




BMJ Open Effectiveness of an individually tailored complex intervention to improve activities and participation in nursing home residents with joint contractures (JointConEval): a multicentre pragmatic cluster-randomised controlled trial

Natalie Nguyen ¹, Regina Thalhammer,² Gabriele Meyer,¹ Lien Le,³ Ulrich Mansmann ³, Markus Vomhof,^{4,5} Stefanie Skudlik,² Katrin Beutner ¹, Martin Müller^{2,6}

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NN and RT are joint first authors. KB and MM are joint senior authors.

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For numbered affiliations see end of article.

Correspondence to

Dr Katrin Beutner;
katrin.beutner@medizin.uni-halle.de

ABSTRACT

Objective This study aims to examine the effects of the individually tailored complex intervention Participation Enabling Care in Nursing (PECAN) on activities and participation of residents with joint contractures.

Design Multicentre pragmatic cluster-randomised controlled trial.

Setting 35 nursing homes in Germany (August 2018–February 2020).

Participants 562 nursing home residents aged ≥65 years with ≥1 major joint contracture (303 intervention group, 259 control group).

Interventions Nursing homes were randomised to PECAN (18 clusters) or optimised standard care (17 clusters) with researcher-concealed cluster allocation by facsimile. The intervention targeted impairments in activities and participation. Implementation included training and support for selected staff. Control group clusters received brief information.

Primary and secondary outcome measures The primary endpoint PaArticular Scales combined residents' activities and participation at 12 months. The secondary outcome comprised quality of life. Safety measures were falls, fall-related consequences and physical restraints. Residents, staff and researchers were unblinded. Data collection, data entry and statistical analysis were blinded. Primary analyses were intention-to-treat at cluster level and individual level using a generalised mixed-effect regression model and imputation of missing data.

Results Primary outcome analyses included 301 intervention group residents and 259 control group residents. The mean change on the Activities Scale was –1.47 points (SD 12.2) in the intervention group and 0.196 points (SD 12.5) in the control group and –3.87 points (SD 19.7) vs –3.18 points (SD 20.8) on the Participation Scale. The mean differences of changes between the groups were not statistically significant: Activities Scale: –1.72 (97.5% CI –6.05 to 2.61); Participation Scale: –1.24 (97.5% CI –7.02 to 4.45). We found no significant difference in the secondary outcome and no effects on safety measures.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The study design of this multicentre, randomised controlled trial and structured intervention development followed rigorously the updated Medical Research Council framework for complex interventions.
- ⇒ The primary outcome measure is a contracture-specific, Rasch-validated and International Classification of Functioning, Disability and Health (ICF)-based instrument that is eligible for the parametric statistics and provides a good conceptual fit for the ICF-based intervention.
- ⇒ Primary and secondary outcomes are limitation-oriented, we did not assess positive aspects of health.

Conclusion The complex intervention did not improve the activities and participation of nursing home residents on the PaArticular Scales at 12 months. Current nursing conditions in Germany may hamper implementation.

Trial registration number DRKS00015185.

BACKGROUND

Nursing home residents encounter joint contractures with a prevalence between 20% and 75% due to different definitions, settings and assessments.¹ Many joint contractures develop within the first 5 years of admission² related to inactivity and health conditions such as stroke and dementia.³ Immobility appears to be the most important modifiable risk factor.²

Joint contractures increase risk of falling, bed confinement, pressure sores and pain impairing social participation and daily activities such as eating, dressing and

walking.^{1 4} Potentially preventive or therapeutic interventions for joint contractures such as stretching, positioning or splinting have not proven effective for frail older people.^{5 6} We, therefore, developed⁷ and pilot-tested^{8 9} the individually tailored complex intervention 'Participation Enabling Care in Nursing' (PECAN) to improve disability of nursing home residents with joint contractures, following the UK Medical Research Council (MRC) framework.¹⁰ This cluster-randomised controlled trial (c-RCT) provides the third step of the MRC framework (evaluation). The objectives included (1) evaluating the effectiveness of PECAN in improving activities and participation of nursing home residents with joint contractures, (2) assessing the safety of PECAN in terms of falls, fall-related injuries and physical restraints and (3) conducting a health economical evaluation. The process evaluation will be reported elsewhere.

