenkonzept Promoting Action on Research Implementation in Health Services (PARIHS), die im Deutschen mit dem Begriff eines Multiplikators gleichgesetzt werden kann. Multiplikatorinnen und Multiplikatoren sind Pflegende, die in jedem Heim ernannt werden, federführend für die PECAN-Implementierung verantwortlich zu sein (Harvey & Kitson, 2016). Diese begleiten die Einrichtung und Einzelpersonen durch den Veränderungsprozess, den die Implementierung mit sich bringt (Berta et al., 2015). Die Multiplikatoren der PECAN-Implementierung wurden als Expertinnen und Experten für kontraktursensible Pflege, kurz EKON, nominiert.

8.1.2 Kontrollintervention

In den Pflegeheimen der Kontrollgruppe wurde eine einmalige 40-minütige Informationsveranstaltung für Bewohnerinnen und Bewohner, deren Familien und das Pflegeheimpersonal durchgeführt. Die Themen umfassten Ursachen, Risiken und Folgen von Gelenkkontrakturen sowie allgemeine Informationen zum Projektablauf.

8.1.3 Teilnehmende und Setting

Pflegeheime wurden als Cluster in zwei Regionen Deutschland (in und um München und in und um Halle (Saale)) aus einer Gelegenheitsstichprobe eines bestehenden Kooperationsnetzwerks von Praxispartnern gewonnen. Die Einladung der Pflegeheime erfolgte postalisch und telefonisch zur Studienteilnahme. Eine Vorstellung der Studie im Pflegeheim wurde angeboten. Ein Pflegeheim konnte an der Studie teilnehmen, wenn mindestens 25 Bewohnerinnen und Bewohner der Einrichtung eine Gelenkkontraktur aufwiesen.

Die Gewinnung der Bewohnerinnen und Bewohner startete unmittelbar nach der Zustimmung der Einrichtungsleitung zur Studienteilnahme. Bewohnerinnen und Bewohner konnten an der Studie teilnehmen, wenn sie mindestens 65 Jahre als waren und mindestens eine Gelenkkontraktur hatten, die durch einen Arzt, einen Ergotherapeuten, Physiotherapeuten oder durch eine Pflegende festgestellt wurde. Ausschlusskriterien waren eine terminale Erkrankung.

Aus datenschutzrechtlichen Gründen wurde die Überprüfung der Studieneignung der Bewohnerinnen und Bewohner und die Erstinformation der Bewohnerinnen und Bewohner über die Studie durch die Pflegedienstleitung übernommen. Die Kontaktdaten der Bewohnerin oder des Bewohners wurden an das Forscherteam weitergeleitet, wenn die Bewohnerin oder der Bewohner bzw. deren gesetzliche

Vertreter Interesse an der Studienteilnahme bekundete. Bevor die Studie startete, wurde die schriftliche Einwilligung der Bewohnerinnen und Bewohner bzw. deren gesetzliche Vertreter eingeholt.

Obwohl die PECAN Intervention im gesamten Pflegeheim implementiert wurde, war die Anzahl der einzuschließenden Bewohnerinnen und Bewohnern aus Gründen der Umsetzbarkeit der Intervention auf 25 pro Pflegeheim limitiert.

Die Prozessevaluation der Interventionsimplementierung richtete sich an alle, die mit der Interventionsumsetzung in engen Kontakt kamen, insbesondere die Multiplikatoren, Pflegende des Heims, im Heim angestellte sowie ambulant tätige Physio- und Ergotherapeuten, Angehörige, Mitarbeiter/-innen des Sozialen Dienstes und die Mitglieder des Forschungsteams, die als Peer Mentoren die Implementierung begleiteten.

8.1.4   Randomisierung und Verblindung

Für die Clusterzuteilung zu den Gruppen wurden computergenerierte Randomisierungslisten verwendet, stratifiziert nach der Region (Halle (Saale) und München). Die studienverantwortlichen Personen in den Pflegeheimen wurden über die Gruppenzuteilung nach Abschluss der Erhebung der Baselinedaten durch einen Statistiker informiert, der nicht in die vorherigen Studienprozesse einge-bunden war. Um möglichst viel über die Implementierungsprozesse der Intervention zu erfahren, wurden mehr Pflegheime in die Interventionsgruppe eingeschlossen als in die Kontrollgruppe (Eldridge et al., 2016). Alle Datenerhebungen wurden durch Interviewer erhoben, die gegenüber der Gruppenzuteilung verblindet waren. Die Dateneingabe und -auswertung erfolgte ebenfalls verblindet. Aufgrund der Natur der Intervention war es nicht möglich, die Pflegenden im Heim und die Bewohnerinnen und Bewohner zu verblinden.

8.1.5   Datenerhebung

Die Interviewer wurden in einer halbtägigen Schulung auf die Durchführung der Datenerhebung vorbereitet. Zusätzlich stand zur Durchführung eine schriftliche Anleitung zur Verfügung. Die Daten zu den Haupt- und Nebenzielgrößen wurden in strukturierten Face-to-Face-Interviews mit den Bewohnerinnen und Bewohner und durch Sichtung der Bewohnerdokumentation des Heimes zu Baseline, nach drei und nach sechs Monaten durchgeführt. Wenn die Bewohnerin oder der Bewohner nicht in der Lage war zu kommunizieren, wurde das Interview mit einer Bezugsperson (in der Regel die verantwortliche Pflegende) geführt. Daten zur Charakterisierung der Heime wurden zu Studienbeginn in einem strukturierten Interview mit der Pflegedienstleitung erfasst. Die Tabelle 1 fasst die Komponenten und Methoden der Prozessevaluation zur Interventionsimplementierung zusammen.

Tabelle 1 - Komponenten und Methoden der Prozessevaluation

Bereich	Fragestellung	Methodik	Teilnehmende	Zeitpunkt
Bereitstellung für Cluster	Welche Interventionen wurden tatsächlich in jedem Heim bereitgestellt? Wurden die Komponenten wir geplant umgesetzt?	Schriftliche standardisierte Evaluation des Multiplikatoren-Workshops	Forscherteam	Während und nach jeder Implementierungs-komponente
		Schriftliche standardisierte Evaluation der Informationsveranstaltung	Forscherteam	
		Schriftliche standardisierte Evaluation des Peer-Mentor-Besuchs	Forscherteam	
		Schriftliche standardisierte Evaluation des Peer-Mentorings	Forscherteam	
Umsetzung durch die Cluster	Wie wurde die Intervention von den Heimen übernommen? Gab es Unterschiede zwischen den Heimen?	Standardisierte Fragebögen, Multiplikatoren - Tagebuch, Feldnotizen zum Feedback zu den Implementierungskomponenten und den -prozess	Multiplikatoren	Während der Implementierung und zu Interventionsende nach sechs Monaten
			Teilnehmer der Informations-veranstaltung	
			Forscherteam	
	Gab es Änderungen in den Abläufen des pflegerischen Alltags?	Standardisierte schriftliche Befragung zu Erfahrungen und wahrgenommenen Veränderungen in der Einstellung und im Verhalten	Pflegende	Zu Baseline und nach sechs Monaten
	Was wurde als Förderfaktoren und Barrieren der Implementierung wahrgenommen?	Problemzentrierte Interviews und Gruppendiskussionen	Multiplikatoren	Zu Interventionsende nach sechs Monaten
			Therapeutinnen/ Therapeuten, Mitarbeiterinnen und Mitarbeiter des Sozialen Dienstes und Angehörige	
			Peer-Mentoren	
Context	In welchen Kontext wurde die Intervention implementiert?	Literaturrecherche zur Beschreibung des erweiterten Kontextes zu nationalen Standards von Pflegeheimen	Forscherteam	Vor Baseline

Bereich	Fragestellung	Methodik	Teilnehmende	Zeitpunkt
		Standardisiertes Interview zu Strukturmerkmalen der Cluster	Pflegedienstlei-tung	Zu Baseline
	Wie beeinflussen Kontextfaktoren den Implementierungs-prozess?	Problemzentrierte Interviews und Gruppendiskussionen	Multiplikatoren	Zu Interventionsende nach sechs Monaten

(1) Primäre und sekundäre Zielgrößen

Primäre Zielgröße der strukturierten Bewohnerbefragung war die Teilhabe der Bewohnerinnen und Bewohner und wurde mit Hilfe der PaArticular Scales erhoben (Müller et al., 2016). Als sekundäre Zielgrößen wurden instrumentelle Aktivitäten des täglichen Lebens mit Lawton IADL Scale bestimmt (Lawton & Brody, 1969), die Aktivitäten mit der Subskala Aktivitäten der PaArticular Scales. Die gesundheitsbezogene Lebensqualität wurde mit dem EQ-5D-3L (EuroQol, 1990) in der Bewohnerbefragung erfasst. Zur Untersuchung der Sicherheit der Intervention wurden Stürze und sturzbedingte Frakturen erfasst.

Hinsichtlich der Machbarkeit des Studiendesigns wurden Daten zur Rekrutierung der Heime und Bewohnerinnen und Bewohner und zu deren Verbleib in der Studie, zur Verblindung anhand von standardisierten Erhebungsprotokollen erfasst. Zur Akzeptanz und Angemessenheit der Erhebungs-instrumente zur Erfassung der Haupt- und Nebenzielgrößen wurde die Interviewdauer und fehlende Informationen in den Bögen ausgewertet.

Um zu entscheiden ob die Bewohnerinnen und Bewohner kognitiv zu einer Selbstauskunft fähig waren, wurde zur Baselineerhebung die Dementia Screening Scale eingesetzt (DSS) (Köhler, Weyerer, & Schaufele, 2007). Die DSS ist ein valides Instrument mit sieben Items zur Fremdeinschätzung der Gedächtnisleistung und der Orientierung. Der maximale Score ist 16 („größtmögliche Beeinträchti-gung") mit einem Cut-off von vier Punkten für eine kognitive Beeinträchtigung („moderate bis schwere Demenz") (Köhler et al., 2007). Im Fall einer solchen kognitiven Beeinträchtigung der Bewohnerin/des Bewohners wurde die standardisierte Befragung mit der/dem verantwortlichen Pflegenden durchgeführt.

Zur Überprüfung der Übereinstimmung von selbstberichteter und fremdberichteten Daten der PaArticular Scales wurde zusätzlich eine Substichprobe bei Bewohnerinnen und Bewohnern ohne kognitive Einschränkungen drei Monate nach Interventionsstart erhoben. Die Interviews zu den PaArticular Scales wurden am selben Tag vom selben Interviewer mit Bewohnerinnen und Bewohnern und den verantwortlichen Pflegenden geführt.

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(2) Machbarkeit des Evaluationskonzeptes zur Erhebung implementierungsbezogener Kosten

Zur Erprobung der implementierungsbezogenen Kostenevaluation in Vorbereitung einer später geplanten gesundheitsökonomischen Evaluation wurden Heil- und Hilfsmittel standardisiert anhand der Routinedokumentation oder durch Befragung der Pflegenden bewohnerbezogen erfasst.

(3) Stichprobengröße

Da bei dieser Pilotstudie Fragen der Machbarkeit und Akzeptanz im Vordergrund standen und nicht Fragen der Interventionswirksamkeit, wurde keine Stichprobenkalkulation getätigt. Anhand praktischer Überlegungen zur Umsetzbarkeit der Intervention wurde eine Stichprobengröße von insgesamt 150 Bewohnerinnen und Bewohnern in sechs Clustern mit je 25 Teilnehmenden geplant.

8.1.6 Datenauswertung

Die Methoden der deskriptiven Statistik wurden zur Beschreibung der Baselinecharakteristika der teilnehmenden Heime und Bewohnerinnen und Bewohner, der Inanspruchnahme von Heil- und Hilfsmitteln und bei den Daten zur Machbarkeit von Implementierung und Studienmethodik eingesetzt. Alle Daten zum Studiendesign wurden stratifiziert nach Interventions- und Kontrollgruppe ausgewertet.

Mit Hilfe linearer gemischter Modelle, die nach Alter und Geschlecht adjustiert waren, wurde der Zusammenhang der primären Zielgröße und der Intervention ausgewertet. Für alle statistischen Auswertungen wurde die Software R Version 3.3.2 verwendet.

Die Auswertung der problemzentrierten Einzel- und Gruppeninterviews erfolgte unter Anwendung eines gemischten deduktiv-induktiven Vorgehens basierend auf der direkten Inhaltsanalyse (Hsieh & Shannon, 2005) mit Hilfe der Auswertungssoftware MAXQDA Version 12.

8.2 Ergebnisse der PECAN Pilotstudie

8.2.1 Rekrutierung

Die Rekrutierung fand von Februar bis März 2016 statt. 12 Pflegeheime wurden kontaktiert und sieben haben der Studienteilnahme zugestimmt. Gründe der Nichtteilnahme waren fehlende Zeit (n=3), kein Interesse am Studienthema (n=1) und eine fehlende Anzahl an Bewohnerinnen und Bewohnern mit Gelenkkontrakturen (n=1).

In den teilnehmenden sieben Pflegeheimen entsprachen 265 Bewohnerinnen und Bewohner den Einschlusskriterien, von denen 129 einwilligten an der Studie teilzunehmen. Gründe für eine Nichtteilnahme der Bewohnerinnen und Bewohner war ein schlechter Gesundheitszustand (n=62),

persönliche Gründe (n=12) und Versterben vor dem Studieneinschluss (n=1). Zu insgesamt 61 Bewohnerinnen und Bewohnern lag keine Angabe zu Gründen der Nichtteilnahme vor. Abbildung 8 zeigt den Rekrutierungsverlauf und den Verbleib der Bewohnerinnen und Bewohner in der Studie.

Einschluss

Eingeladene Pflegeheime (n=12)

Teilnahmeablehnung der Pflegeheime (n=5)
Zu wenig Zeit (n=3)
Eine Interesse an Studienthema (n=1)
Geringe Prävalenz an Gelenkkontrakturen (n=1)

Teilnehmende Pflegeheime (n=7)

Eingeladene Bewohnerinnen und Bewohner (n=265)

Teilnahmeablehung durch Bewohner (n=136)
Schlechter Gesundheitszustand (n=62)
Ohne Angabe von Gründen (n=61)
Persönliche Gründe (n=12)
Verstorben vor Rekrutierung (n=1)

Baseline

Teilnehmende Bewohnerinnen und Bewohner (n=129)

Baseline assessment
Pflegeheime (n=7)
Bewohnerinnen und Bewohner (n=129)

Zufällig zugeteilte Pflegeheime (n=7)

Gruppenzuteilung

Interventionsgruppe (PECAN)
Pflegeheime (n=4)
Bewohnerinnen und Bewohner (n=64)

Kontrollgruppe
Pflegeheime (n=3)
Bewohnerinnen und Bewohner (n=65)

Vorzeitige Beendigung (n=4)
Verstorben (n=3)
Einwilligung zurückgezogen (n=1)

Vorzeitige Beendigung (n=9)
Verstorben (n=8)
Umgezogen (n=1)

3-Monats-Follow-up

Pflegeheime (n=4)
Bewohnerinnen und Bewohner (n=60)

Pflegeheime (n=3)
Bewohnerinnen und Bewohner (n=56)

Vorzeitige Beendigung (n=3)
Verstorben (n=1)
Schlechter Gesundheitszustand (n=1)
Einwilligung zurückgezogen (n=1)

Vorzeitige Beendigung (n=4)
Verstorben (n=3)
Einwilligung zurückgezogen (n=1)

6-Monats-Follow-up

Pflegeheime (n=4)
Bewohnerinnen und Bewohner (n=57)

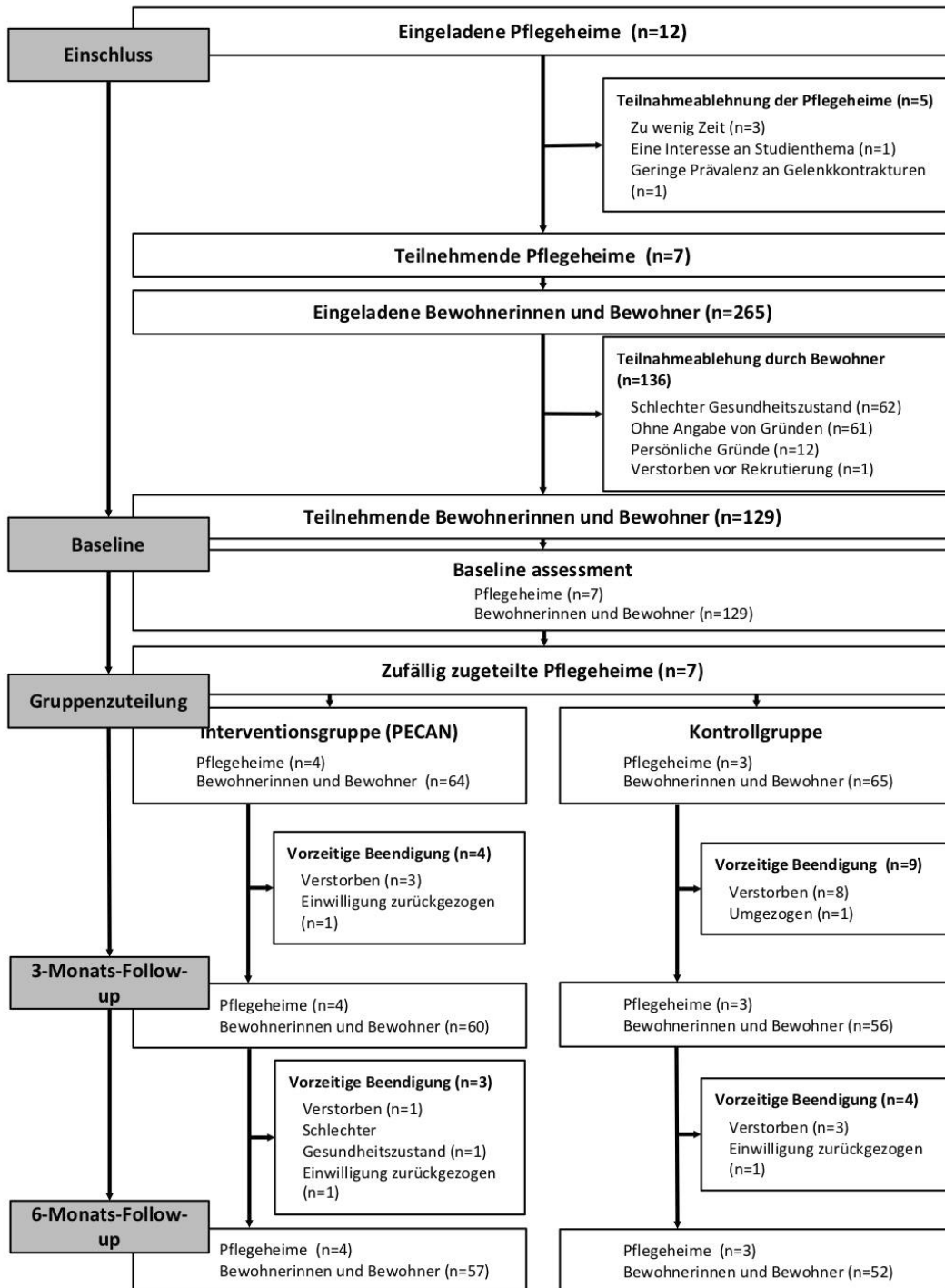Pflegeheime (n=3)
Bewohnerinnen und Bewohner (n=52)

Abbildung 8 - Übersicht zu Rekrutierungsverlauf und Studienverbleib der teilnehmenden Einrichtungen und Bewohnerinnen und Bewohner (Saal, Klingshirn, et al., 2019)

8.2.2 Charakteristika der teilnehmenden Pflegeheime und Bewohnerinnen und Bewohner

Die sieben Pflegeheime hatten zwischen 40 und 171 Langzeitpflegeplätze. Die Quote von Pflegfachkräften zu Bewohnern lag im Mittel bei 0,19 mit einem Range von 0,16 bis 0,28. Die Gesamtprävalenz an Gelenkkontrakturen betrug 28 % mit einem weiten Range von 19 % bis 96 %. Die Merkmale der Pflegeheime sind in Tabelle 2 beschrieben.

Tabelle 2 - Merkmale der eingeschlossenen Pflegeheime zu Studienbeginn

	Interventionsgruppe				Kontrollgruppe			Gesamt
	C1	C2	C3	C4	C5	C6	C7	
Studienteilnehmende, n	9	20	11	24	24	23	18	129
Langzeitpflegeplätze, n	40	107	171	165	48	128	115	774
Wohnbereiche, n	3	4	4	6	2	4	6	29
Bewohner je Wohnbereich	13	27	43	28	24	32	18	27
Geschätzte Prävalenz der Gelenkkontrakturen	0,40	0,96	0,19	0,21	0,50	0,31	0,60	0,28
Pflegende-Bewohner-Quote (Pflegfachkräfte und Pfleghilfskräfte)	0,49	0,30	0,35	0,38	0,32	0,34	0,30	0,35
Pflegefachkraft-Bewohner-Quote	0,28	0,16	0,19	0,20	0,17	0,16	0,16	0,19

Insgesamt nahmen 129 Bewohnerinnen und Bewohner an der Studie teil. Das mittlere Alter betrug 85,7 Jahre (SD = 7.0), 80 % waren weiblich und 40 % hatten die Pflegestufe drei. Die Pflegebedürftigkeit variierte zwischen den Clustern insbesondere bei Teilnehmerinnen und Teilnehmern mit der Pflegestufe 2 (Range: 4 % bis 70 % je Cluster) und der Pflegestufe mit Härtefallregelung (Range: 0 % bis 62 % je Cluster). Die Hälfte der Bewohnerinnen und Bewohner war kognitiv eingeschränkt, so dass 65 Befragungen nicht als Selbstauskunft, sondern in einem Interview mit verantwortlichen Pflegekräften durchgeführt wurden. In sechs Fällen sank der kognitive Status während der sechsmonatigen Intervention und die Befragung wurde dann statt mit den Bewohnerinnen und Bewohnern mit den verantwortlichen Pflegenden durchgeführt. Die Gruppen unterschieden sich bezüglich der Lokalisation der Gelenkkontraktur (Arme und Beine betroffen n=23, 57 % in der Interventionsgruppe im Vergleich zu n=45, 69 % in der Kontrollgruppe) und des Anteils an Interviews mit verantwortlichen Pflegekräften

(n=28, 44 % in der Interventionsgruppe im Vergleich zu n=37, 57 % in der Kontrollgruppe). Die Charakteristika der teilnehmenden Bewohnerinnen und Bewohner sind in der Tabelle 3 zusammengestellt.

Tabelle 3 - Charakteristika der teilnehmenden Heimbewohnerinnen und Heimbewohner zu Studienbeginn

	Interventionsgruppe (n = 64)	Kontrollgruppe (n = 65)	Gesamt (n = 129)
Alter, Jahre, Mittelwert (SD)	86,1 (6,3)	85,2 (7,7)	85,7 (7,0)
Frauen, n (%)	49 (76,6)	54 (83,1)	103 (79,8)
Lokalisation der Gelenkkontraktur, n (%)			
Obere Extremität	11 (17,5)	7 (10,9)	18 (14,2)
Untere Extremität	16 (25,4)	13 (20,3)	29 (22,8)
Beide	36 (57,1)	45 (68,8)	81 (63)
Pflegestufe, n (%)			
keine	1 (1,6)	0 (0)	1 (0,8)
Pflegestufe 1	0 (0)	2 (3,1)	2 (1,6)
Pflegestufe 2	23 (35,9)	18 (27,7)	41 (31,8)
Pflegestufe 3	24 (37,5)	27 (41,5)	51 (39,5)
Härtefall	16 (25,0)	18 (27,7)	34 (26,4)
DSS, Mittelwert (SD)	4,69 (5,0)	5,46 (4,3)	5,09 (4,6)
Art der Befragung, n (%)			
Selbstauskunft	35 (55,6)	28 (43,1)	63 (49,2)
Fremdauskunft	28 (44,4)	37 (56,9)	65 (50,8)

Fehlende Werte: Lokalisation der Gelenkkontraktur (n=1); Dementia Screening Scale (DSS) (n=2); Art der Befragung (n=1); Standardabweichung- SD

8.2.3 Erhaltung der Verblindung

Einige Befragungen mussten entgegen des Studienprotokolls zum 3-Monats-Follow-up und zum 6-Monats-Follow-up unverblindet aufgrund eines zu knapp kalkulierten Personalaufwandes durchgeführt werden. Die Erhebungen konnten bei 81 Bewohnerinnen und Bewohnern (70 %) zum 3-Monats-Follow-up und bei 74 Bewohnerinnen und Bewohnern (68 %) zum 6-Monats-Follow-up durchgeführt werden. In drei Fällen kam es zu einer zusätzlichen Entblindung der Interviewer; in zwei Fällen durch eine versehentliche Bekanntgabe der Gruppenzugehörigkeit durch die Pflegenden im

Heim und in einem weiteren Fall im Forscherteam. Die Interviewer wurden gebeten, eine Schätzung über die Gruppenzugehörigkeit der Heime unmittelbar nach der Befragung abzugeben. Zum 3-Monats-Follow-up schätzten die verblindeten Interviewer in 40 % aller Fälle die Gruppenzugehörigkeit und zum 6-Monats-Follow-up 70 % korrekt ein.

8.2.4 Verbleib in der Studie

Alle sieben Pflegeheime beendeten planmäßig die Studie. Den Verbleib der teilnehmenden Bewohnerinnen und Bewohner fasst Abbildung 8 zusammen.

8.2.5 Erhebungsinstrumente

The Effekt der PECAN Intervention auf Teilhabe, Aktivitäten, selbsteingeschätzten Gesundheitsstatus und die instrumentellen Aktivitäten des täglichen Lebens werden in der Tabelle 4 dargestellt. Die Ergebnisse der Subskala Teilhabe und der Subskala Aktivitäten der PaArticular-Scales and der EQ-5D-3L weisen auf eine leichte Reduzierung der Aktivitäten, der Teilhabe und des selbsteingeschätzten Gesundheitsstatus innerhalb der sechs Monate hin, obwohl die Daten ebenfalls auf eine leichte Verbesserung in den instrumentellen Aktivitäten des täglichen Lebens zeigen. Es gab keine signifikanten Unterschiede zwischen Interventions- und Kontrollgruppe im Hinblick auf die primäre Zielgröße Teilhabe.

Tabelle 4 - Effekte der PECAN Intervention auf Partizipation, Aktivitäten, instrumentelle Aktivitäten des täglichen Lebens und Lebensqualität

	Interventionsgruppe (n = 57)			Kontrollgruppe (n = 52)			Gruppen-differenz[a]	LMM [b]
	t_0 Mittel-wert (SD)	t_2 Mittel-wert (SD)	Mittel-wert-differenz t_2-t_0 (SD)	t_0 Mittel-wert (SD)	t_2 Mittel-wert (SD)	Mittel-wert-differenz t_2-t_0 (SD)	Mittelwert (95 % CI)	Coefficient (95 % CI)
Subskala Partizipation	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)
Subskala Aktivitäten	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-3L	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 Skala	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-Monats-Follow-up.

Fehlende Werte: Subskala Partizipation t_2 (n=5); Subskala Aktivitäten t_2 (n=3); Visuelle Analogskala der European Quality of Life 5 Dimensions 3 Level Version (VAS EQ-5D-3L) t_0 (n=1), t_2 (n=4); und Lawton Instrumental Activities of Daily Living (IADL) Skala t_0 (n=18), t_2 (n=1).

[a] Differenz zwischen der Mittelwertdifferenz (t_2-t_0) der Interventionsgruppe und der Mittelwertdifferenz (t_2-t_0) der Kontrollgruppe.

[b] Lineares gemischtes Modell (LMM) unter Berücksichtigung von Unterschieden in den Clustern und deren teilnehmenden Bewohnerinnen und Bewohnern, adjustiert für Alter und Geschlecht.

Die Protokolle der Interviewer weisen darauf hin, dass einige Items der PaArticular Scales, insbesondere in der Subskala Aktivitäten (*die Körperposition beibehalten, eine stehende Position beibehalten, Transfer aus dem Sitz, Transfer aus dem Liegen*), aufgrund der sich ähnelnden Inhalte für die Befragten schwierig zu verstehen waren. Die Antwortverteilung zu den Items beschreibt der Online Anhang der Publikation in Anlage 3 näher.

Zum 3-Monats-Follow-up wurden die PaArticular Scales aus 14 Befragungen mit Bewohnerinnen und Bewohnern mit Fremdauskünften von verantwortlichen Pflegenden verglichen. Die Abbildung 9Abbildung 380 und Abbildung 10Abbildung 382 illustrieren grafisch die Übereinstimmung der Einschätzungen. Abbildung 9 weist auf eine Korrelation zwischen der Einschätzung der Bewohnerinnen

und Bewohnern und den Pflegenden hin, während Abbildung 10Abbildung 382 keinen Zusammenhang zwischen Bewohnerinnen und Bewohnern und den Pflegenden bezüglich der Einschätzung zur Teilhabe findet.
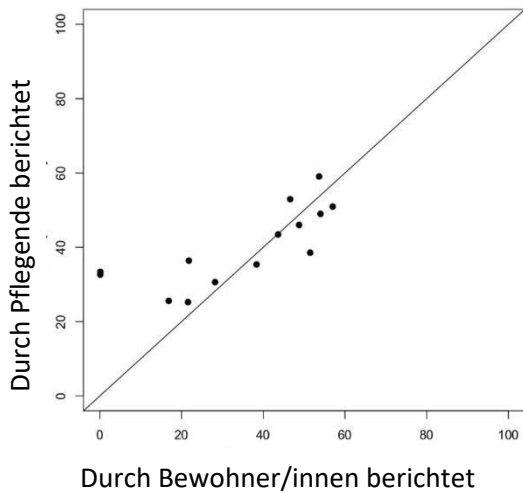

Abbildung 9 - Übereinstimmung der Bewohner- und Pflegendeneinschätzung in der Subskala Aktivitäten
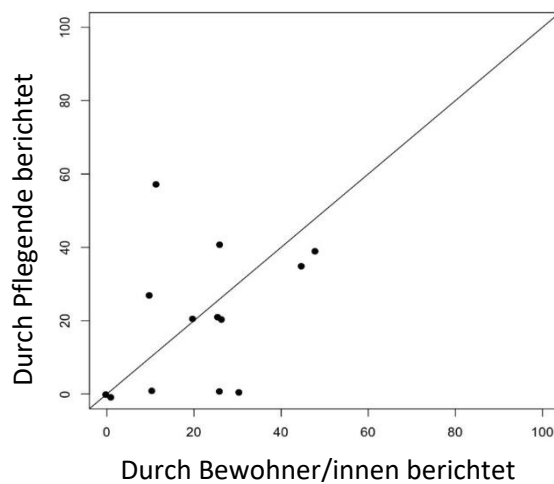
Abbildung 10 - Übereinstimmung der Bewohner- und Pflegendeneinschätzung in der Subskala Partizipation

Die Lawton IADL Skala hatte die höchste Anzahl an fehlenden Werten (n=18, 16 %). Insbesondere das Item *Essen zubereiten* wies die meisten Missings bei 15 Bewohnerinnen und Bewohner (12 %) auf. Einige Bewohnerinnen und Bewohner verwiesen darauf, dass das Essen vom Heim bereitgestellt wird und diese Frage somit nicht relevant für die Bewohnerinnen und Bewohner sei.

Der EQ-5D-3L erwies sich als gut durchführbar und nur sehr wenige Bewohnerinnen und Bewohner benötigten eine nähere Erläuterung bei der Einschätzung ihres Gesundheitszustandes anhand der Visuellen Analogskala.

Im Durchschnitt dauerte die Befragung 35 Minuten bei Bewohnerinnen und Bewohnern und 15 Minuten bei Pflegenden.

8.2.6 Sicherheit

Stürze und sturzbedingte Frakturen während der Studienlaufzeit sind in der Tabelle 5 dargestellt. Es ergaben sich keine Unterschiede zu Anzahl und Frequenz der Stürze und sturzbedingten Frakturen zwischen der Interventions- und Kontrollgruppe.

Tabelle 5 - Effekte der PECAN Intervention auf Stürze

	Interventionsgruppe (n = 57)			Kontrollgruppe (n = 52)		
	Baseline	3 Monate	6 Monate	Baseline	3 Monate	6 Monate
Bewohner mit Stürzen innerhalb der letzten 4 Wochen, n (%)	7 (12)	7 (12)	8 (14)	2 (4)	6 (12)	5 (10)
Mittelwert der Stürze je Bewohner innerhalb der letzten 4 Wochen	1,57	1,86	1,25	1,00	1,83	1,00
Bewohner mit Stürzen innerhalb der letzten 6[a] oder 3[b] Monate, n (%)	13[a] (23)	12[b] (21)	14[b] (25)	19[a] (37)	9[b] (18)	11[b] (21)
Mittelwert der Stürze je Bewohner innerhalb der letzten 6 Monate	2,23	3,25	1,93	2,63	2,11	1,55
Bewohner mit sturzbedingten Frakturen, n (%)	2 (4)	0 (0)	0 (0)	2 (4)	1 (2)	0 (0)

n=109; t_0 = Baseline, t_1 = 3-Monats-Follow-up, t_2 = 6-Monats-Follow-up;
Fehlende Werte: Mittelwert der Stürze je Bewohner innerhalb der letzten 4 Wochen t_0 (n=1); Bewohner mit Stürzen innerhalb der letzten 6 Monate t_0 (n=1) oder 3 Monate t_1 (n=1); und Bewohner mit sturzbedingten Frakturen t_0 (n=1), t_1 (n=1)

8.2.7 Gesundheitsökonomische Evaluation

Die Gesamtkosten der implementierungsbezogenen Kostenkomponenten betragen 12.163,50 €, von denen der größte Anteil Personalkosten waren (9.396,20 €) (Anlage 3, Supplementary appendix, Tabelle A2). Die implementierungsbezogenen Kosten pro Heim variierten aufgrund der Anzahl und Qualifikation der Multiplikatoren. Die Kosten betrugen pro Bewohner 109,58 €.

8.2.8 Inanspruchnahme von Gesundheitsleistungen

Die Hilfsmittel, die von den Bewohnerinnen und Bewohnern genutzt wurden, unterschieden sich zur Baselinerhebung (t0) nicht zwischen den Gruppen. In Anlage 3 sind die in Anspruch genommenen Hilfsmittel näher beschrieben. Zum 6-Monats-Follow-up kamen folgende Hilfsmittel hinzu: vier Rollstühle (Interventionsgruppe n=2; Kontrollgruppe n=2), zwei multi-funktionale Rollstühle (Interventionsgruppe n=1; Kontrollgruppe n=1), eine Gehbank (Interventionsgruppe) und ein Gehstock (Interventionsgruppe). Zusätzlich wurden zwei Rollstühle (Interventionsgruppe n=1; Kontrollgruppe n=1) und eine Gehbank (Kontrollgruppe) nicht mehr benötigt.

Die Aufzeichnungen der Interviewer weisen darauf hin, dass verordnete Hilfsmittel nicht regulär in der Pflegedokumentation erfasst werden, so dass die Informationen zusätzlich durch eine Befragung des Pflegepersonals erhoben wurden.

Informationen zur Inanspruchnahme von Physiotherapie und Ergotherapie waren in den meisten Fällen verfügbar (zu jedem Messpunkt fehlten nur jeweils in 5 % aller Fälle die entsprechenden Informationen). In Falle der Inanspruchnahme therapeutischer Leistungen war es jedoch in weniger als der Hälfte aller Fälle möglich, die genaue Frequenz in Erfahrung zu bringen.

8.2.9 Fallzahlkalkulation in Vorbereitung der Hauptstudie

Aus den Erfahrungen während der Rekrutierung der teilnehmenden Bewohnerinnen und Bewohner lässt sich schließen, dass 15 eine geeignete Anzahl an teilnehmenden Bewohnerinnen und Bewohnern je Pflegeheim ist. Aus diesem Grund basiert die Fallzahlkalkulation auf Clustern im Mittel bei 15 Teilnehmenden. Unter Nutzung der Daten aus der Pilotstudie wird der Intracluster-Korrelations-koeffizient (ICC) auf 0,38 geschätzt. Das ergibt einen Inflationsfaktor von (1 - (15 - 1) * 0,38) = 6.32. Die Varianz, die in der Pilotstudie beobachtet wurde, betrug circa 200, die Effektdifferenz für die Subskala Partizipation zwischen der Kontroll- und Interventionsgruppe wurde als 10 oder in manchen Fällen auch als 12 angenommen. Erfahrungen aus der Pilotstudie zeigten, dass die PECAN-Intervention Partizipation und Aktivitäten gleichermaßen adressierten, so dass in der Hauptstudie beide Subskalen als zwei unabhängige primäre Endpunkte eingesetzt werden. Die Größe einer Gruppe in der Hauptstudie wird bei einer Power von 80 % n=241 (38*6,32) betragen unter Berücksichtigung der notwendigen Bonferroni Korrektur des Signifikanzniveaus (0,05/2= 0,025). Damit ergeben sich 16 Cluster je Studienarm (241/15 = 16,1). Eine zusätzliche Berücksichtigung vorzeitiger Studienbeendigungen von circa 15 % resultiert in 30 Clustern mit 18 Teilnehmenden je Cluster und zwei Clustern mit 19 Teilnehmenden, so dass die Fallzahl der Hauptstudie n=578 beträgt.

8.2.10 Ergebnisse zur Akzeptanz und Machbarkeit der Interventionsimplementierung

(1) Umsetzungsgrad der Interventionskomponenten

Die Tabelle 6 beschreibt den Umsetzungsgrad der Intervention. Alle Implementierungskomponenten konnten gemäß Interventionsprotokoll umgesetzt werden. Die praktische Relevanz der Inhalte der PECAN-Intervention wurde überwiegend als hoch eingeschätzt (hoch n=10; teilweise n=4; niedrig n=0). Nach dem Workshop schätzten 12 von 14 Multiplikatoren ein, ausreichend gerüstet für die Umsetzung der PECAN-Intervention zu sein. Die Qualität des Workshops wurde mit 1,7 (SD 0,45) auf einer Skala von 1 (sehr gut) bis 4 (unzureichend) bewertet.

Die Inanspruchnahme der Informationsveranstaltung stellte sich bezüglich der Anzahl und Zusammensetzung der Teilnehmenden sehr heterogen dar. Insgesamt wurde die Qualität der Informationsveranstaltung von den Teilnehmenden mit 1,9 (auf einer Skala von 1 = sehr gut bis 4 = unzureichend) eingeschätzt, was auf eine gute Akzeptanz der Umsetzung schließen lässt.

Aufgrund von Krankheit und Urlaub konnte vier der 14 Multiplikatoren nicht am Peer-Mentor-Besuch teilnehmen. Die stark variierende Anzahl der Beratungskontakte (zwischen ein bis sieben) zwischen den Studienzentren steht im Zusammenhang mit den unterschiedlichen Beratungsstrategien an den Standorten, die vorher nicht festgelegt wurden. An einem Studienzentrum wurden die Besprechungstermine und -inhalte im Voraus festgelegt (Cluster 1 und 2), während im anderen Studienzentrum eine offene und bedarfsorientierte Strategie angewendet wurde, die die Multiplikatoren zur Kontaktaufnahme eingeladen hat, ohne Termine vorzugeben.

Tabelle 6 - Umsetzung der Interventionskomponenten

	Cluster 1	Cluster 2	Cluster 3	Cluster 4
Kick-off Meeting				
Meeting protokollgemäß durchgeführt	✓	✓	✓	✓
Deklaration unterzeichnet	✓	✓	✓	✓
Multiplikatoren-Workshop				
Agenda und Inhalt protokollgemäß	✓	✓	✓	✓
Zahl der teilnehmenden Multiplikatoren	2/2	2/2	4/4	6/6
Qualifikation der Multiplikatoren entsprechend der Vorgaben	2/2	2/2	4/4	6/6
Informationsveranstaltung				
Durchführung protokollgemäß	✓	✓	✓	✓
Zahl der Teilnehmenden je Veranstaltung				
Pflegende	0	2	11	11
Bewohner	4	3	3	0
Angehörige	1	1	0	2
Andere	0	1	1	1
Gruppenzugehörigkeit unbekannt	0	3	1	1
Gesamt	5	10	16	15
Peer-Mentoring				
Peer-Mentor-Besuch				
Agenda und Inhalt protokollgemäß	✓	✓	✓	✓
Zahl der teilnehmenden Multiplikatoren	2/2	2/2	2/4	4/6

	Cluster 1	Cluster 2	Cluster 3	Cluster 4
Teilnahme der Pflegedienstleitung	✓	✓	✓	✓
Teilnahme eines externen Peer-Experten	✓	✓	-	✓
Telefonisches Peer-Mentoring				
Anzahl der Beratungsgespräche	6	7	1	2
Anzahl der beratenen Multiplikatoren	2/2	2/2	1/4	1/6
Interviewdauer in Minuten, Mittelwert (Range)	85 (105-30)	31 (75-10)	10 (10-10)	13 (10-15)
Zusätzliche Materialien für die Cluster				
Projektflyer	10	10	30	30
Spezifische Flyer für Angehörige, Therapeutinnen/Therapeuten, Ärztinnen/Ärzte	35	40	21	21
Poster zur Bewegungsförderung	3	3	4	6
Materialset zur Sensibilisierung und Schulung des Pflegeteams	-	-	4	7
Artikel für die Heimzeitung	-	-	1	-
Multiplikatoren-Tagebuch				
Rücklauf der Multiplikatoren -Tagebücher	2/2	1/2	3/4	4/6
Monatliche Arbeitszeit je Multiplikator in Stunden, Mittelwert (Range)	20 (20-20)	5 (5-5)	19 (17-20)	5 (1-10)

Die Multiplikatoren setzten eine Reihe von Maßnahmen zur Implementierung der Intervention ein. Die Analyse der Multiplikatoren-Tagebücher (n=10) zeigt, dass folgende Maßnahmen in allen Pflegeheimen umgesetzt wurden: kritische Sichtung der Pflegdokumentation auf Teilhabeaspekte und Anpassung der Pflegeplanung, (Weiter-) Entwicklung einrichtungsspezifischer Standards zur Pflege bei Gelenkkontrakturen, intra- und interprofessionelle Fallkonferenzen, die Teilhabeaspekte bei Bewohnerinnen und Bewohnern mit Gelenkkontrakturen berücksichtigen, Beratung von Kolleginnen und Kollegen sowie Angehörigen, Vorgesetzten, Therapeutinnen und Therapeuten, Mitarbeiterinnen und Mitarbeiter des Sozialen Dienstes, Ärztinnen und Ärzten, kritische Sichtung von Hilfsmitteln und Umfeldanpassungen des Pflegeheimes.

(2) Einstellung und Verhalten der Pflegenden

Nach sechs Monaten fühlten sich knapp 30 % (13/45) aller Pflegenden nicht ausreichend über die PECAN-Intervention informiert und 27 % (12/45) gaben an, nicht ausreichend Beratung und Anleitung durch den Multiplikator erhalten zu haben. Die Gesamtzufriedenheit der Pflegenden („sehr zufrieden" und „zufrieden") schwankte zwischen den Pflegeheimen zwischen 8 % und 100 %. Es zeigten sich

dennoch Änderungen im Pflegealltag. Während nach sechs Monaten in der Interventionsgruppe 20 % mehr Pflegende angaben, (t_0 43 %, 6 Monats-Follow-up 67 %) darüber im Team zu diskutieren wie die Pflege der Bewohnerinnen und Bewohner teilhabeorientierter erfolgen kann, kam es in der Kontrollgruppe nur zu einer Steigerung von 9 % (t_0 38 %, 6 Monats-Follow-up 47 %).

(3) Förderfaktoren und Barrieren der Implementierung

Von 57 angefragten Personen nahmen 28 an den qualitativen Gruppen- und Einzelinterviews teil: 13 Multiplikatoren (13/14), fünf Angehörige (5/24), vier Therapeutinnen und Therapeuten (4/13), vier Mitarbeiterinnen und Mitarbeiter des Sozialen Dienstes (4/4), und zwei Peer Mentorinnen (2/2).

In Anlage 4, fasst Tabelle 5 die Förderfaktoren und Barrieren zusammen, die sich in Einflussfaktoren der Implementierungsstrategie und kontextbedingte Einflussfaktoren einteilen. Während hinsichtlich der Implementierungsstrategie unter anderem der mangelnde Einbezug von Vorgesetzten und anderen relevanten Akteuren wie Mitarbeiterinnen und Mitarbeitern des Sozialen Dienstes als hemmende Einflussfaktoren benannt wurden, wurden hinsichtlich der Kontextfaktoren unter anderem das mangelnde Interesse der Heimmitarbeiterinnen und -mitarbeiter an der PECAN-Intervention, beschränkte Möglichkeit der Einflussnahme auf organisatorische Abläufe, zu wenig Zeit und unzureichende Qualifizierung als relevante Barrieren der Implementierung berichtet.

8.2.11 Zusammenfassung der Ergebnisse der PECAN-Pilotstudie

Die Pilotstudie ergab wertvolle Hinweise zur Verbesserung der Rekrutierungsstrategie. Um die Vergleichbarkeit der Merkmale der teilnehmenden Bewohnerinnen und Bewohner in den Clustern zu verbessern, sind für die folgende Wirksamkeitsstudie die Einschlusskriterien zu konkretisieren. Es wird fokussiert auf Bewohnerinnen und Bewohner mit Gelenkkontrakturen in großen Gelenken, welche die Aktivitäten des täglichen Lebens beeinträchtigen und die mindestens in eine sitzende Position mobilisiert werden können. Eine zusätzliche Schulung der für den Screeningprozess verantwortlichen Person im Heim und eine Review durch Forschende soll den Prozess des Teilnehmereinschlusses weiter verbessern.

Die verwendeten Erhebungsinstrumente haben sich in unterschiedlichem Maße bewährt: der EQ-5D-3L wies kaum fehlende Werte auf, die IADL Skala hatte aufgrund der fehlenden Passfähigkeit der Items für das Setting Pflegeheim eine hohe Anzahl an fehlenden Werten und kann für eine weitere Nutzung nicht empfohlen werden. Die PaArticular Scales, die das erste Mal in einer RCT eingesetzt wurde, beinhaltete Items, die für Bewohnerinnen und Bewohner nicht in jedem Fall selbsterklärend waren. Geeignete settingspezifische Beispiele bleiben im Nutzermanual zu ergänzen. Inhaltlich haben sich sowohl die Subskala Aktivitäten als auch die Subskala Partizipation der PaArticular Scales als

bedeutsam für das interessierende Konstrukt Teilhabe erwiesen, so dass in der Wirksamkeitsstudie beide als kombinierte Endpunkte untersucht wurden.

Im Pflegeheim gibt es einen hohen Anteil an Bewohnerinnen und Bewohnern mit kognitiven Einschränkungen. Aus diesem Grund wurde die PaArticular Scales auf ihre Eignung als Fremdeinschätzungsinstrument überprüft. Da Teilhabe ein sehr individuelles Konzept ist, waren die geringere Übereinstimmung von Selbst- und Fremdeinschätzung in der Subskala Partizipation im Vergleich zur Subskala Aktivitäten erwartbar. Da es bei der Hälfte der Teilnehmenden nicht möglich war, Angehörige für eine Proxybefragung zu gewinnen, war die Befragung der verantwortlichen Pflegenden in der Regel der einzige Weg, eine Fremdeinschätzung zu Bewohnerinnen und Bewohnern zu erhalten. Die geringe Anzahl im eingeschlossenen Vergleich (n=14) erlaubt ohne eine weitere Untersuchung mit einer größeren Fallzahl keine belastbaren Rückschlüsse auf die Eignung des Instruments zur Fremdeinschätzung.

Es zeigten sich nur geringe Veränderungen in beiden Subskalen durch die PECAN-Intervention, in der Subskala Partizipation noch geringer als in der Subskala Aktivitäten. Ein Grund hierfür liegt in der Art der Codierung. Dem ICF-Modell folgend werden Aktivitätsbeeinträchtigungen und Einschränkungen der Teilhabe vor dem Hintergrund der aktuellen Lebenssituation des Individuums bestimmt. Somit werden Aktivitäten, die (momentan) nicht Bestandteil des Alltagslebens sind, als nicht einschränkend betrachtet, unabhängig von der tatsächlichen Fähigkeit des Befragten, diese ausführen zu können. In der folgenden Wirksamkeitsstudie sollte diesem Problem deutlicher Rechnung getragen werden.

Ein weiterer Grund für die eher geringen Veränderungen lag im Implementierungsgrad der Intervention. Die Intervention könnte wie geplant mit der Schulung der Multiplikatoren umgesetzt werden, allerdings erreichte die PECAN-Intervention nicht alle Pflegenden, nicht das interprofessionelle Team und somit auch nicht immer die Bewohnerinnen und Bewohner. Als Gründe dafür wurden unter anderem unklare Verantwortlichkeiten, strikte Trennung von Arbeitsbereichen, fehlende Kultur des Austausches und der Veränderungsbereitschaft, zu wenig Zeit und fehlende Kompetenzen benannt.

9 Diskussion

Ziel der in dieser Schrift präsentierten Forschungsarbeiten war es, die teilhabeorientierte Gesundheitsversorgung von Menschen mit Gelenkkontrakturen in Pflegeheimen zu verbessern. Dafür wurden aktuelle Konzepte und Methoden der Entwicklung komplexer Interventionen in stationären

Settings am Beispiel der PECAN Intervention für die Phasen der Interventionsentwicklung und Pilotierung erprobt und kritisch reflektiert.

Das MRC Rahmenkonzept zur Entwicklung komplexer Interventionen hat großes Potential, Interventionen, die im Wesentlichen Verhaltens- und Einstellungsänderungen adressieren, sorgfältig und entsprechend der vorherrschenden Rahmenbedingungen zu entwickeln. Das Rahmenkonzept ist nicht als fertige „Anleitung" zur Entwicklung komplexer Interventionen zu verstehen, sondern zeigt zentrale Aspekte und Fragestellungen in den einzelnen Phasen auf, mit denen sich Forschende auseinandersetzen sollten, um eine erfolgreiche Intervention zu entwickeln.

Das zu adressierende Ziel der Verbesserung der Teilhabe für Menschen mit Gelenkkontrakturen unterliegt einem vielfältigen Zusammenspiel verschiedenster Faktoren, so dass Forschungsmethoden zu singulären Maßnahmen bisher nur unzureichend für solche Art von Interventionen geeignet waren. Die dezidierte Dreiteilung der Aufgaben der Entwicklungsphase in die Identifikation der Evidenzbasis, die Identifikation/Entwicklung der Theorie und die Modellierung der Prozesse und Outcomes legt ein weitaus größeres Gewicht auf die Entwicklungsphase und gibt ihr mehr Struktur als bisher.

Eine wesentliche Erkenntnis aus den vorliegenden Arbeiten ist, das bereits in der Phase der Entwicklung die einflussnehmenden Kontextfaktoren berücksichtigt werden sollten. Als Grundlage für die Entwicklung eines Verständnisses für die Wirkmechanismen einer Intervention ist das vorliegende Gesundheits- oder Versorgungsproblem mit deren einflussnehmenden Kontextfaktoren zentral. Der Widerspruch zwischen dem inflationären Gebrauch der Begriffe Komplexität in der Gesundheitsversorgung sowie komplexen Interventionen und den bisher überwiegend unzureichenden Bemühungen, die Komplexität tatsächlich sichtbar zu machen, wird zunehmend häufiger diskutiert (Greenhalgh & Papoutsi, 2018; G. F. Moore & Evans, 2017). Eine dezidierte Beschreibung des Gesundheits- oder Versorgungsproblems, die von Beginn an der Komplexität des Geschehens Rechnung trägt, wird im MRC Rahmenkonzept noch nicht ausreichend berücksichtigt. Die Erkenntnisse aus den in dieser Schrift dargelegten Forschungsarbeiten sprechen für eine weitere Differenzierung der Entwicklungsphase, wie sie auch von Bleijenberg et al. (Bleijenberg et al., 2018) vorgeschlagen wurde: Problemidentifikation und -definition, Festlegung der Adressaten der Intervention, Identifikation der Bedarfe der Provider, Untersuchung des Ist-Standes und des Kontextes und das Interventionsdesign.

Zudem wurde in der Bearbeitung der Forschungsfrage deutlich, dass das Rahmenkonzept in der Entwicklungsphase kaum Empfehlungen vorhält falls keine Evidenzbasis vorhanden ist und dadurch eine Neukonzeption statt einer Adaptation einer Intervention angezeigt ist. Die Erfahrungen aus den vorliegenden Arbeiten zeigen, dass bei fehlender Evidenz zu möglichen Interventionskomponenten eine Einbindung aller am Versorgungsprozess beteiligten Personengruppen (zu einem sehr frühen

Zeitpunkt der Interventionsentwicklung und wiederholt im weiteren Verlauf) sowie eine konsequente Orientierung an Interventionszielen wesentlich für eine gelungene Interventionsentwicklung ist. Die vorliegenden Arbeiten bieten eine gute Orientierung für ein methodisches Vorgehen.

Weiterhin hat sich als sehr hilfreich erwiesen, sich in der Identifikation der zugrundeliegenden Theorie nicht nur auf eine Theorie zu beschränken, die die geplanten Veränderungen aufgrund der Interventionsimplementierung erklärt (*Theory of change*). Auch die zusätzliche Auseinandersetzung mit einem Modell, das die avisierte Perspektivänderung durch die Intervention (in vorliegenden Fall die biopsychosoziale Perspektive der Pflegenden) abbildet, war sehr von Nutzen, um die Wirkmechanismen der Intervention erklären zu können.

Als eine inhaltliche Limitierung in diesem Zusammenhang ist zu werten, dass die verwendete *Theory of Change* (in unserem Falle die Theory of planned behaviour) ausschließlich auf Aspekte der Verhaltensänderung beruht und keine Aspekte der Kontextfaktoren berücksichtigt, die im Sinne des biopsychosozialen Modells der ICF ebenso von Bedeutung sind. Eine umfassend erklärende Programmtheorie zur PECAN Intervention bedarf in einem weiteren Schritt der Fusion beider Theorien.

Auch in der Entwicklung des Implementierungs- und Studiendesigns zeigte sich die Notwendigkeit, stärker danach zu unterteilen was originäre Bestandteile und Ziele der Intervention sind und was als Ziele und Bestandteile der Implementierung zu werten ist. Auf eine solche Unterscheidung wird im aktuellen MRC Rahmenkonzept bisher wenig eingegangen, im Gegensatz zum Context and Implementation of Complex Interventions (CICI) Rahmenkonzept (Pfadenhauer et al., 2017), einem Konzept zur Entwicklung von Public Health Interventionen. Das Vorliegen des CICI-Rahmenkonzeptes zu Beginn der PECAN Interventionsentwicklung hätte das Implementierungskonzept beeinflusst. Entsprechend wird in der nachfolgenden Wirksamkeitsstudie (Nguyen et al., 2019) das Interventions-protokoll und die Programmtheorie entsprechend überarbeitet. Die differenzierten theoretischen Überlegungen zur Implementierung des CICI Rahmenkonzeptes können das MRC Rahmenkonzept zur Entwicklung komplexer Interventionen bereichern.

Zur Implementierung des Wissens nutzten wir den Ansatz der *Facilitation*, der sich bereits in anderen Studien zur Implementierungen von Veränderungen in Pflegeheimen bewährt hat (Abraham et al., 2015; Köpke et al., 2012; Plambech, Lurie, & Ipsen, 2012; Richter et al., 2015) und ein zentraler Ansatz des i-PARIHS Rahmenkonzeptes (Promoting Action on Research Implementation in Health Services) ist (Harvey & Kitson, 2016).

Obwohl das MRC Rahmenkonzept zur Entwicklung komplexer Interventionen das derzeit am häufigsten verwendete forschungslogische Rahmenkonzept darstellt, existieren eine Reihe von

Rahmenkonzepten, die einen besonderen Fokus auf die Implementierung von Gesundheitsintervention in die Praxis legen (Nilsen, 2015) und die Implementierungsplanung in der Entwicklungsphase wesentlich bereichern können wie zum Beispiel das Rahmenkonzept Promoting Action on Research Implementation in Health Services (PARiHS), das Consolidated Framework for Implementation Research (CFIR) oder das Rahmenkonzept des Context and implementation of complex interventions (CICI).

Die Pilotierung der geplanten Intervention mit dem beabsichtigten Studiendesign hat eine Reihe von Optimierungsbedarfen aufgezeigt und somit einen wesentlichen Beitrag zur Qualitätsentwicklung im Forschungsvorhaben beigetragen. In der aktuell geführten Diskussion zur Abgrenzung und zum Einsatz von Machbarkeitsstudien im Vergleich zu Pilotierungsstudien (Eldridge et al., 2016), bekräftigen die Ergebnisse aus den vorliegenden Arbeiten die Sinnhaftigkeit des Einsatzes einer randomisierten Pilotstudie. In einer solchen Umsetzung ist es möglich, gleichzeitig die Machbarkeit und Akzeptanz der Intervention als auch die Machbarkeit des späteren Studiendesigns zu erproben.

10 Zusammenfassung

Chronische Gesundheitsbeeinträchtigungen haben diverse Implikationen auf Teilhabe an der Gesellschaft und unabhängige Lebensführung. Um derart individuelle Zielgrößen wie Teilhabe an der Gesellschaft positiv zu beeinflussen, braucht es sorgfältig an den Bedarfen der Adressaten ausgerichtete Interventionen, die die Mehrdimensionalität eines chronischen Gesundheitsproblems berücksichtigen. Im vergangenen Jahrzehnt entstanden deshalb zahlreiche methodische Rahmenkonzepte, die bei der Interventionsentwicklung die Vielschichtigkeit der Versorgungssituation stärker berücksichtigten. Das MRC Rahmenkonzept zur Entwicklung komplexer Interventionen stellt dabei aktuell ein Referenzmodell dar und wurde bisher am häufigsten in Studien zur Entwicklung von Multikomponenteninterventionen eingesetzt (Corry et al., 2013). Es gibt einen Handlungskorridor zur Entwicklung komplexer Interventionen, der einen deutlichen Umsetzungsspielraum je Ziel, Setting und Zielgruppen eröffnet. Da bisher konkrete Methodenkonzepte für die stationäre Langzeitpflege fehlten, war es nicht nur das Ziel dieser Arbeit, eine Intervention zur Verbesserung der sozialen Teilhabe von Menschen mit Gelenkkontrakturen im Pflegeheim zu entwickeln, sondern auch ein methodisches Verfahren für die Entwicklungsschritte Modellierung und Pilotierung einer Intervention zu erproben, um zu den methodischen Standards für die Interventionsentwicklung für Menschen in stationären Settings beizutragen.

Das in dieser Arbeit entwickelte methodische Vorgehen hat sich bewährt und kann somit als Vorlage für die Interventionsentwicklung für Menschen mit anderen chronischen Erkrankungen in der Langzeitpflege und mit entsprechenden Adaptionen auch in stationären Settings der Akutversorgung dienen. Der kleinschrittige Entwicklungsprozess und die Pilotierung in einer c-RCT lieferte zahlreiche wertvolle Hinweise zur Verbesserung der Intervention sowie zu deren Implementierungskonzept und zum Studiendesign für eine spätere Überprüfung der Wirksamkeit. Weiterer Bedarf der Verfeinerung methodischen Vorgehens wird dabei insbesondere in der Interventionsentwicklung bei kaum vorhandener Evidenzbasis und in der Entwicklung von Programmtheorien zu hochindividualisierten Interventionen, wie es Interventionen zur Verbesserung der Teilhabe von Menschen mit chronischen Erkrankungen in der Regel sind, gesehen. Um den gesamten, vom MRC Rahmenkonzept beschriebenen Zyklus von der Entwicklung einer Intervention bis zur Implementierung erfolgreich zu durchlaufen, braucht es zusätzlich zu den Empfehlungen des MRC Rahmenkonzeptes weitere Konzepte, die die Implementierung stärker in den Fokus nehmen.

11 Literaturverzeichnis

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Aus dem Institut für Gesundheits- und Pflegewissenschaft

der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg

(Direktorin: Prof. Dr. Gabriele Meyer)

Thesen der Habilitationsschrift

Teilhabeorientierte Gesundheitsversorgung von älteren Menschen mit Gelenkkontrakturen in Pflegeheimen

zur Erlangung des akademischen Grades

eines habilitierten Doktors der Medizinischen Wissenschaften (Dr. rer. medic. habil.)

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der Martin-Luther-Universität Halle-Wittenberg

von Dr. rer. medic. Susanne Saal

geboren am 24.09.1977 in Merseburg

12 Thesen

1. Um individuelle Zielgrößen wie Teilhabe an der Gesellschaft positiv zu beeinflussen, braucht es sorgfältig an den Bedarfen der Adressaten ausgerichtete Interventionen, die die Mehrdimensionalität eines chronischen Gesundheitsproblems berücksichtigen.

2. Das MRC Rahmenkonzept zur Entwicklung komplexer Interventionen stellt zur Entwicklung solch komplexer Interventionen aktuell ein Referenzmodell dar (Corry et al., 2013), aber beinhaltet einen deutlichen Umsetzungsspielraum, so dass bisher konkrete Methodenkonzepte zur Entwicklung von komplexen Interventionen in der stationären Versorgung fehlen.

3. Ziel dieser Arbeit ist es, am Beispiel einer Interventionsentwicklung zur Verbesserung der Teilhabe an der Gesellschaft von Menschen mit Gelenkkontrakturen im Pflegeheim Methoden zur Entwicklung komplexer Interventionen zu erproben und kritisch zu reflektieren.

4. Als Grundlage für die Entwicklung eines Verständnisses für die Wirkmechanismen einer Intervention ist das Gesundheitsproblem mit seinen einflussnehmenden Kontextfaktoren zentral. Eine dezidierte Beschreibung des Gesundheitsproblems, die von Beginn an der Komplexität des Geschehens Rechnung trägt, wird im MRC Rahmenkonzept (noch) nicht ausreichend berücksichtigt.

5. Das MRC Rahmenkonzept hält in der Entwicklungsphase bisher unzureichend Empfehlungen vor für den Fall, dass keine Evidenzbasis für das vorliegende Gesundheitsproblem vorhanden ist. Bei fehlender Evidenz zu möglichen Interventionskomponenten ist eine Einbindung aller am Versorgungsprozess beteiligten Personengruppen (zu einem sehr frühen Zeitpunkt der Interventionsentwicklung und im wiederholt in weiterer Verlauf) sowie eine konsequente Orientierung an Interventionszielen wesentlich für eine gelungene Interventionsentwicklung.

6. Hochindividualisierte Interventionen wie Interventionen zur Verbesserung der Teilhabe sind keine *Black Box*. Bei dieser Art von Interventionen ist es möglich und dringend notwendig, zugrundeliegende Wirkannahmen ausreichend transparent zu machen und eine Überprüfung zu ermöglichen.

7. Eine Programmtheorie zur Erklärung zugrundeliegender Wirkannahmen sollte sowohl die Wirkmechanismen der Intervention selbst beinhalten, als auch Annahmen zur Wirkweise der Interventionsimplementierung.

8. Um den gesamten, vom MRC Rahmenkonzept beschriebenen Zyklus von der Entwicklung einer Intervention bis zur Implementierung erfolgreich zu durchlaufen, braucht es zusätzlich zu den Empfehlungen des MRC Rahmenkonzeptes weitere Konzepte, die die Implementierung stärker in den Fokus nehmen.

13 Anlagen

Anlage 1 - 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. 2017; Age Ageing; 46(3): 373-382.

Anlage 2 - 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 Geriatrics 2018; 18 (1): 61.

Anlage 3 - 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. 2019; Trials; 20 (1): 411.

Anlage 4 - Klingshirn H, Müller M, Beutner K, Hirt J, Strobl R, Grill E, Meyer G, Saal S. (2020). 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 Geriatrics, 20(1):270. doi: 10.1186/s12877-020-01655-z.

Interventions for the prevention and treatment of disability due to acquired joint contractures in older people: a systematic review

Susanne Saal[1], Katrin Beutner[1], Julia Bogunski[1], Kathrin Obermüller[2], Martin Müller[2,3], Eva Grill[2,4], Gabriele Meyer[1]

[1]Institute of Health and Nursing Science, Medical Faculty, Martin-Luther-University Halle-Wittenberg, Halle an der Saale, Germany
[2]Ludwig-Maximilians-Universität München, Medical Faculty, Institute for Medical Information Processing, Biometrics and Epidemiology, München, Germany
[3]Hochschule Rosenheim, Faculty of Applied Health and Social Sciences, Rosenheim, Germany
[4]Ludwig-Maximilians-Universität München, German Center for Vertigo and Balance Disorders, München, Germany

Address correspondence to: S. Saal. Tel: (+49) 345 5574474; Fax: (+49) 345 5574471. Email: susanne.saal@uk-halle.de

Abstract

Background: acquired joint contractures have significant effects on quality of life and functioning.
Objective: to determine the effects of interventions to prevent and treat disabilities in older people with acquired joint contractures.
Methods: systematic search (last 8/2016) *via* Cochrane Library, PubMed, EMBASE, PEDro, CINAHL, trial registries, reference lists of retrieved articles and scientific congress pamphlets. Controlled and randomised controlled trials in English or German comparing an intervention with another intervention or standard care were included. Two independent researchers performed the selection of publications, data extraction and critical appraisal.
Results: seventeen studies with 992 participants met the inclusion criteria: 16 randomised controlled trials and 1 controlled trial (nursing homes = 4, community settings = 13). The methodological quality of the studies varied. Splints were examined in four studies, stretching exercises in nine studies, and ultrasound, passive movement therapy, bed-positioning and group exercise were each examined in one study. Studies on splints revealed inconclusive results regarding joint mobility or spasticity. Five of seven studies that assessed active stretching programmes for healthy older people reported statistically significant effects on joint mobility in favour of the intervention. Pain, quality of life, activity limitations and participation restrictions were rarely assessed.
Conclusion: the evidence for the effectiveness of interventions to prevent and treat disability due to joint contractures is weak, particularly for established nursing interventions such as positioning and passive movement. Better understanding is required regarding the delivery of interventions, such as their intensity and duration. In addition to functional issues, activities and social participation should also be studied as outcomes.

Keywords: *systematic review, contracture, older people*

Introduction

Joint contractures are common in older people in geriatric settings [1, 2]. They are characterised by restrictions in physiological joint mobility and can even lead to immobility [3]. Older people with joint contractures may experience high levels of disability, and limitations in mobility may lead to restricted participation [2, 4]. However, studies on the topic have focused mainly on body functions, and especially range of motion. This focus is reflected in the existing reviews. A Cochrane review analysed the effectiveness of stretching in the treatment and prevention of contractures in

35 studies with 1,391 participants of various ages across all health care settings [5]. Stretching interventions did not show any clinically important effects on joint mobility in older people with contractures, nor did they reveal which people were at risk of contractures. Another Cochrane review of passive movement for the treatment and prevention of contractures provided no clear evidence from two studies that included 122 participants with neurological conditions [6].

An earlier systematic review summarised eight studies that dealt with interventions to prevent contractures in geriatric settings. The internal validity varied, and the results were inconclusive [7]. The focus of the review was prevention, and only outcomes for body functions and body structures were investigated. Studies of joint contractures in specific diseases such as stroke were excluded.

Recent studies have revealed that from the perspective of the affected individuals and that of experts in the management and care of individuals with joint contractures, activity limitations and participation restrictions are the most relevant aspects [8–10]. Thus, a review of a broad scope of interventions to address the whole range of functioning and disability, from body functions to activities and participation, in a variety of settings and populations, seems justified.

We performed a systematic review of interventions for the prevention and treatment of disabilities from joint contractures in older people compared with other interventions or standard care.

Methods

A systematic literature search was conducted in the Cochrane Controlled Trial Register, MEDLINE (*via* PubMed), EMBASE, PEDro, CINAHL and the International Clinical Trials Registry Platform (ICTRP). The initial search took place between November 2014 and February 2015; an update was conducted in August 2016. The reference lists in the retrieved articles were reviewed for additional studies. Experts in the field who were personally known to the authors were contacted to identify unpublished or ongoing studies. A forward citation search was conducted for references of the included studies in Google Scholar, Web of Science and Scopus. The search strategy followed the recommendation of the Cochrane Handbook for Systematic Reviews of Interventions 5.1.0 [11]. A manual search for abstracts written for various scientific congresses was performed. The search strategy and a list of conference proceedings are provided in the Supplementary data, available at *Age and Ageing* online.

Selection criteria

Titles, abstracts or full texts of identified studies were examined independently by two researchers applying the following predefined inclusion criteria:

- randomised or non-randomised controlled study,
- any intervention for the prevention and/or treatment of disability from joint contractures together with

another intervention or usual care or non-treated control group,
- living in residential care facilities or community dwelling,
- age 65 years or greater,
- joint mobility and any aspect of functioning and disability as an outcome,
- any publication date.

The categories of interventions are described in detail in the Supplementary data, available at *Age and Ageing* online.

The exclusion criteria were

- congenital contractures, Dupuytren's contractures, Ledderhose's contractures or burn scars,
- medication intervention or surgical therapy,
- acute care hospital or rehabilitation facilities,
- language other than English or German.

Critical appraisal

Two independent authors (S.S. and J.B.) assessed the reported methodological quality of the studies to identify any potential source of systematic bias. Disagreements were resolved by discussion and finding a consensus, or by consulting a third researcher (G.M.). Critical appraisal followed the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0 [11]. The data extraction sheet is available from the authors on request.

Data extraction and synthesis

The data from the included studies were extracted independently by two reviewers (S.S. and J.B.), using the template for intervention description and replication (TIDieR) and the Cochrane Handbook for Systematic Reviews of Interventions, version 5.1.0, and cross-checked for accuracy [11, 12]. Disagreements were resolved by discussion and consensus finding.

As anticipated, the included studies were heterogeneous in terms of settings, interventions and outcome measures. Therefore, a narrative synthesis was conducted following generally accepted methods for systematic reviews, as suggested by the York Centre for Reviews and Dissemination [13]. In cases in which the effect sizes were missing in the original papers, the mean differences between the study groups were calculated from means, standard deviations (SDs) and the number of analysed cases per group derived from the original papers (conducted by S.S.). Harvest plots were used for visualisation [14].

Results

Our search revealed a total of 1,816 papers; 1,799 papers were excluded for various reasons as displayed in Figure 1. The analysis sample comprised 17 studies with 992 participants. Sixteen studies were individually randomised, and one was a non-randomised controlled trial. The studies were published in seven countries between 1984 and 2013. The sample sizes ranged from 8 to 208 participants, and the mean age ranged from 58 to 86 years. In one study, the mean age of the control group participants was 58 years, which is lower than the age predefined in the inclusion criteria. Because the mean age of the participants in the intervention group was 66 years, we decided to include the study in our review. Four studies took place in nursing homes, and the others took place in the community. The characteristics of the included studies are displayed in Table A, Supplementary data, available at *Age and Ageing* online. In two cases, the corresponding author of the primary study was contacted. Both authors responded; one author provided the requested information on baseline characteristics [18], and the other informed us that the requested data on the predefined follow-up assessments were unavailable [29].

The methodological quality of the studies varied widely. Four studies discussed splints, nine studies discussed stretching exercises and one study was found for each of the following interventions: ultrasound, passive movement therapy, a bed-positioning programme and a group exercise programme. The methodological quality of each study (see Table B, Supplementary data), a 'risk of bias' summary on all studies (see Figure A, Supplementary data), a description of the study characteristics (see Table B, Supplementary data)

and details of the intervention in each of these studies (see Table B, Supplementary data) are available at *Age and Ageing* online.

Outcome measures

In all, 13 of the 17 studies investigated joint mobility [16, 17, 19–27, 29, 30], 3 investigated spasticity [15, 18, 28] and pain [28–30], 5 investigated performance-oriented items such as gait speed [21–23, 25, 26] and 2 used self-rated questionnaires with items that addressed activities of daily living [17, 31].

Effects of interventions

The results of the studies are summarised in Table 1 and depicted visually in Figure B, Supplementary data, available at *Age and Ageing* online.

Splinting

Four studies investigated the effects of splinting; three compared splinting with usual care (76 participants) [15–17] and one investigated wearing splints for two different lengths of time (14 participants) [18].

Only one study reported significant improvement in the passive range of motion in wrist extension after radial fracture (mean difference, 6°; 95% confidence interval, 1°–12°) [17]. Neither of the other two studies reported significant effects between groups regarding range of motion or spasticity. It also remains unclear whether wearing splints over different lengths of time affects spasticity after a stroke [18]. One study assessed hand function with the Patient Rated Hand Wrist
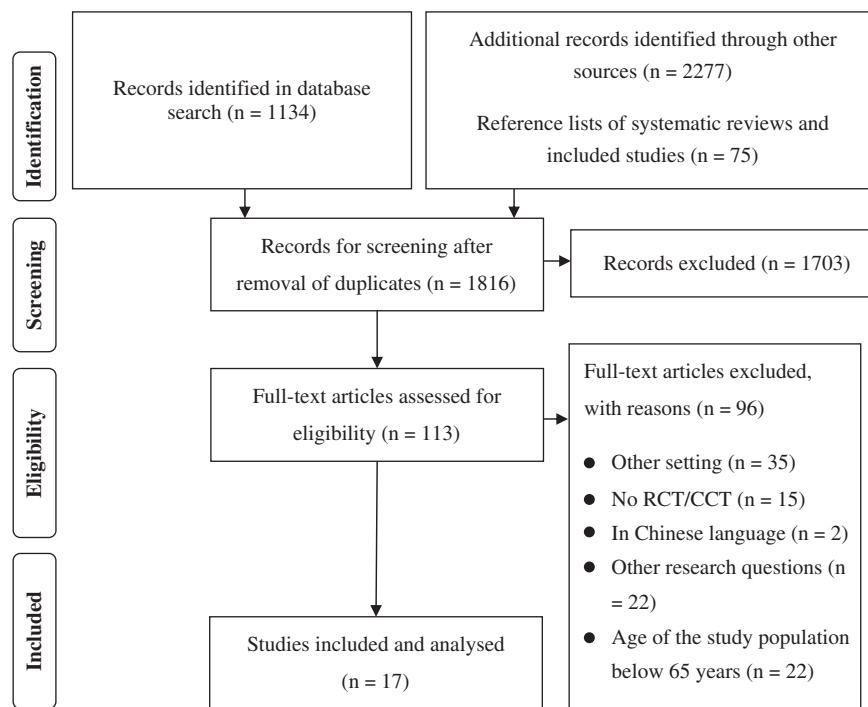

Figure 1. Flow diagram.

Table 1. Summary of study results.

Reference	Change direction	Joint mobility	Change direction	Spasticity	Change direction	Activities and Participation	Change direction	Further outcomes
McPherson et al. [15]		– (Not reported)	Unclear	Reduction of hypertonus of the wrist in the splinted group ($t = 4.59$, $P = 0.019$), but not in CG ($t = 1.94$, $P = 0.15$); data for calculation of mean differences were not reported		–		–
Steffen and Mollinger, [16][a]	⇔	Maintenance of knee extension in −2.00° (95% CI, −17.36–13.36)		–		–		–
Jongs et al. [17]	⇑	Increase in passive wrist extension (primary outcome measure) in 6° (95% CI, 1–12)		–	⇔	Maintenance of the PRHWE score (primary outcome measure) 2 points (95% CI, −5–9) Maintenance of COPM; subscale 'performance' 0 points (95% CI, −1.3–1.4) and subscale 'satisfaction' −0.1 points (95% CI, −1.1–0.9)		Adverse events: transient numbness in the index finger ($n = 1$) and pain in the wrist ($n = 1$); adverse events resolved immediately when splints were removed, no long-term effects were noted
Sheehan et al. [18]		–	⇔	Maintenance of amount of resistance in the stroke-affected wrist and finger flexors 1.5 N (95% CI, −9.96–12.96) Maintenance of rate of change in resistance in the stroke-affected wrist and finger flexors of 5.2% (95% CI, −37.8–48.1)		–		–
Light et al. [27]	⇑	Increase in passive knee extension, a 10° difference in favour of the low-load prolonged stretch ($P ≤ 0.05$)		–		–		–
Falconer et al. [30]	⇔	Maintenance of active knee ROM; means, SDs and effect sizes not reported, results only visualised by figures; authors stated that IG subjects were not significantly different from CG subjects in active ROM after treatment		–		–	⇔	Maintenance of pain; means, SDs and effects sizes not reported, results only visualised by figures; authors stated that IG group subjects were not significantly different from CG subjects in pain after treatment
Feland et al. [19][a]	⇑	Reduction in passive knee extension restrictions at the 10th week: in favour of IG1 (60-s stretching) compared with IG4 (no stretching) at 8.15° (95% CI, 10.46–5.84)		–		–		–

Kerrigan et al. [20][a]	⇔	Maintenance of static peak hip extension at 0.30° (95% CI, −1.31–1.91) Maintenance of dynamic hip extension at FWS at 1.70° (95% CI, −1.42–4.82) Maintenance of dynamic hip extension at CWS at 1.70° (95% CI, −1.40–4.80) Maintenance of anterior pelvic tilt (CWS) at −2.00° (95% CI, −4.24–0.24) Maintenance of anterior pelvic tilt (FWS) at −1.60° (95% CI, −3.86–0.66)	–		–		No adverse events
Christiansen, [21]	⇑	Increase in passive hip extension 5.70° ($P = 0.023$) Increase in passive ankle dorsiflexion at 5.2° ($P = 0.020$)	–	⇑	Increase in freely chosen gait speed to 0.07 m/s ($P = 0.016$)		Maintenance of stride length during FWS ($P = 0.188$) Maintenance of stride length during CWS ($P = 0.216$) Adverse events: a fall was reported in IG
Cristopoliski et al. [22][a]	Unclear	Increase in passive hip extension at 24.00° (95% CI, 18.96–29.04) Maintenance of knee ROM at 1.40° (95% CI, −3.78–6.58) Maintenance of ankle ROM at 1.80° (95% CI, −0.97–4.57)	–	⇑	Increase in gait speed to 0.16 m/s (95% CI, 0.06–0.26)		Further gait variables also reported: cycle duration, swing phase duration, stance phase duration, double stance duration, step length, heel contact velocity, pelvic anterior leaning, pelvic lateral tilt, pelvic rotation and toe clearance
Gajdosik et al. [23][a]	Unclear	Maintenance of maximal passive dorsiflexion angle at 3.20° (95% CI, −1.02–7.42)	–	⇔	Maintenance of timed agility course at −0.23 s (95% CI, −3.28–2.82)	⇔	Maintenance of maximal passive DF force 29.50 N (95% CI, −6.51–65.51) Maintenance of mean passive resistive force 11.80 N (95% CI, −2.99–26.59) Maintenance of average passive-elastic stiffness 0.45 N/deg (95% CI, −0.63–1.53)
		Increase of ROM angle to 7.40° (95% CI, 1.41–13.39)			Maintenance of 10-m walk at −0.84 s (95% CI, −1.80–0.12)	Unclear	Increase of absorbed passive-elastic energy 540.0 deg N (95% CI, 52.44–1,027.56)
					Maintenance of functional reach test at 1.81 cm (95% CI, −2.09–5.71)		Maintenance of retained passive-elastic energy 517.00 deg N (95% CI, −7.20–1,041.20)
Reid and McNair [24][a]	Unclear	Maintenance of knee extension ROM (at 50% of baseline peak torque) –of 5.00° (95% CI, −14.45–4.45) Maintenance of stiffness in the final 10% of knee extension ROM 0.18 (95% CI, −0.01–0.37); after baseline adjustment authors reported sign. Improvements in favour of IG ($P < 0.05$)	–		–	⇑	Maintenance of peak passive torque at 5.40 Nm (95% CI, −0.97–11.77); after baseline adjustment authors reported sign. Improvements in favour of IG ($P < 0.05$)

Continued

Table 1. Continued

Reference	Change direction	Joint mobility	Change direction	Spasticity	Change direction	Activities and Participation	Change direction	Further outcomes
Watt et al. [25][a], USA	⇔	Maintenance of passive hip extension ROM at 0.00° (95% CI, −2.77–2.77) Maintenance of dynamic peak hip extension 1.50° (95% CI, −2.02–5.03) Maintenance of peak anterior pelvic tilt at 0.40° (95% CI, −1.94–2.74)		–	⇔	Maintenance of gait speed (CWS), authors: 'No significant changes in gait speed were found for either group'[b]		Maintenance of stride length (CWS), authors: 'No significant changes in gait speed were found for either group'[b]
Watt et al. [26][a]	⇔	Maintenance of peak hip extension (CWS) at 1.70° (95% CI, −17.88–21.28) Maintenance of peak anterior pelvic tilt (CWS) at –0.30° (95% CI, −2.91–2.31) Maintenance of passive peak hip extension (CWS) at 2.90° (95% CI, −0.82–6.62) Maintenance of peak hip extension (FWS) at 1.00° (95% CI, −2.01–4.01) Maintenance of peak anterior pelvic tilt (FWS) at 0.10° (95% CI, −2.35–2.55) Maintenance of passive peak hip extension (FWS) at 2.90° (95% CI, −0.82–6.62)		–	Unclear Unclear	Increase in walking speed (CWS) to 0.10 m/s (95% CI, 0.01–0.19) Maintenance of walking speed (FWS) at 0.03 m/s (95% CI −0.11–0.17)	⇔ Unclear	Maintenance of cadence (CWS) 1 at 0.30 steps/min (95% CI, −3.23–5.83) Maintenance of cadence (FWS) at –0.90 steps/min (95% CI, −7.76–5.96) Increase in stride length (CWS) of 0.10 m (95% CI, 0.01–0.19) Maintenance of stride length (FWS) at 0.07 m (95% CI, −0.02–0.16)
Hobbelen et al. [28]		–	Unclear	Maintenance of paratonia arms in points (MAS) (95% CI, −1.9–4.2); mean change in IG 2.3 (7.9); mean change in CG 1.2 (6.9)[b] Increase in paratonia legs in points (MAS) (95% CI, 0.1–4.1); mean change in IG, 2.2 (4.9); mean change in CG, 0.1 (4.9)[b]		–	⇔ ⇔	Maintenance of pain in points (95% CI, −1.4–0.6); mean change (SD) in IG, −0.4 (2.4); mean change (SD) in CG, −0.8 (2.5)[b] Maintenance of caregiver burden using Clinical Global Impressions (CGI) scale in points (95% CI, −0.05–0.09); mean change (SD) in IG, −0.3 (1.3); mean change (SD) in CG, 0.2 (1.2) Maintenance of caregiver burden using modification of Dutch Patient-Specific Complaint (PSC) list: PSC problems 1, 2 and 3, respectively (95% CIs, −7.3–7.3; −5.8–7.9; and −7.2–6.7)
Fox et al. [29][c]	⇔	Maintenance of passive range of knee extension 1.64° (95% CI, −0.98–4.26)		–		–	⇔	Maintenance of pain −0.30 points (95% CI −1.10–0.51) Reddening of skin over knees caused by bed sheet, (n) not reported

Evaluation (PRHWE) and the Canadian Occupational Performance Measure (COPM) and showed no significant improvement [17], and none of the studies considered pain as an outcome. One of the four splinting studies reported transient numbness or pain after wearing the splints in 2 of the 19 participants [17]. None of the other studies reported a predefined assessment of adverse events.

Stretching interventions

Seven studies investigated the effects of stretching programmes in healthy older people (388 participants) [19–25] and two studies reported on stretching approaches on frail older people (111 participants) [26, 27].

Stretching interventions in healthy older people

Two of the seven studies in healthy older people in which stretching interventions were compared with no interventions or with sham interventions reported a significant improvement in range of motion (rate of change in passive extension restriction 60-s stretching group [±standard error] of -2.37 ± 0.27 compared with 0.40 ± 0.32 in the no-stretching group [$P < 0.05$]; an increase in passive hip extension in the intervention group of $5.70°$ [$P = 0.023$] compared with the control group) [19, 21]. Three studies showed inconclusive results for joint mobility [22–24] and two studies reported no difference between groups regarding range of motion [20, 25]. The two studies that showed effects on range of motion conducted stretching for longer than 30 s [19, 21], whereas two of the three studies that were inconclusive or had no effect on the range of motion used stretching durations of 30 s or less [20, 23].

Two studies in healthy older people demonstrated effects by improving gait speed (increase in freely chosen gait speed of 0.07 m/s; $P = 0.016$; mean [±SD] 1.22 ± 0.13 m/s in the intervention group compared with 1.06 ± 0.09 in the control group; $P < 0.05$) [21, 22], whereas two studies showed no differences in gait speed [23, 25]. One study reported no adverse events [20], and another reported an accidental fall in the intervention group, although no further circumstances were described [21]. None of the other studies reported a predefined assessment of adverse events.

Stretching interventions in frail older people

One study in which active stretching exercises for hip extension were compared with a sham intervention in frail older people showed no improvement in range of motion and unclear results regarding gait speed [26]. The authors presumed that the effect of the exercises (performed in a kneeling position) was reduced by the frail study population's multiple health problems and reduced abilities. Another study compared low-load passive stretching for 1 h with a traction device (modified Buck's skin traction, used after leg fractures) with manual passive stretching and passive movement therapy in non-ambulatory older people. This study found an improvement of $10°$ in passive knee

Kudo et al. [31], Japan

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Improvement in physical function, pain and stiffness used Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Only mean changes by time reported: IG mean change in points (SD) 10.2 (10.3) and CG 3.2 (8.7); authors' comment: 'The group exercise showed significantly higher improvement in WOMAC than the home exercise according to unpaired *t*-test ($P < 0.05$)'

ROM, range of motion; FWS, fast walking speed; CWS, comfortable walking speed; IG, intervention group; CG, control group.
[a]Where effect sizes were missing in the original paper, the mean difference between groups was calculated from means and SDs derived from the original papers. Where more than one measure was used for an outcome, the primary outcome measure is displayed in the table.
[b]Calculation of mean difference was not appropriate because of baseline differences between groups.
[c]Results from the first phase of the crossover study were taken from Ref. [5].

extension in favour of the low-load prolonged stretch ($P <$ 0.05) [27]. None of the studies reported a predefined assessment of adverse events.

Passive movement interventions

One study investigated passive movement interventions in 102 participants [28]. Passive movement therapy carried out by physical therapists was compared with standard care in persons with severe paratonia caused by dementia. Spasticity of the legs in the intervention group increased compared with the control group (modified Ashworth Scale, mean change ± SD 2.2 ± 4.9 in the intervention group and 0.1 ± 4.9 in the control group; 95% confidence interval, 0.1–4.1), whereas no significant difference regarding the spasticity of arms or pain was observed between the groups.

Bed-positioning programmes

One study compared a bed-positioning programme with standard care for 18 people in a chronic care hospital [29]. No group differences in range of motion or pain were observed. Reddening of the skin over the knees caused by the bed sheet was reported as an adverse effect, but the number of affected persons was not specified.

Ultrasound

One study investigated ultrasound combined with exercise therapy in comparison with exercise therapy alone in 74 older people with osteoarthritis of the knee [30]. No group differences were observed in range of motion or pain. No other outcomes or adverse events were assessed.

Group exercise programme

One study compared a group exercise programme with a self-administered home exercise programme in 209 women with osteoarthrosis [31]. A significant difference between groups was observed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) (mean change ± SD 10.2 ± 10.3 in the group exercise programme and 3.2 ± 8.7 in the control group; $P < 0.05$). None of the studies assessed adverse events.

Discussion

Our systematic review deals with studies in which interventions for the prevention and treatment of disabilities from acquired joint contractures in older people were compared with other interventions or with standard care. We identified several different interventions.

Few studies assessed the effects of splints. Although the scope of our review differed from that of a Cochrane review on stretching for treatment and prevention of joint contractures and the sample of included studies thus deviated [15], our results point in the same direction. The

Cochrane review reported that splinting has no effects on joint mobility (mean difference 0°; 95% confidence interval –1° to 0° [15]. No evidence was found regarding the effects of splints on pain, quality of life or participation.

Stretching exercises seem to be effective as another common intervention for healthy older people with joint contractures. But the evidence is insufficient to allow the effect in frail older people to be estimated, possibly because frail older people are barely able to perform most of the standardised stretching exercises, such as stretching the hip flexors. Frail older people are less likely than healthy older people to use their full range of motion in activities of daily living. Thus, randomised controlled trials that provide exercises tailored to the capacity of frail older people are needed.

The effects of stretching intensity on range of motion are uncertain [32]. Despite the weak body of evidence, a relationship seems to exist between the effectiveness and the duration of static stretching. A 30-s duration has been assumed to be effective for enhancing range of motion [33] and was used in most studies of stretching exercises. However, the findings of a study in older people suggested that a stretching time of 60 s is more effective than 30 s [19]. This ambiguity might explain the heterogeneity of the results of stretching exercises in older people; the studies that reported significant improvements with active stretching exercises used a stretching time of 45–60 s per stretch, whereas the studies that did not show significant improvements used a stretching time of only 30 s. To further verify this relationship, comparative studies in older people are needed. Although our review indicates that stretching might influence activities such as gait speed, nothing is known about whether stretching exercises affect quality of life, pain or participation. The benefit of active stretching exercises in frail older people remains unclear.

Common measures for the prevention of joint contractures in frail older people, such as positioning or passive movements, have barely been addressed by clinical studies. The few existing studies indicate missing effects and, in the case of passive movements, even a risk of increasing spasticity in patients with severe paratonia caused by dementia.

Our systematic review unveils the unsatisfying body of knowledge regarding interventions for the prevention and treatment of disability from acquired joint contractures in older people. Most of the identified studies focussed on outcomes related to body functions and body structures, specifically joint mobility. Aspects of activities involving more comprehensive outcomes were rarely examined, and aspects of participation or quality of life remain unaddressed. Adverse events were not reported by default. Only a few studies investigated frail older people in nursing homes.

Limitations

Our results are difficult to interpret due to the heterogeneity of the interventions and the study populations. The review has limitations owing to the shortcomings of the underlying studies. Ten of the 17 included studies gave an

inadequate description of the randomisation procedure or group allocation. Nine studies raised uncertainties concerning the handling of incomplete data. In several studies, no predefined primary or secondary endpoints were stated. Twelve studies did not report the assessment of adverse events or reported an insufficient estimate of the effect size. The reports on the interventions used in the control group and in usual care were incomplete in about half of the studies.

We did not check for publication bias; a meta-analysis was not reasonable due to the heterogeneity of the interventions and study populations. A language bias introduced by the English and German language restriction could not be ruled out.

Our search of the reference lists of systematic reviews revealed only a few additional references. To minimise the risk of missing further eligible studies, we also conducted a forward citation search [34], contacted experts in the field and searched trial registers. Further valuable strengths of our review include an unlimited search period and our assessment of the comprehensive description of the interventions according to recently published reporting statements [12].

Conclusions

Our systematic review revealed a significant lack of research on interventions for the prevention and treatment of disability from joint contractures in older people. Sufficiently robust randomised controlled trials using valid effect size estimates on patient-relevant outcomes are needed to assess the effects of established measures for the prevention and treatment of joint contractures on activities and participation in older people. The heterogeneity of outcomes and assessments indicates the importance of a consensus regarding a core outcome set for joint contractures. Assessment of adverse events must be an integral part of the outcome assessment. Future studies should contribute to a better understanding of the influence of the frequency, duration and intensity of interventions on the results and should take into consideration the specific conditions of older people. Amongst other things, the superiority of 60-s stretches over 30-s stretches in older people requires confirmation. Improved study reporting is urgently required to ease the appraisal of the studies' internal validity and the intervention components [12, 35].

Future studies should account for the abilities of older people when modelling and assessing interventions. Interventions should be broad and should consider more than simply issues of body functions and structures, which are undoubtedly relevant. Aspects of activities such as self-care, walking or shopping and self-determined participation, including leisure activities, are very relevant from the patients' perspective and should be addressed.

The results indicate that active stretching programmes for healthy older people might be effective in increasing joint mobility. In accordance with the Cochrane review [5],

the use of splints in participants with joint mobility restrictions seems to have no benefits. However, the findings of our systematic review are not sufficient to lead to clear implications for clinical practice. Future studies should not simply consider functional issues but should also investigate activities and participation.

Key points

- Little is known about the effects of nursing interventions that target care-dependent older people with joint contractures.
- Active stretching programmes for healthy older people might improve joint mobility, whereas the use of splints might not.
- Further research is needed to understand the effects of established nursing interventions and to explore the optimal frequency, duration and intensity of these interventions.
- Interventions and outcome measures should not only address functional issues but should also investigate activities and participation.

Supplementary data

Supplementary data are available at *Age and Ageing* online.

Authors' contributions

G.M., M.M. and K.B. initially planned the review. K.B., G. M., M.M. and E.G. wrote the study protocol. K.B. registered the review in PROSPERO. K.O., K.B., J.B. and S.S. selected studies for inclusion/exclusion. S.S. and J.B. evaluated the methodological quality of the included trials and extracted data. S.S. and G.M. interpreted the study data. S.S. corresponded with the study authors and wrote the drafts of the review supported by G.M. All of the authors approved the last version of the manuscript.

Conflicts of interest

None declared.

Registration

URL: http://www.crd.york.ac.uk/PROSPERO/ Identifier: CRD42014015076.

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PLEASE NOTE: The very long list of references supporting this review has meant that only the most important are listed here and are represented by bold type throughout the text. The full list of references is available in the Supplementary data, available at *Age and Ageing* online.

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Interventions for Prevention and Treatment of Disability due to Acquired Joint Contractures in

Older People: A Systematic Review

Table of contents

1. Search terms

The overall search strategy used the following combined search terms for database searches: contracture [MeSH], joint contracture, social participation, Aged [MeSH], randomized controlled trial, controlled clinical trial, meta-analysis, systematic review. First, we searched for systematic reviews and meta-analysis in addition to RCTs and CCTs in order to retrieve relevant RCTs and CCTs. In a second step, only RCTs and CCTs were included in the analysis.

Search Strategy:

Medline	((joint contracture) OR contracture [MESH]) NOT (dupuytren OR ledderhose OR (burn scar)) Filter: CCT, RCT, meta-analysis and systematic review
CINAHL	contracture NOT (Dupuytren's OR ledderhose OR burn) Filter: clinical trial, meta-analysis, randomized controlled trial, systematic review
PEDro	contracture
Cochrane Library CDSR CENTRAL	(contracture OR (joint contracture)) NOT (dupuytren's OR ledderhose OR burn scar)

Search for unpublished studies in abstracts of scientific congresses

Conference proceedings of the following scientific congresses were searched:

- IAGG World Congress of Gerontology & Geriatrics
- The Gerontological Society of America's Annual Scientific Meeting
- Congress of the European Union Geriatric Medicine Society
- European Congress of Gerontology

- Asia/Oceania Regional Congress of Gerontology and Geriatrics

- European Federation of National Associations of Orthopaedics and Traumatology (EFORT) Congress

- International Conference and Exhibition on Orthopedics & Rheumatology

2. Types of included interventions

Since the review explored interventions and intervention components that address body functions, body structures, environmental and personal factors as well as social participation and quality of life, the interventions are categorised as follows:

a). Educational or counselling interventions:

These interventions include either programmes for nursing staff or programmes for nursing home residents or older people in the community requiring long-term geriatric care. There are a range of different approaches varying, for example, in terms of length and content. The educational or counselling programme contents were assumed to include all or some of the following components: impact of mobility and activity, environmental (risk) factors for restriction in activity and social participation, adverse outcomes of disuse and inactivity, reasons for and management of specific behavioural problems, meaning of compensatory strategies, correct use of medical aid. Following the UK Medical Research Council framework for development and evaluation of complex interventions, it was not be possible to extract the effective or ineffective components of the educational programmes [1], but components of included programmes could be analysed in detail.

b) Organisational or environmental interventions:

Organisational or environmental approaches include interventions that aim to change organisational or physical (risk) factors, which for instance inhibit people from moving or participating in different life domains.

c) Interventions that improve body functions and structures:

Since activity and social participation may be influenced by body functions and body structures, these interventions include programmes/training for different body functions such as dynamic balance,

muscle power or endurance, mobility of single or several joints, general physical endurance, e.g. body positioning, passive movements, moving or stretching programmes or functional exercises.

d) Interventions that enhance activity or social participation restrictions:

Participation is defined as involvement in daily life situations and activity as the execution of tasks or actions by an individual [2]. Therefore, these interventions include programmes/training, e.g. for improving

- mobility, such as training to change body position, carry or move objects, walk, run or climb several distances and on different surfaces, use of different types of transportation, or skills to avoid a fall,
- self-care and domestic life or
- participation in recreational or leisure activity, interpersonal interactions and relationships.

e) Other interventions:

All interventions that cannot be included in the above four categories will be considered.

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3. Summary of characteristics of the included studies – Table A

Ref.	Source/Country	Design	Setting	Study participants, n (included)	Age in years, Mean (Range)	Study Groups Intervention group	Control group	Intensity of intervention
**Organisational or environmental interventions**								
15	Mc Pherson et al. 1985 USA	CCT	Community	4/4; persons following stroke	75.75 (71-84)/ 77.75 (67-86)	Dynamic splint for arms and fingers and exercise programme	Passive stretching and exercise programme	**IG:** 3 times per week; for 1 h; over 5 weeks **CG:** 3 times per week; 60 sec stretch, 5 repetitions per session, for 5 weeks
16	Steffen and Mollinger 1995 USA	RCT	Nursing home	28 (bilateral comparison); nursing home residents	86 (73-95)	Passive range of motion therapy, manual stretching and static splinting of the knee	Passive range of motion therapy and manual stretching of the knee	**IG:** splint: 5 times per week; time per session progressed from 1h to 3h within 1 week; for 6 months; PROM and manual stretching see IG 2 **CG:** 2 times per week; 3 hip-knee extension for 10 sec at maximum resistance, repeated until maximum knee extension reached, then held for 1 min; 5 times ankle dorsiflexion held for 5 sec; for 6 months
17	Jongs et al. 2012 Australia	RCT	Community	19/21; persons following distal radial fracture	66 (56-72)/ 58 (52-65)	Home exercise programme and dynamic splinting for the wrists	Home exercise programme for the wrists	**IG:** splint each day as long as possible, but at least 6 hours in total; supervised over 8 weeks; unsupervised about 12 weeks **IG/ CG:** home exercise programme: at least 3 sessions a day, for 12 weeks, *duration of exercises not reported*
18	Sheehan et al. 2006 Australia	RCT	Community	8/6; persons with stroke	74 (8.7)/ 70 (7.5)*	Static splinting of wrist and fingers "short-term" (since week 3 -7)	Static splinting of wrist and fingers "long-term" (since week 2 -7)	**IG:** *frequency and time per sessions not reported*; for 5 weeks **CG:** *frequency and time per sessions not reported*; for 6 weeks

Ref.	Source/Country	Design	Setting	Study participants, n (included)	Age in years, Mean (Range)	Study Groups Intervention group	Study Groups Control group	Intensity of intervention
27	Light et al. 1984 USA	RCT	Nursing home	11 (bilateral comparison); "geriatric subjects"	"Geriatric subjects"* *(not further described)*	Low-load prolonged stretch per Modified Buck's skin traction apparatus and a passive movement therapy for lower extremity	Manual passive stretching (high load brief) and a passive movement therapy for lower extremity	**IG:** 2 times per day; 5 days per week; 1 h per session; for 4 weeks, traction weight was increased weekly **CG:** 2 times per day; 5 days per week; 15 min per session; maintaining end range position for 1 min; force reduced for 15 sec; 15 sec rest; repeated 3 times each session; for 4 weeks **Both groups:** passive movement therapy:1 times per day; 10 repetitions of pelvis-on-trunk rotation and upper extremity PNF diagonals bilaterally
30	Falconer et al. 1992 USA	RCT	Community	37/37; persons with osteoarthritis of the knee	69.4 (13.1)/ 65.7 (12.8)*	Ultrasound therapy and a leg stretching exercise programme (including a home exercise programme)	Sham ultrasound with a leg stretching exercise programme (including a home exercise programme)	**IG:** ultrasound: 4 times 3 min., 2-3 times per week; 12 treatments overall; for 4- 6 weeks **CG:** Sham ultrasound: 4 times 3 min., 2-3 times per week; 12 treatments overall; for 4-6 weeks **Both groups:** exercises: 5-15 min passive stretch; each exercise repeated 10 times; each held for 5 sec; 30 min overall

	Interventions that improve body functions and structures and/or interventions that enhance activity or social participation restrictions							

Ref.	Source/Country	Design	Setting	Study participants, n (included)	Age in years, Mean (Range)	Intervention group	Control group	Intensity of intervention
19	Feland et al. 2001 USA	RCT	Community	17/17/15/13; healthy people aged 65 years or older	83.2 (68–90)/ 85.5 (80–93)/ 85.2 (65–92)/ 85.1 (70–97)	**IG1** Passive static stretching for lower extremity (60 sec-stretches)	**IG2** Passive static stretching for lower extremity (15 sec-stretches)	**IG 1,2, 3:** 5 times per week; 4 stretches; 10-sec rest between stretches; for 6 weeks **IG 1:** 60 sec for each stretch **IG 2:** 15 sec for each stretch **IG 3:** 30 sec for each stretch
						IG 3 Passive static stretching for lower extremity (30 sec-stretches)	**IG 4** No stretching	

Ref.	Source/Country	Design	Setting	Study participants, n (included)	Age in years, Mean (Range)	Study Groups		Intensity of intervention
						Intervention group	Control group	
20	Kerrigan et al. 2003 USA	RCT	Community	50/50; older, healthy persons aged ≥65 years	n.a.* (≥65 years)	Hip stretching exercise programme	Shoulder deltoid– stretching exercise programme	**IG/CG:** 2 times per day; 4 repetitions; stretching for 30 sec; for 5 min a session; for 10 weeks
21	Christiansen 2008 USA	RCT	Community	20/20; healthy older people	72.1 (62-82)	Hip and ankle stretching programme	No intervention	**IG:** 2 times per day; 3 repetitions per session; 45 sec each stretch; 9 min a session; for 8 weeks
22	Cristopoliski et al. 2009 Brazil	RCT	Community	12/12; older healthy women	65.9 (4.2)/ 65.4 (2.9)*	Stretching exercise programme lower extremity	No intervention	**IG:** 12 sessions; 3 times per week; each stretching exercises performed 4 times and held for 60 sec (a total of 240 sec for each segment); for 4 weeks
23	Gajdosik et al. 2005 USA	RCT	Community	10/9; healthy older women	73.1 (65-87)/ 75.3 (65-89)	Stretching exercise of the calf muscles	No intervention	**IG:** 3 times per week; 15 sec each stretch, 10 repetitions per session; for 8 weeks
24	Reid & McNair 2011 New Zealand	RCT	Community	14/10/8/11; older adults with and without knee osteoarthritis	68.7 (60-78)	**IG 1** Lower limb stretching programme of participants with Osteoarthritis	**KG 1** No intervention	**IG:** once a day for at least five days a week; 60 sec each stretch, 3 repetitions on each muscle group and on each leg per session; for 6 weeks
						IG 2 Lower limb stretching programme of participants without Osteoarthritis	**KG 2** No intervention	
25	Watt et al. 2011a USA	RCT	Community	100 *(number of participants per groups not reported)*; healthy older persons	72.6 (65-87)	Hip stretching exercise programme	Shoulder abductor stretching exercise programme	**Both groups:** 2 times per day; 60 sec each stretch; 4 min per session; for 10 weeks

7

Ref.	Source/Country	Design	Setting	Study participants, n (included)	Age in years, Mean (Range)	Study Groups		Intensity of intervention
						Intervention group	Control group	
26	Watt et al. 2011b USA	RCT	Community	100 *(number of participants per groups not reported)*; frail older persons	77 (65-87)	Hip stretching exercise programme	Shoulder abductor stretching exercise programme	**Both groups:** 2 times per day; 60 sec each stretch;4 min per session; for 10 weeks
28	Hobbelen et al. 2012 Netherlands	RCT	Nursing homes	48/54; persons with severe paratonia caused by dementia	84 (67-98)	Passive movement therapy	Positioning the participant supine in bed and sitting silently alongside for 20 min	**Both groups:** 3 times per week; 20 min per session; for 4 weeks
29	Fox et al. 2000 Canada	Cross-over[a]	Chronic care hospital	9/9; institutionalised older adults	82 (71-93)	Bed positioning programme	Usual care *(not further described)*	**IG:** 4 times per week; for 40 min (in total of 160 min per week); for 8 weeks **CG**: *not reported*
31	Kudo et al. 2013 Japan	RCT	Community	81/128; persons with knee osteoarthritis	63.8 (5.9)/ 65.6 (5.1)*	Group exercise therapy	Home exercise programme (with exercises similar to those in the group exercise therapy)	**IG:** 2 times per week; 90 min each session; for 3 months; bike riding exercise started from the intensity for 20 min to be around 55-65 % of the predicted maximum heart rate, and carried out for 40 min in the end **CG:** 2 times per week; 90 min each session; for 3 months

*Standard deviation, since range was not reported; IG=Intervention group; CG=Control group; sec=second; min=minute; h=hour; [a] Data of the first comparison phase extracted from Katalinic OM et al. (2010).

4. Summary of the methodological quality of included studies – Figure A

Figure A: 'Risk of Bias' summary

Other bias: Unclear sample size calculation, unclear inclusion/exclusion criteria, unequal treatment of both groups, non-defined or unclear primary/secondary outcome.

5. Methodological quality of included studies – Table B

Christiansen 2008

Item	Authors´ judgement	Description
Adequate sequence generation?	Yes	Quote: "Blocked random assignment to groups was used to ensure comparable group sizes.", p1422.
Allocation concealment?	Yes	Quote: " […] blind selection of numbers from a pool of numbers […]", p1422.
Blinding? Assessors	Yes	Quote: "Data were reduced with experimenters blinded to group allocation until statistical analysis was complete.", p1424.
Incomplete outcome data addressed? All outcomes	Yes	Comment: 3/40 dropout. Reasons for dropout were plausible.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.
Free of other bias?	No	Comment: Inclusion/exclusion criteria not clearly stated.

Cristopoliski et al. 2009

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Comment: Not reported.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Unclear	Comment: Not reported.
Incomplete outcome data addressed? All outcomes	Unclear	Comment: 4/24 dropouts. Reasons for dropouts were not reported. No detailed information about statistical handling of dropouts.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes reported.
Free of other bias?	No	Comment: Inclusion/exclusion criteria not clearly stated, sample size calculation not reported, study groups treated equally (except of intervention or control) unclear, primary outcome not clearly stated.

Falconer et al. 1992

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Comment: Not reported.
Allocation concealment?	Unclear	Comment: Not reported.

Blinding? Assessors	Yes	Quote: "Patients and evaluators were blinded to the assigned treatment.", p30.
Incomplete outcome data addressed? All outcomes	No	Comment: 18/74 dropouts. Reasons for high dropout-rate at catamnesis were not stated. No intention-to-treat analysis.
Free of selective reporting?	Yes	Comment: All pre-stated outcomes reported. Data were reported as figures only.
Free of other bias?	No	Comment: Sample size calculation not reported, unclear whether study groups were treated equally (except intervention or control), primary outcome not clearly stated.

Feland et al. 2001

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Comment: Not reported.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Yes	Comment: "The research assistant who performed the measurements was unaware of group assignment.", p1112.
Incomplete outcome data addressed? All outcomes	Yes	Comment: 6/62 dropout. Reasons for dropouts were plausible.
Free of selective reporting?	Yes	Comment: Pre-stated outcome reported.
Free of other bias?	No	Comment: Sample size calculation not reported, unclear whether study groups were treated equally (except intervention or control).

Fox et al. 2000

Item	Authors´ judgement	Description
Adequate sequence generation?	Yes	Quote: "The study participants were randomly assigned to 2 groups by a random numbers table.", p365.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Yes	Quote: "A single rater blinded to the intervention assessed participants […]", p366.
Incomplete outcome data addressed? All outcomes	No	Comment: 6/18 dropouts due to death. No intention-to-treat analysis.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.

Item	Authors´ judgement	Description
Free of other bias?	No	Comment: Sample size calculation not reported.

Gajdosik et al. 2005

Item	Authors´ judgement	Description
Adequate sequence generation?	Yes	Quote: "To ensure random assignments, the group names were placed in visually secure envelopes and put in a box and mixed thoroughly. Then each subject selected one envelope to determine their group assignment.", p976.
Allocation concealment?	Yes	Quote: "To ensure random assignments, the group names were placed in visually secure envelopes and put in a box and mixed thoroughly. Then each subject selected one envelope to determine their group assignment.", p976.
Blinding? Assessors	Unclear	Comment: Not reported.
Incomplete outcome data addressed? All outcomes	Yes	Comment: No dropouts.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.
Free of other bias?	No	Comment: Sample size calculation was not reported. Primary outcome was not clearly stated.

Hobbelen et al. 2012

Item	Authors´ judgement	Description
Adequate sequence generation?	Yes	Quote: "After computerized and concealed block randomization (block size of 4), patients were assigned to one of two groups.", p835.
Allocation concealment?	Yes	Quote: "The randomization code (per patient) was only available to the assigned therapists and was kept secret from all other personnel involved, including the primary investigator.", p835f.
Blinding? Assessors	Yes	Quote: "Nursing staff and all assessors were blinded for treatment allocation.", p836.
Incomplete outcome data addressed? All outcomes	Yes	Comment: 4/102 dropout. Reasons for dropout were plausible. Intention-to-treat analysis was carried out.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.

Free of other bias?	Yes	Comment: Appears to be free of other bias.

Jongs et al. 2012

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Quote: "[…] a computerised blocked randomisation sequence was generated prior to the commencement of the trial by an independent offsite person.", p174.
Allocation concealment?	Yes	Quote: "[…] placed in opaque sealed and sequentially numbered envelopes that were held off-site. A participant was considered to have entered the trial once his/her envelope was opened.", p174.
Blinding? Assessors	Yes (at 8 weeks) No (at 12 weeks)	Quote: "A blinded assessor performed assessments at 8 weeks", p174. Quote: "[…] an assessor not blinded to group allocation performed assessments at 12 weeks.", p174.
Incomplete outcome data addressed? All outcomes	Yes	Comment: 8/40 dropouts. Intention-to-treat analysis was carried out.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.
Free of other bias?	Yes	Comment: Appears to be free of other bias.

Kerrigan et al. 2003

Item	Authors´ judgement	Description
Adequate sequence generation?	Yes	Quote: "[…] participants were randomized, on the basis of a computer-generated block randomization, into 1 of 2 groups.", p2.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Yes	Quote: "[…] the evaluators were blinded towards the treatment and control group.", p5.
Incomplete outcome data addressed? All outcomes	Yes	Comment: 4/100 dropouts. Reasons for dropouts were plausible.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes reported.
Free of other bias?	No	Comment: Sample size calculation not reported, unclear whether study groups were treated equally (except intervention or control).

Kudo et al. 2013

Item	Authors´	Description

	judgement	
Adequate sequence generation?	Yes	Quote: "Subjects were randomly allocated into either a group performing group exercise therapy conducted in a class (group exercise) or a group performing home exercise therapy (home exercise) by drawing lots.", p933.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Unclear	Comment: Not reported.
Incomplete outcome data addressed? All outcomes	No	Comment: 6/209 dropouts. Dropouts only in the intervention group. Reasons for dropouts not reported. No intention-to-treat analysis.
Free of selective reporting?	Yes	Comment: Pre-stated outcome reported.
Free of other bias?	No	Comment: No adequate sample size calculation, no reporting of effect size (incomplete reporting).

Light et al. 1984

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Comment: Not reported.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Unclear	Comment: Not reported.
Incomplete outcome data addressed? All outcomes	Yes	Comment: No dropouts.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes reported.
Free of other bias?	Yes	Comment: Appears to be free of other bias.

Mc Pherson et al. 1985

Item	Authors´ judgement	Description
Adequate sequence generation?	No	Comment: Clinical Controlled Trial.
Allocation concealment?	No	Quote: "Eight individuals, […] were matched by age and sex and assigned to two groups of four […]", p250.
Blinding? Assessors	Yes	Quote: "Spring-weighted scale assessments were gathered by an occupational therapist in the patients room who was not aware of the subject's condition assignment.", p250.
Incomplete outcome data addressed? All outcomes	Yes	Comment: No dropouts.

Free of selective reporting?	Yes	Comment: Pre-stated outcome reported.
Free of other bias?	No	Comment: No sample size calculation, no inclusion/exclusion criteria, no outcomes stated.

Reid & McNair 2011

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Quote: "The process of randomisation was undertaken by two allied staff within the University who were unaware of the study and not aware of the group allocation indicated in a sealed envelope.", p6.
Allocation concealment?	Yes	Quote: "All participants were randomly allocated to one of four groups via a sealed envelope.", p6.
Blinding? Assessors	Yes	Quote: "The two research assistants, who undertook the Kincom® assessments, the WOMAC, and LLTQ assessments, were blinded to the group allocation. The two research assistants, who supervised the stretching intervention, were also blinded to the assessment results.", p6.
Incomplete outcome data addressed? All outcomes	No	Comment: No dropouts. Exclusion of four participants after randomisation and baseline assessment due to an acute episode of low back pain (1) and high BMI`s (3). No intention-to-treat analysis.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.
Free of other bias?	Yes	Comment: Appears to be free of other bias.

Sheehan et al. 2006

Item	Authors´ judgement	Description
Adequate sequence generation?	Yes	Quote: "Numbers from a random numbers table […]", p1033.
Allocation concealment?	Yes	Comment: Participants and investigators could not foresee assignment.
Blinding? Assessors	Yes	Quote: "Participants and carers were continually reminded by the independent clinician that under no circumstances should the researcher become aware of an individual's splintwearing regime.", p1033.
Incomplete outcome data addressed? All outcomes	No	Comment: 2/14 dropouts. Both persons were part of the intervention group. One person did not accept the intervention. No

intention-to-treat analysis.

Item	Authors´ judgement	Description
Free of selective reporting?	Yes	Comment: Pre-stated outcomes were reported.
Free of other bias?	No	Comment: No adequate sample size calculation.

Steffen and Mollinger 1995

Item	Authors´ judgement	Description
Adequate sequence generation?	No	Quote: "Use of the prolonged stretch was alternately assigned to the right or left knee as each subject entered the study.", p889.
Allocation concealment?	No	Comment: Alternation.
Blinding? Assessors	Yes	Quote: "The physical therapists performing the measurements were not involved In treatment of the subjects, nor were they mare of the side of the experimental treatments.", p888.
Incomplete outcome data addressed? All outcomes	No	Comment: 10/28 dropouts. Incomplete data were not adequately explained. No intention-to-treat analysis.
Free of selective reporting?	No	Comment: No pre-stated outcomes reported.
Free of other bias?	No	Comment: Sample size calculation unclear, inclusion/exclusion criteria not clearly stated, primary outcome not clearly stated.

Watt et al. 2011b

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Comment: Not reported.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Yes	Quote: "Each technician performing the assessments had no role in the intervention and was blinded to each subject's treatment or control group designation.", p326.
Incomplete outcome data addressed? All outcomes	No	Comment: 18/100 dropouts. Reasons for dropouts reported. No intention-to-treat analysis.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes reported.
Free of other bias?	No	Comment: Sample size calculation not reported, unclear whether study groups were treated equally (except intervention or control), primary outcome not clearly stated.

Watt et al. 2011b

Item	Authors´ judgement	Description
Adequate sequence generation?	Unclear	Comment: Not reported.
Allocation concealment?	Unclear	Comment: Not reported.
Blinding? Assessors	Yes	Quote: "Each technician performing the assessments had no role in the intervention and was blinded to each subject's treatment or control group designation.", p332.
Incomplete outcome data addressed? All outcomes	No	Comment: 26/100 dropouts. Reasons for dropouts not reported. No intention-to-treat analysis.
Free of selective reporting?	Yes	Comment: Pre-stated outcomes reported.
Free of other bias?	No	Comment: Sample size calculation not reported, unclear whether study groups were treated equally (except intervention or control), primary outcome not clearly stated.

Risk of other bias: Unclear sample size calculation, unclear inclusion/exclusion criteria, unequal treatment of both groups, non-defined or unclear primary/secondary outcome.

6. Harvest plots summarising effects of included studies – Figure B
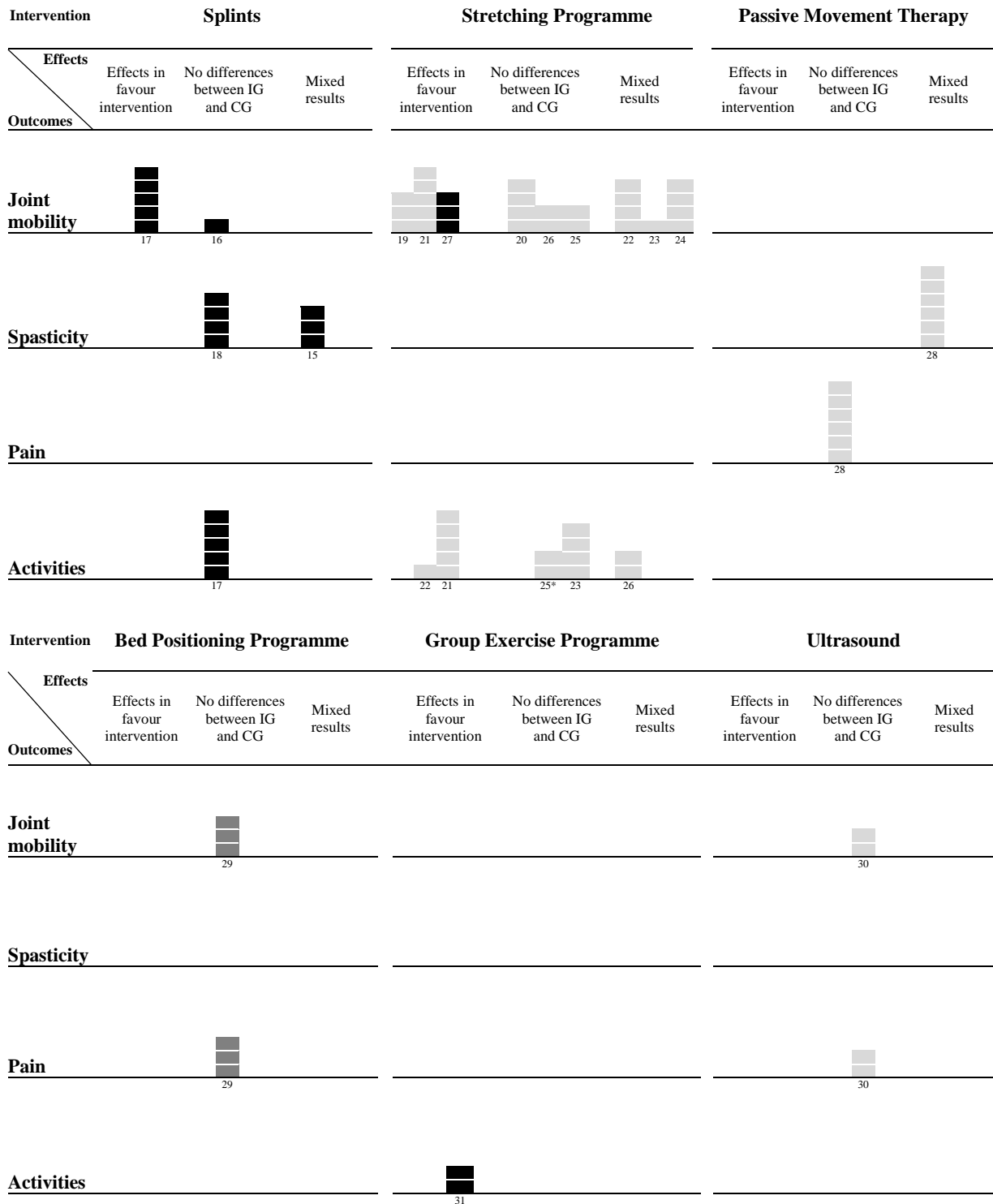
The appropriateness of the methods of the study design is indicated by the height of the bar (the higher the bar the lower the risk of bias; according the 'Risk of Bias' Summary, displayed in the Appendix in the supplementary data on the journal website http://www.ageing.oxfordjournals.org/, Figure A). The numbers below the bars indicate the reference number. The colour of the bar indicates the type of comparison (light grey – intervention compared versus no intervention/sham intervention, dark grey – added to usual care; black – compared to other intervention). 'Mixed results mean studies reported both, effects in favour of the intervention (or control in case of study 28) and no effect.

7. **Summary of descriptions of interventions in the included studies- Table C**

Ref.	Author Year	Groups	Rationale/Goal	What (materials)?		Who provided?		How delivered?		Where?		When and How much?						Modifications		Tailoring		Adherence/Fidelity	Costs
												Frequency		Period of time		Time of session							
				IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG		
15	Mc Pherson et al. 1985	IG - Dynamic splint for arms and fingers and exercise programme CG - Passive stretching and exercise programme	x	x	x	o	o	x	x	x	x	x	x	x	x	x	x	o	o	x	x	o	o
16	Steffen and Mollinger 1995	IG - Passive range of motion therapy, manual stretching and static splinting of the knee CG - Passive range of motion therapy and manual stretching of the knee	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	o	o	x	x	x	x
17	Jongs et al. 2012	IG - A home exercise programme and dynamic splinting wrist CG - A home exercise programme	x	x	x	x	x	x	x	x	o	o	o	o	o	o	o	o	o	o	o	x	o
18	Sheehan et al. 2006	IG - Static splinting of wrist and fingers "short-term" (since week 3 -7) CG - Static splinting of wrist and fingers "long-term" (since week 2 -7)	x	x	x	o	o	x	x	x	x	o	o	x	x	o	o	o	o	x	x	o	o
27	Light et al. 1984	IG - Low-load prolonged stretch per Modified Buck's skin traction apparatus and a passive movement therapy for lower extremity CG - Manual passive stretching (high load brief) and a passive movement therapy for lower extremity	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	o	o	o	o	o	o
30	Falconer et al.	IG - Ultrasound therapy and a leg	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	o	x	o	x	o

Ref.	Author Year	Groups	Rationale/Goal	What (materials)?		Who provided?		How delivered?		Where?		When and How much? Frequency		Period of time		Time of session		Modifications		Tailoring		Adherence/Fidelity	Costs
				IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG		
	1992	stretching exercise programme (including a home exercise programme) CG - Sham ultrasound with a leg stretching exercise programme (including a home exercise programme)																						
19	Feland et al. 2001	IG1 - Passive static stretching for lower extremity (60 second-stretches) IG2 - Passive static stretching programme for lower extremity (15 second-stretches) IG3 - Passive static stretching programme for lower extremity (30 second-stretches) IG4 - No stretching	x	IG1 x / IG2 x ; IG3 x / IG4 x		IG1 o / IG2 o ; IG3 o / IG4 o		IG1 x / IG2 x ; IG3 x / IG4 x		IG1 o / IG2 o ; IG3 o / IG4 o		IG1 x / IG2 x ; IG3 x / IG4 x		IG1 x / IG2 x ; IG3 x / IG4 x		IG1 x / IG2 x ; IG3 x / IG4 x		IG1 o / IG2 o ; IG3 o / IG4 o		IG1 o / IG2 o ; IG3 o / IG4 o		x	o
20	Kerrigan et al. 2003	IG - Hip stretching exercise programme CG - Shoulder deltoid-stretching exercise programme	x	x	x	o	o	x	x	x	x	x	x	x	x	x	x	o	o	o	o	x	o
21	Christiansen 2008	IG - Hip and ankle stretching programme CG - No intervention	x	x	x	o	x	x	x	x	x	x	x	x	x	x	x	o	x	o	x	x	o
22	Cristopoliski et al. 2009	IG - Stretching exercise programme lower extremity CG - No intervention	x	x	x	o	x	x	x	x	x	x	x	x	x	x	x	o	o	x	x	o	o
23	Gajdosik et al. 2005	IG - Stretching exercise CG - No intervention	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	o	o	o	o	x	o
24	Reid & McNair 2011	IG 1 - Lower limb stretching programme of participants with Osteoarthritis	x	IG1 x / CG1 x		IG1 x / CG1 x		IG1 x / CG1 x		IG1 x / CG1 x		IG1 x / CG1 x		IG1 x / CG1 x		IG1 x / CG1 x		IG1 o / CG1 x		IG1 x / CG1 x		x	o

Ref.	Author Year	Groups	Rationale/Goal	What (materials)?		Who provided?		How delivered?		Where?		When and How much?						Modifications		Tailoring		Adherence/Fidelity	Costs
												Frequency		Period of time		Time of session							
				IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG	IG	CG		
		CG 1 - No intervention IG 2 – Lower limb stretching programme of participants without Osteoarthritis CG 2 - No intervention		IG2 x	CG2 x	IG2 x	CG2 x	IG2 x	CG2 x	IG2 x	CG2 x	IG2 x	CG2 x	IG2 x	CG2 x	IG2 x	CG2 x	IG2 o	CG2 x	IG2 x	CG2 x	x	o
25	Watt et al. 2011a	IG - Hip stretching exercise programme CG - Shoulder abductor stretching exercise programme	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	o	o	x	o	x	o
26	Watt et al. 2011b	IG - Hip stretching exercise programme CG - Shoulder abductor stretching exercise programme	x	x	x	o	o	x	x	x	x	x	x	x	x	x	x	o	o	o	o	x	o
28	Hobbelen et al. 2012	IG - Passive movement therapy CG - Positioning the participant supine in bed and sitting silently alongside for 20 min.	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	o	x	x	x	o	o
29	Fox et al. 2000	IG - Bed positioning programme CG - Usual care *(not further described)*	x	x	o	x	o	x	o	x	o	x	o	x	o	x	o	o	o	x	o	x	o
31	Kudo et al. 2013	IG - Group exercise therapy CG - Home exercise programme (with exercises similar to those in the group exercise therapy)	x	x	x	x	x	x	x	o	x	x	x	x	x	x	x	o	o	x	o	x	x

x - Information available, o - information not available.

Adherence/Fidelity was only marked as "available" if information was reported on both intervention and control groups.

"Who provided" was only marked as "available", if provider's profession was reported (e.g. physical therapist, nurse) and - in the case of the intervention needing specific knowledge - the further qualification of the provider was reported.

Interventions were marked as entirely reported, if all the aspects according to all the components of the intervention were reported (e.g. if home exercise programme was not further described, the section was marked as "information not available").

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

Susanne Saal[1]* , Gabriele Meyer[1], Katrin Beutner[1], Hanna Klingshirn[2], Ralf Strobl[2], Eva Grill[2,3], Eva Mann[4], Sascha Köpke[5], Michel H. C. Bleijlevens[6], Gabriele Bartoszek[1,7], Anna-Janina Stephan[2], Julian Hirt[1] and Martin Müller[8,1]

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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* Correspondence: Susanne.Saal@uk-halle.de
[1]Institute of Health and Nursing Sciences, Medical Faculty, University of Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany
Full list of author information is available at the end of the article

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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

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Fig. 1 Overview of the intervention development process
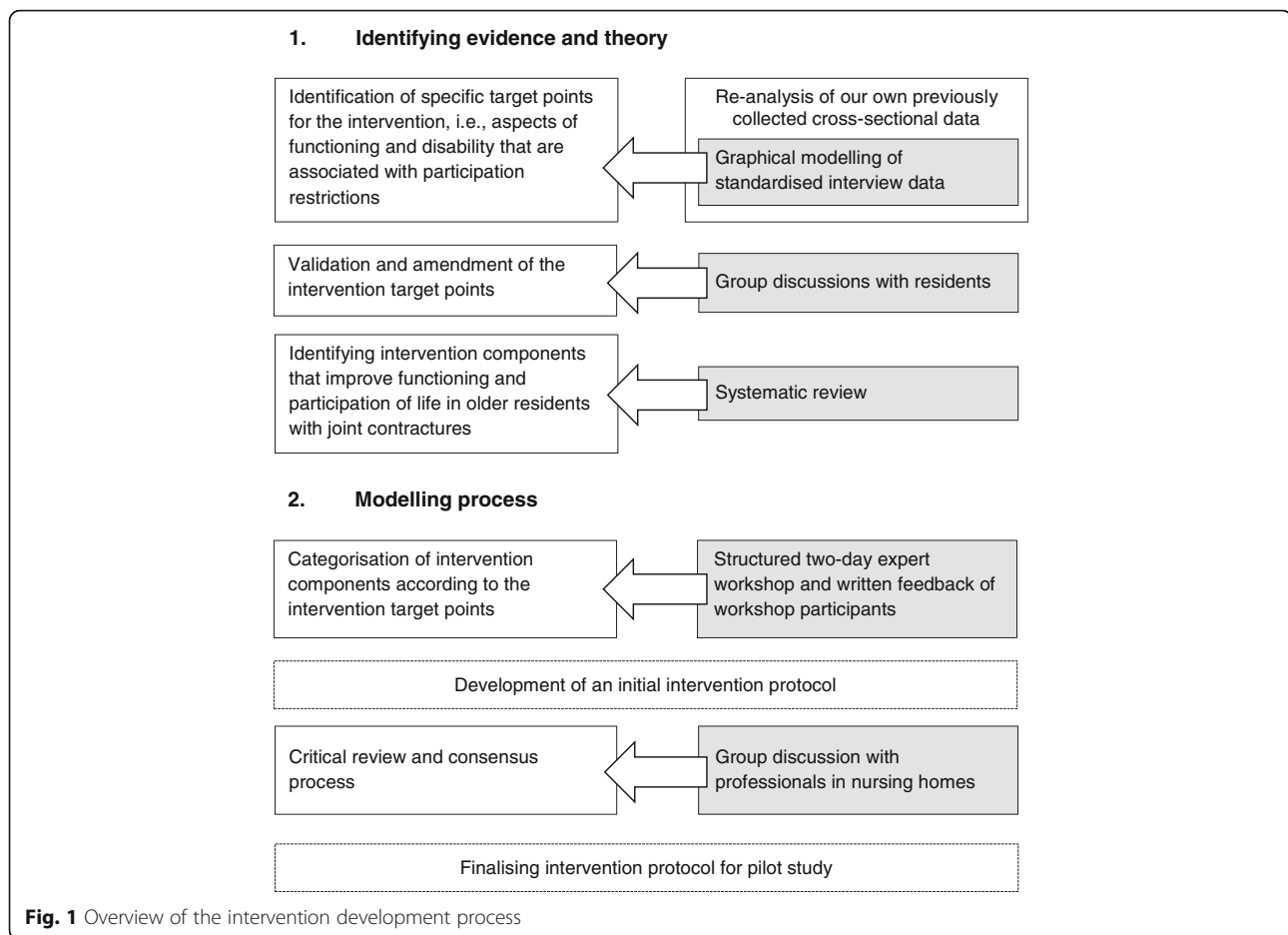
hospitals in and around Munich, Bavaria (Germany) and in eleven nursing homes and three geriatric rehabilitation hospitals in and around Witten, North Rhine–Westphalia (Germany). Two hundred ninety-four participants 65 years of age or older with at least one diagnosis of joint contracture were interviewed 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.

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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.

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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

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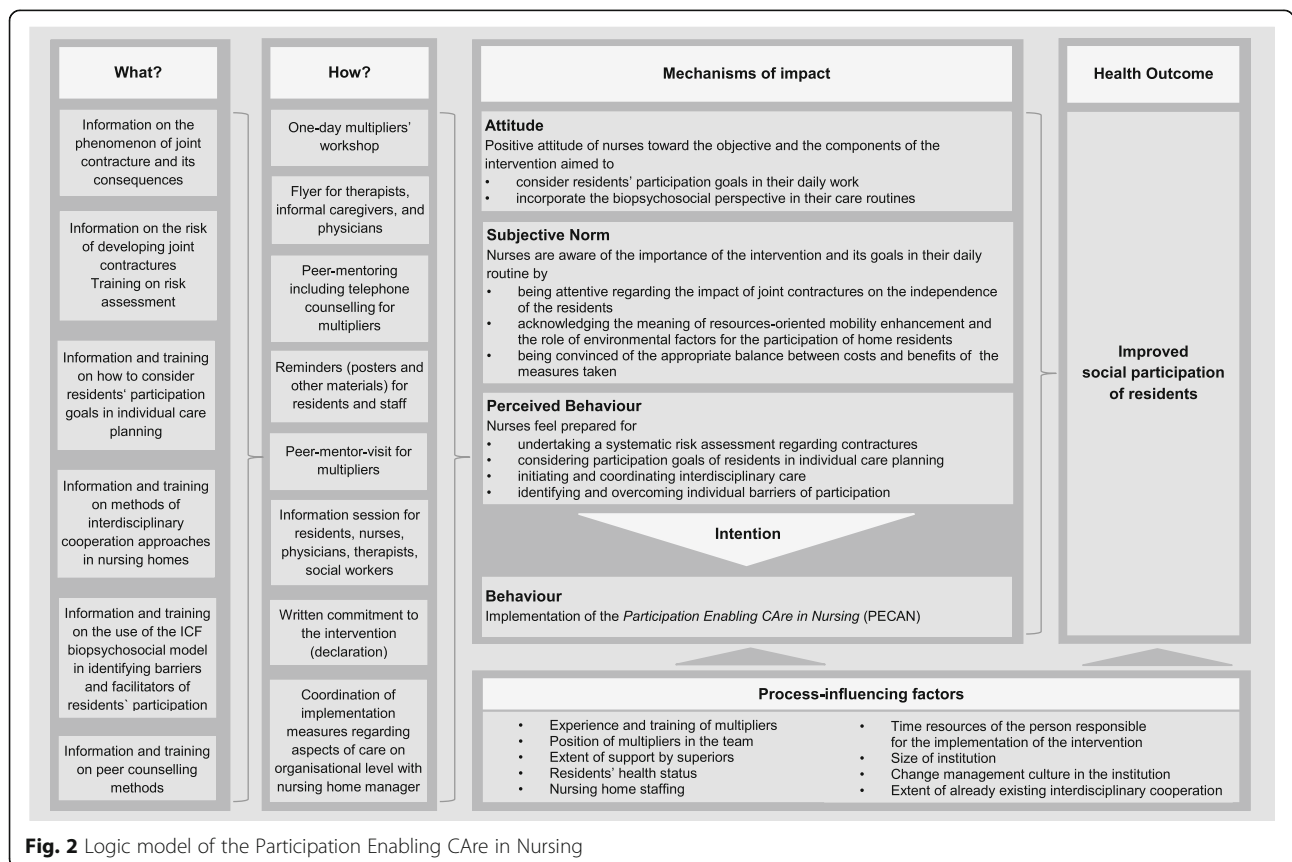
- Presentation of information on methods of interdisciplinary collaboration;
- Training in the use of the ICF biopsychosocial model to identify barriers and facilitators of residents' participation;
- Provision of information on measures to prevent and treat joint contractures and their suitability for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

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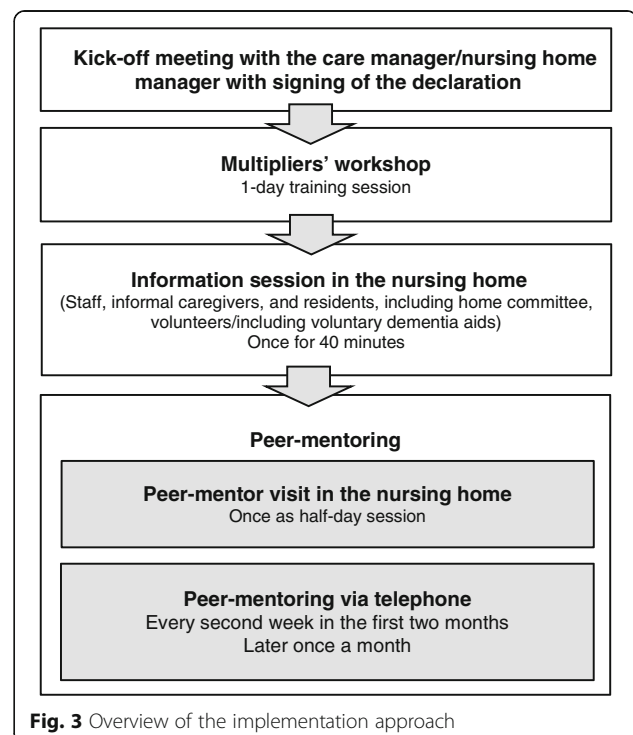
As a result of this modelling process, we developed a qualification scheme for nurses and an approach to support transfer into daily routine for the implementation of the intervention.

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.

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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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Author details
[1]Institute of Health and Nursing Sciences, Medical Faculty, University of Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany. [2]Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig-Maximilians-University Munich, Marchioninistr. 15, 81377 Munich, Germany. [3]German Center for Vertigo and Balance Disorders, Ludwig-Maximilians-University Munich, Marchioninistr. 15, 81377 Munich, Germany. [4]Institute for General, Family and Preventive Medicine, Paracelsus Medical University, Strubergasse 21, 5020 Salzburg, Austria. [5]Institute of Social Medicine and Epidemiology, Nursing research group, University of Lübeck, Ratzeburger Allee 160, 23538 Lübeck, Germany. [6]CAPHRI Care and Public Health Research Institute, Department of Health Services Research, Living Lab on Ageing and Long-Term Care, Maastricht University, Universiteitssingel 40, 6229 ER Maastricht, The Netherlands. [7]University of Applied Sciences for Social Work, Education and Nursing, Dürerstraße 25, 01307 Dresden, Germany. [8]Faculty of Applied Health and Social Sciences, Rosenheim University of Applied Sciences, Hochschulstraße 1, 83024 Rosenheim, Germany.

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Trials

RESEARCH

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

Susanne Saal[1*†] , Hanna Klingshirn[2†], Katrin Beutner[1], Ralf Strobl[2,3], Eva Grill[2,3], Martin Müller[4†] and Gabriele Meyer[1†]

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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* Correspondence: susanne.saal@uk-halle.de
Susanne Saal and Hanna Klingshirn are first author.
†Martin Müller and Gabriele Meyer are senior author.
[1]Institute of Health and Nursing Sciences, Medical Faculty, Martin Luther University, Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany
Full list of author information is available at the end of the article

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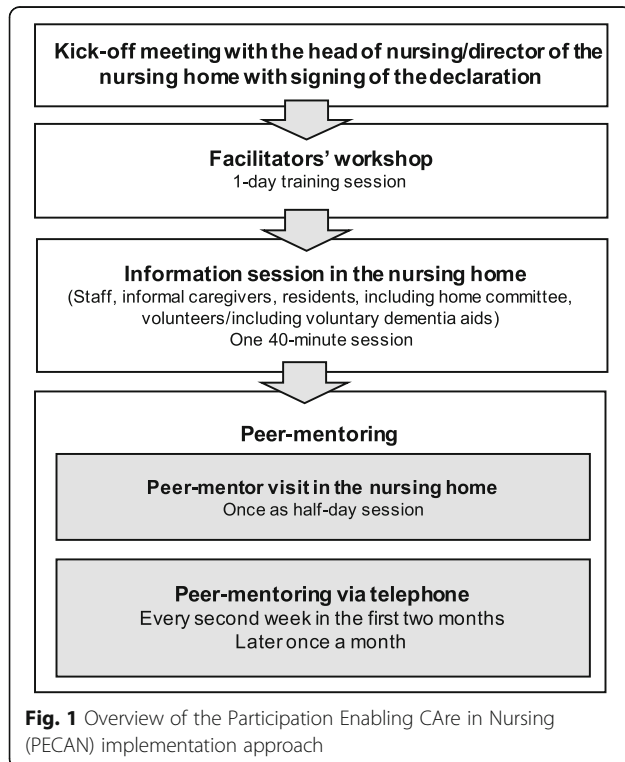
The written material comprised leaflets with information about the intervention and contact details of the facilitators and the research team. Further details of the intervention and its development are described elsewhere [16].

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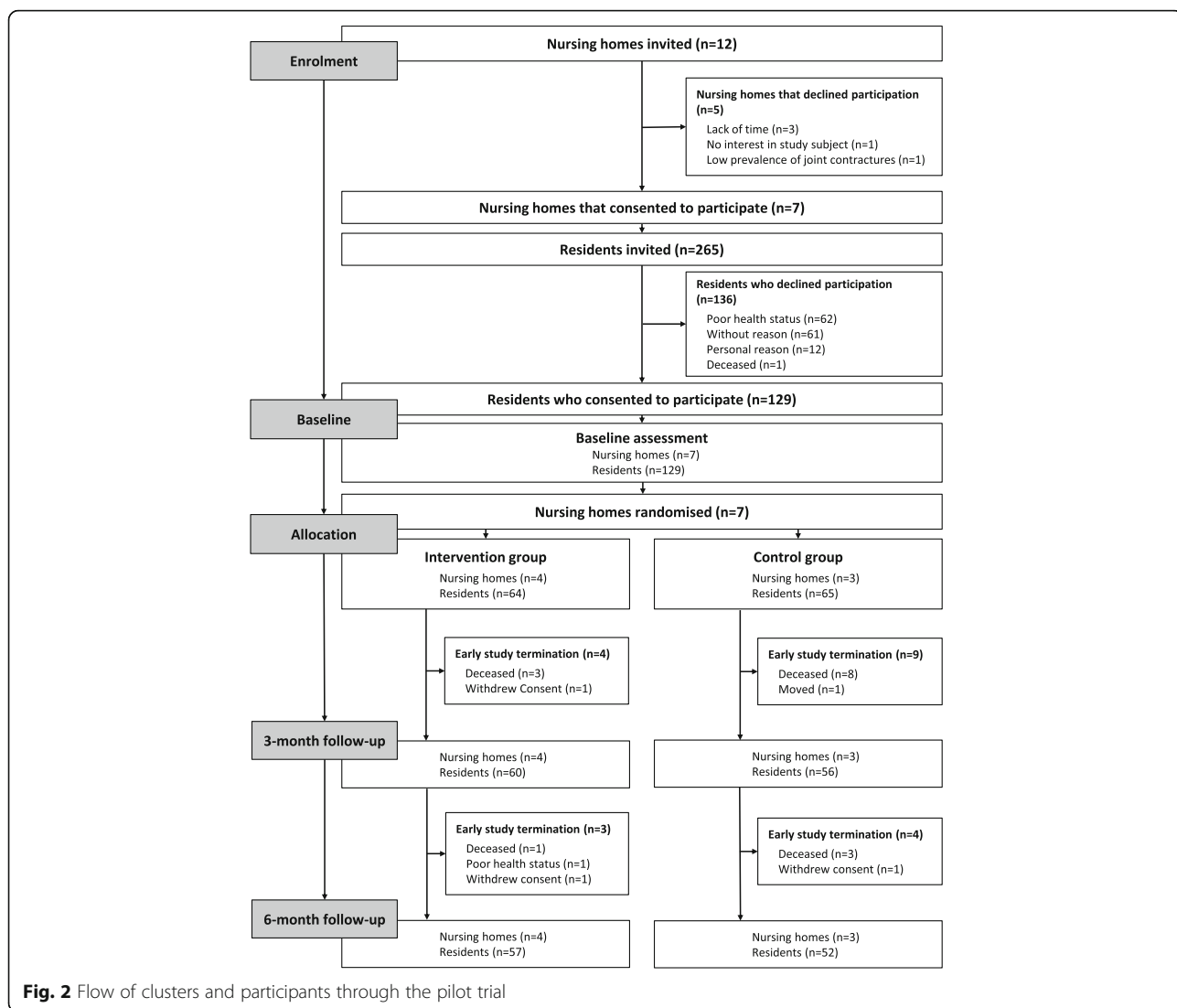
Fig. 2 Flow of clusters and participants through the pilot trial

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

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

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.

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
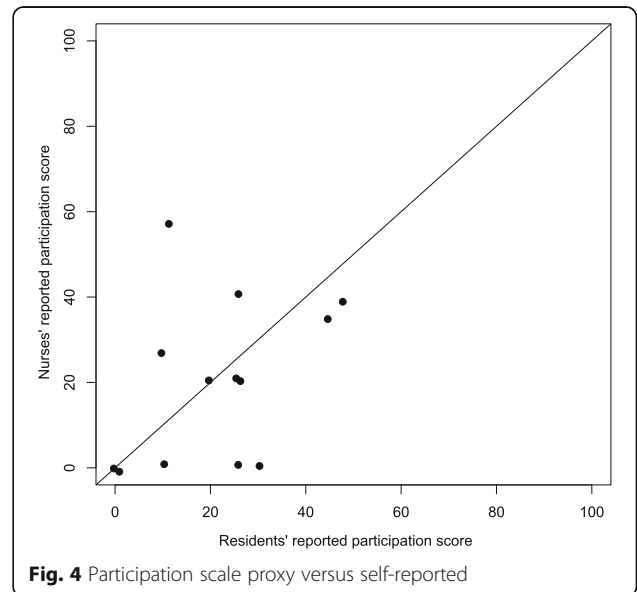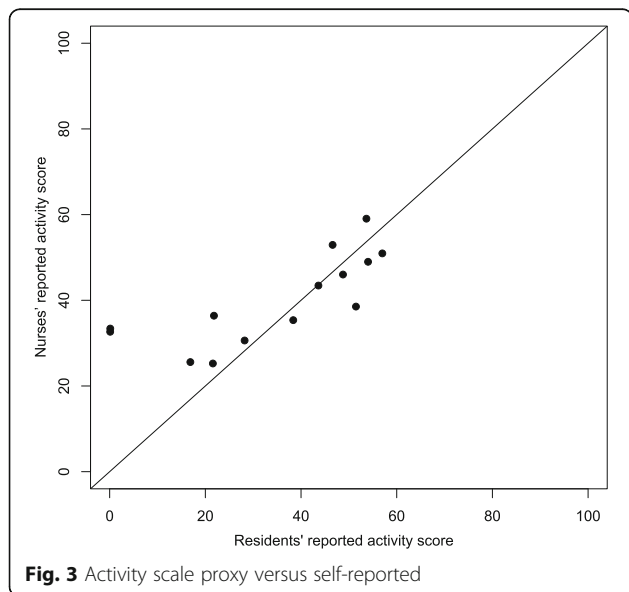
Table 4 Falls and fall-related fractures during the study

	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

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

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

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

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.

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.

Author details
[1]Institute of Health and Nursing Sciences, Medical Faculty, Martin Luther University, Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany. [2]Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig -Maximilians-University Munich, Marchioninistr 15, 81377 Munich, Germany. [3]German Center for Vertigo and Balance Disorders, Ludwig- Maximilians-University Munich, Marchioninistr. 15, 81377 Munich, Germany. [4]Faculty of Applied Health and Social Sciences, Rosenheim Technical University of Applied Sciences, Hochschulstraße 1, 83024 Rosenheim, Germany.

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Publisher's Note

Supplementary appendix

Supplement to: Saal S[1], Klingshirn H[1], Beutner K, Strobl R, Grill E, Müller M[2], Meyer G[2].
Improved participation of older people with joint contractures living in nursing homes:
Feasibility of study procedures in a cluster-randomised pilot trial.

[1] shared first authorship

[2] shared senior authorship

Table A1 Problems in participation of residents with joint contractures during the study

Code [a] / Item			Intervention group (n=57)		Control group (n=52)	
			Baseline	6 months	Baseline	6 months
d660	Assisting others	No	20 (35)	23 (40)	14 (27)	17 (33%)
		Mild or moderate	0 (0)	5 (9)	4 (8)	3 (6)
		Severe	5 (9)	6 (11)	5 (10)	3 (6)
		Complete	32 (56)	23 (40)	29 (56)	28 (55)
d7105	Physical contact in relationships	No	24 (42)	33 (58)	18 (35)	38 (73)
		Mild or moderate	11 (19)	4 (7)	18 (35)	1 (2)
		Severe	11 (19)	6 (11)	11 (21)	5 (10)
		Complete	11 (19)	14 (25)	5 (10)	8 (15)
d750	Informal social relationships	No	26 (46)	31 (54)	17 (33)	28 (54)
		Mild or moderate	9 (16)	4 (7)	20 (38)	3 (6)
		Severe	7 (12)	3 (5)	6 (12)	5 (10)
		Complete	15 (26)	19 (33)	9 (17)	16 (31)
d910	Community life	No	22 (39)	26 (46)	22 (43)	19 (37)
		Mild or moderate	8 (14)	4 (7)	7 (14)	4 (8)
		Severe	16 (28)	5 (9)	13 (25)	2 (4)
		Complete	11 (19)	21 (38)	9 (18)	26 (51)
d9200	Playing	No	22 (39)	35 (61)	25 (48)	26 (50)
		Mild or moderate	11 (19)	1 (2)	8 (15)	3 (6)
		Severe	10 (18)	3 (5)	8 (15)	3 (6)
		Complete	14 (25)	18 (32)	11 (21)	20 (38)
d9201	Sports	No	17 (30)	26 (46)	15 (29)	23 (45)
		Mild or moderate	11 (19)	4 (7)	10 (19)	7 (14)
		Severe	15 (26)	10 (18)	9 (17)	4 (8)
		Complete	14 (25)	17 (30)	18 (35)	17 (33)
d9202	Arts and culture	No	20 (35)	28 (49)	22 (42)	28 (54)
		Mild or moderate	5 (9)	5 (9)	10 (19)	4 (8)
		Severe	12 (21)	4 (7)	12 (23)	7 (13)
		Complete	20 (35)	20 (35)	8 (15)	13 (25)
d9203	Crafts	No	16 (28)	24 (42)	17 (33)	19 (37)
		Mild or moderate	2 (4)	3 (5)	7 (13)	0 (0)
		Severe	12 (21)	7 (12)	6 (12)	8 (15)
		Complete	27 (47)	23 (40)	22 (42)	25 (48)
d9204	Hobbies	No	15 (26)	26 (46)	17 (33)	27 (53)
		Mild or moderate	5 (9)	4 (7)	5 (10)	0 (0)
		Severe	10 (18)	5 (9)	12 (24)	6 (12)

d9205	Socializing	Complete	27 (47)	22 (39)	17 (33)	18 (35)
		No	19 (33)	34 (60)	17 (33)	31 (60)
		Mild or moderate	10 (18)	4 (7)	12 (23)	4 (8)
		Severe	21 (37)	3 (5)	16 (31)	3 (6)
		Complete	7 (12)	16 (28)	7 (13)	14 (27)
d930	Religion and spirituality	No	32 (56)	36 (63)	47 (90)	47 (90)
		Mild or moderate	7 (12)	3 (5)	3 (6)	1 (2)
		Severe	9 (16)	4 (7)	2 (4)	1 (2)
		Complete	9 (16)	14 (25)	0 (0)	3 (6)

^a Code in the first column corresponding to the respective category of the International Classification of Functioning, Disability and Health. Values are n (%)

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Table 2 -Resource use due to implementation of the intervention

Item of resource	Unit of measure	Unit cost (€)	Total cost (€)	Mean cost per intervention cluster (€)	Source
Advertising material/brief information	Item	6.93	865.36	123.63	Invoice by the manufacturer
Education material	Item	9.75	351.12	50.16	Invoice by the manufacturer
Room rental	Hour	12.50	553.44	79.06	Finance department of the Martin Luther University Halle-Wittenberg and the Ludwig-Maximilians-University Munich
Workshop catering	Participant	20.03	388.08	55.44	Invoice by the manufacturer
Travel expenses	Kilometer lump sum	0.30	609.30	87.04	Finance department of the Martin Luther University Halle-Wittenberg
External consultants' fee	Lump sum	3700.00	3700.00	528.57	Invoice by the Martin Luther University Halle-Wittenberg
Peer mentors' salary	Minute	0.32	150.40	21.49	Finance department of the Martin Luther University Halle-Wittenberg and the Ludwig-Maximilians-University Munich
Investigators' salary (total)	Hour	24.87	1840.64	262.95	Finance department of the Martin Luther University Halle-Wittenberg and the Ludwig-Maximilians-University Munich
Facilitators' salary (total)	Hour	23.48	3705.16	529.31	Finance department of nursing homes
Sum			**12163.50**	**1756.85**	

Per resident (n=111)		**109.58**	

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

Hanna Klingshirn[1,2], Martin Müller[2], Katrin Beutner[3], Julian Hirt[3], Ralf Strobl[1,4], Eva Grill[1,4], Gabriele Meyer[3] and Susanne Saal[3*]

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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* Correspondence: susanne.saal@uk-halle.de
[3]Institute for Health and Nursing Sciences, Medical Faculty, Martin Luther University Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany
Full list of author information is available at the end of the article

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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

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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.
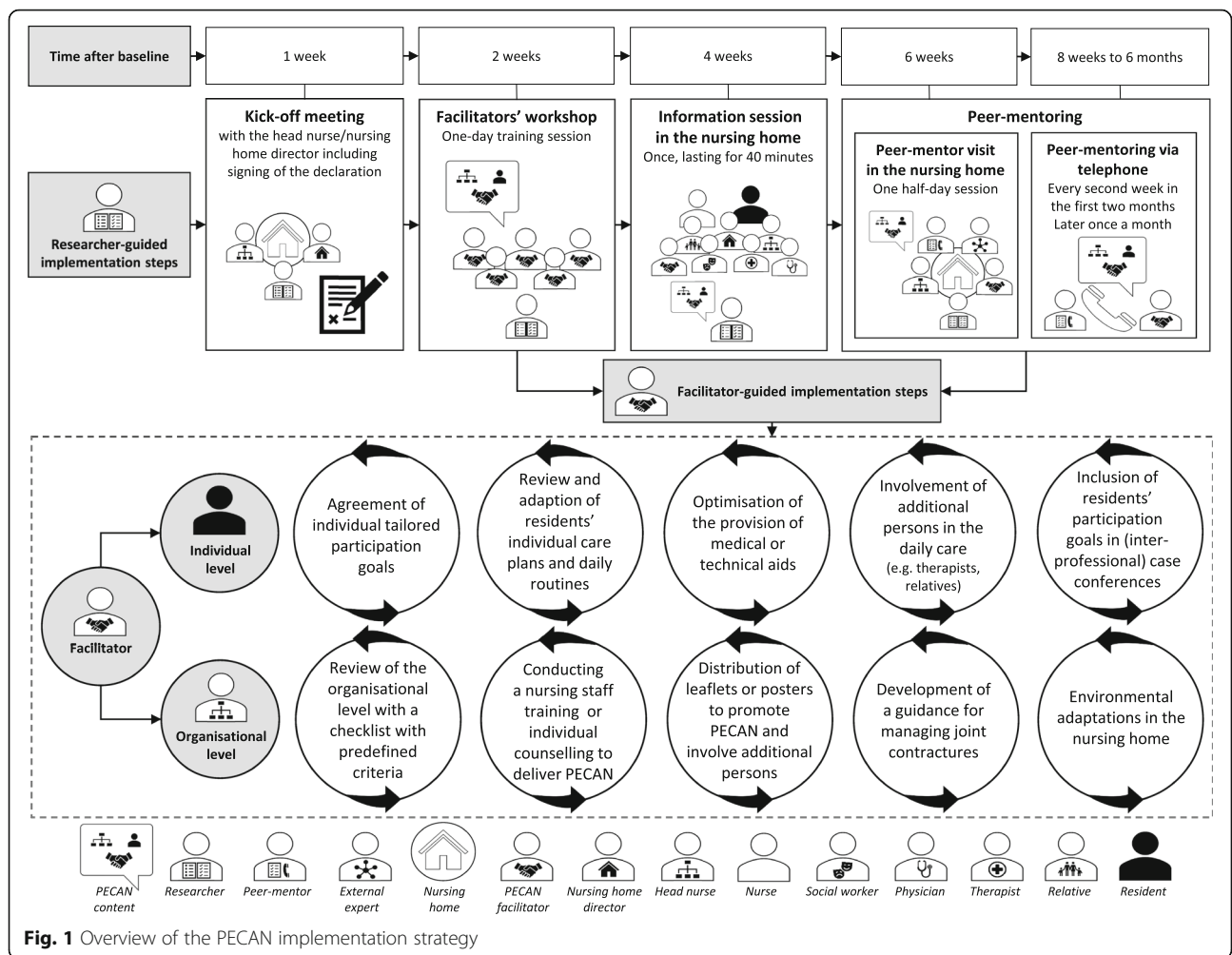
Fig. 1 Overview of the PECAN implementation strategy

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

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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.
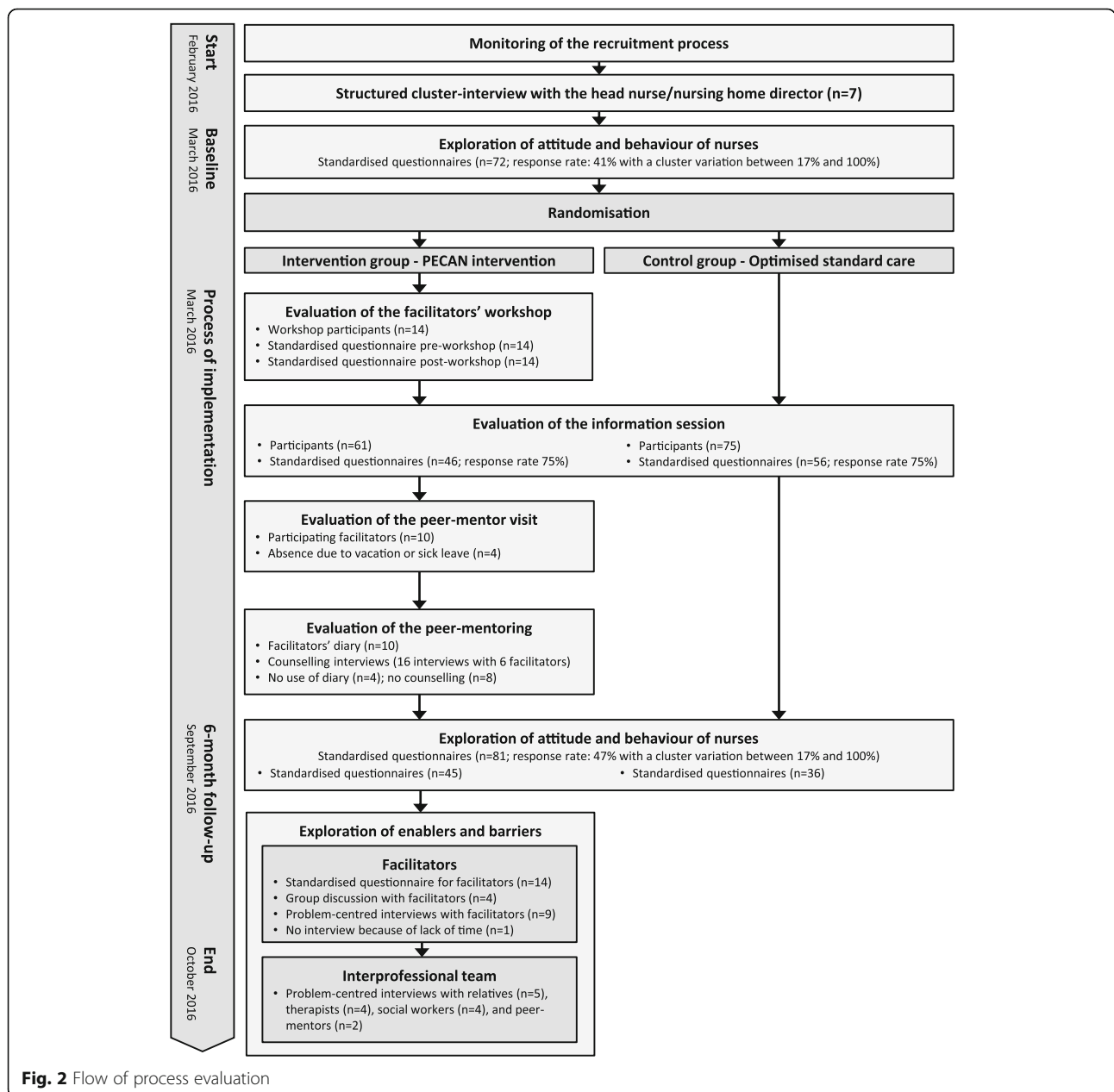
Fig. 2 Flow of process evaluation

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.

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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

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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.

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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.

Author details

[1]Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig-Maximilians-Universität München, Marchioninstr 17, 81377 Munich, Germany. [2]Faculty of Applied Health and Social Sciences, Rosenheim Technical University of Applied Sciences, Hochschulstraße 1, 83024 Rosenheim, Germany. [3]Institute for Health and Nursing Sciences, Medical Faculty, Martin Luther University Halle-Wittenberg, Magdeburger Straße 8, 06112 Halle (Saale), Germany. [4]German Centre for Vertigo and Balance Disorders, Ludwig-Maximilians-Universität München, Marchioninstr 15, 81377 Munich, Germany.

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Publisher's Note

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

Table of Contents

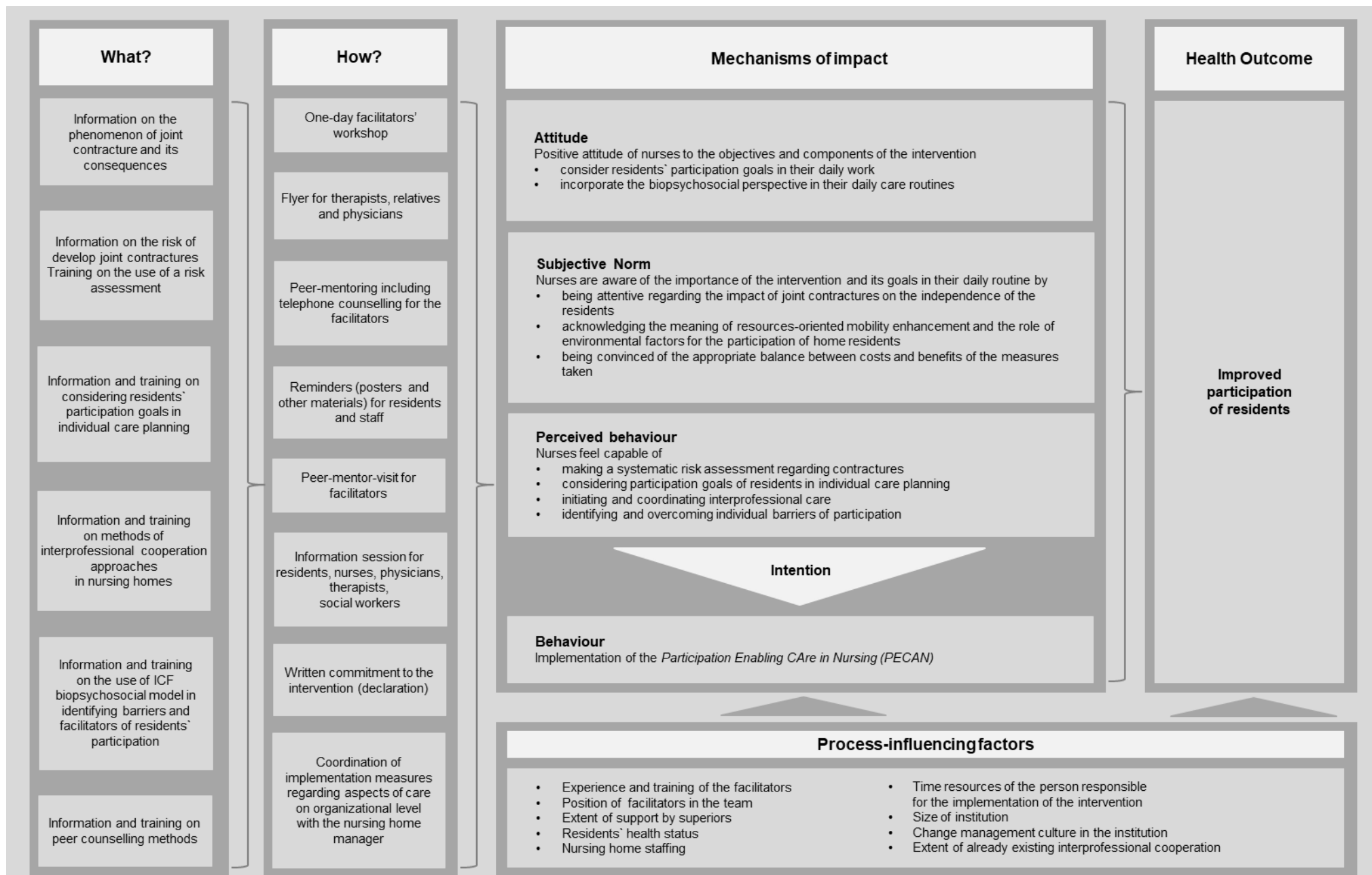**Figure A1** Logic model of the Participation Enabling CAre in Nursing Intervention adapted from Saal et al. (2018)

Saal S, Meyer G, Beutner K, Klingshirn H, Strobl R, Grill E et al. Development of a complex intervention to improve participation of nursing home residents with joint contractures: a mixed-method study. BMC Geriatr. 2018;18(1):61. doi:10.1186/s12877-018-0745-z.

Table A2 Self-assessed preparedness for the role as facilitator after the workshop

	n=14
Competence to use a biographical approach while planning measures.[1]	
Excellent / good	11
Less / not at all	3
Competence to encourage residents for activities.[1]	
Excellent / good	12
Less / not at all	2
Competence to enable the residents to participate without restrictions.[1]	
Excellent / good	12
Less / not at all	2
Competence to identify barriers and initiate changes in the nursing home.[1]	
Excellent / good	9
Less / not at all	4
Competence to be active in the adaptation of care plans.[1]	
Excellent / good	13
Less / not at all	1
Competence to review needs for technical and medical aids together with a therapist.[1]	
Excellent / good	11
Less / not at all	3
Confidence in the own performance of the role as facilitator[2]	
Excellent / good	7
Average	7
Less / not at all	0

[1]Based on a 4-Point-Likert-Scale (1=excellent, 2=good, 3=less, 4=not at all)
[2]Based on a 5-Point-Likert-Scale (1=excellent, 2=good, 3=average, 4=less, 5=not at all)

Table A2 Nursing care of residents with joint contractures

Do you agree with the following statements?	Baseline			6-month follow-up		
	Intervention (n=51)	Control (n=21)	Total (n=72)	Intervention (n=45)	Control (n=36)	Total (n=81)
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
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.						
Agree	22 (43)	8 (38)	30 (41)	30 (67)	17 (47)	47 (58)
Neutral	13 (25)	6 (29)	19 (26)	10 (22)	12 (33)	22 (27)
Disagree	13 (26)	6 (29)	19 (26)	4 (9)	7 (19)	11 (14)
Don't know	3 (6)	1 (5)	4 (6)	1 (2)	0	1 (1)
There are regular team meetings to discuss the care of residents with or at risk of joint contractures.						
Agree	18 (36)	8 (38)	26 (36)	32 (71)	15 (41)	47 (59)
Neutral	11 (22)	3 (14)	14 (19)	3 (7)	12 (33)	15 (19)
Disagree	19 (37)	10 (48)	29 (41)	8 (18)	9 (25)	17 (21)
Don't know	3 (6)	0	3 (4)	2 (4)	0	2 (2)
Individual biography and interests of residents with joint contractures are considered when planning activities and participation.						
Agree	33 (65)	14 (67)	47 (65)	35 (77)	28 (78)	63 (78)
Neutral	6 (12)	4 (19)	10 (14)	7 (16)	4 (11)	11 (14)
Disagree	10 (20)	3 (15)	13 (18)	2 (4)	3 (8)	5 (6)
Don't know	2 (4)	0	2 (3)	1 (2)	1 (3)	2 (2)
Independent action and mobility of residents with joint contractures is more important than the completion of a certain workload.						
Agree	22 (43)	9 (43)	31 (43)	30 (67)	24 (67)	54 (67)
Neutral	8 (16)	6 (29)	14 (19)	8 (18)	6 (17)	14 (17)
Disagree	13 (26)	4 (19)	17 (23)	6 (13)	4 (11)	10 (12)
Don't know	7 (14)	2 (10)	9 (13)	1 (2)	1 (3)	2 (2)
Missing	1 (2)	0	1 (1)	0	1 (3)	1 (1)
Residents with joint contractures are enabled to participate in individual daily activities like cooking, gardening or walking.						
Agree	27 (53)	12 (57)	39 (54)	32 (71)	13 (36)	45 (56)
Neutral	10 (20)	3 (14)	13 (18)	6 (13)	10 (28)	16 (20)
Disagree	9 (18)	6 (28)	15 (21)	7 (15)	10 (27)	17 (21)
Don't know	4 (8)	0	4 (6)	0	3 (8)	3 (4)
Missing	1 (2)	0	1 (1)	0	0	0
The collaboration with the residents' therapists works out well.						
Agree	44 (86)	16 (76)	60 (84)	33 (73)	21 (58)	54 (67)
Neutral	5 (10)	2 (10)	7 (10)	8 (18)	8 (22)	16 (20)
Disagree	2 (4)	3 (15)	5 (7)	2 (4)	4 (12)	6 (8)
Don't know	0	0	0	2 (4)	3 (8)	5 (6)

14 Selbständigkeitserklärung

Hiermit versichere ich an Eides statt, dass ich die vorliegende Habilitationsleistung selbständig verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel benutzt habe.

Halle, 08.09.2020   Dr. rer. medic. Susanne Saal

15 Erklärung über frühere Habilitationsversuche

Hiermit erkläre ich, dass für meine Person an keiner anderen Fakultät oder Universität ein Habilitationsverfahren derzeit anhängig ist bzw. jemals anhängig gewesen ist.

Halle, 08.09.2020   Dr. rer. medic. Susanne Saal