METHODS

Trial design

We conducted a multicentre pragmatic parallel-group c-RCT with 1:1 randomisation on a cluster level and a 12-month follow-up between August 2018 and February 2020. Nursing homes defined the clusters. A cluster design was indicated since PECAN aims to change the professional behaviour of the nursing home staff. A study protocol was published¹¹ and prospectively registered in the German Clinical Trials Register (registration date: 1 August 2018, registration number: DRKS00015185).

Patient and public involvement

Affected individuals and healthcare professionals were involved in developing and piloting PECAN.^{7 8} In this study, residents and staff were included as participants.

Participants

Sample size

The study used a two-component primary outcome: the Activities and the Participation subscale of the PaArticular Scales.¹² Based on data from the pilot study,⁸ we assumed an effect of 10 points (δ), a SD of 14.14 (σ) and an intraclass correlation coefficient (ICC, ρ) of 0.38. Taking the nursing home infrastructure into account, we set the cluster size to 15 individuals (m). To maintain an overall significance level of 5%, we applied Bonferroni adjustment to each component of the primary endpoint ($\alpha=0.025$). The power of the trial was set to 80% ($1-\beta=0.8$). Using the formula of Hemming *et al*,¹³ we derived a group size of 240 individuals resulting in 16 clusters with 15 individuals per arm ($\alpha=0.025$, $\beta=0.2$, $\delta=10$, $\sigma=14.14$, $\rho=0.38$, $m=15$, variance inflation factor $VIF=6.32$). To compensate for early study termination due to death or relocation, we included 15% more individuals, resulting in 30 clusters with 18 individuals and two clusters with 19 individuals, the total study size being 578 individuals.

Setting and eligibility criteria

The study was performed in nursing homes in the areas of Halle (Saale) (Eastern Germany) and Rosenheim

(Southern Germany). Nursing homes qualified for inclusion if at least 18 residents had joint contractures, as assessed in routine documentation. On the individual level, we included residents ≥ 65 years with existing joint contractures that affected their daily life. Joint contractures were defined as restricted joint mobility in at least one major joint (shoulder, elbow, wrist, hip, knee or ankle), diagnosed by a physician, nurse, physiotherapist or occupational therapist. Participants had to be able to cooperate within daily tasks, be able to sit, and understand and speak German. We excluded residents receiving end-of-life care, and residents with congenital or idiopathic contractures that is, Dupuytren's contractures, plantar fibromatosis and scar contractures.

Context of long-term care in Germany

German nursing homes are run by welfare organisations, communities or private owners and are funded by statutory long-term care insurance and co-payments by the residents. The five levels of care dependency range from 1 (low) to 5 (most severe) and are assessed by expert raters from the health insurance medical service. Nursing care by skilled nurses is available to people from care dependency level 2. The nurse-to-resident-ratio depends on the care dependency. By federal law, 50% of the nursing staff must have at least 3 years of vocational training. Social care assistants carry out social activities. Their training ranges from a few months to 2 years. Local outpatient physicians and therapists usually carry out in-home visits. Physicians prescribe mobility aids, other devices and physio-, occupational and speech therapy, which are covered by German statutory health insurance with individual co-payment. A nursing practice guideline dealing with mobility in long-term care was published in 2018.¹⁴

Recruitment

Nursing homes were recruited between February and December 2018 from a convenience sample and enrolled after the nursing home manager signed a written declaration of collaboration. The head nurse identified eligible residents, invited them or their guardians to participate in the study and obtained written consent.

Randomisation, allocation and blinding

Randomisation was computer generated using stratified blocks according to the study region. Clusters and participants were recruited and assessed before randomisation to avoid selection bias. Data managers not involved in study first informed the nursing homes about the allocation by facsimile and then the study centres by password-protected email or facsimile. Due to the nature of the intervention, blinding nursing staff, residents or researchers delivering the intervention was not possible. Data collection, data entry and statistical analysis were performed blinded. In case of unblinding, another blinded outcome assessor was assigned. To estimate the success of blinding, the assessors guessed the group allocation.

Intervention

PECAN intervention

The individually tailored intervention was designed using the biopsychosocial model of the WHO's International Classification of Functioning, Disability and Health (ICF).¹⁵ PECAN aims to (1) reduce activity limitations and participation restrictions caused by contractures by addressing influencing factors at both the individual and organisational level, (2) realise residents' individual goals and (3) address participation as a general care goal (details: online supplemental table S1). Staff should incorporate personal and environmental factors into each resident's care plan and daily routine. Given the weak evidence to prevent and treat joint contractures in older people,⁷ PECAN does not target the contracture itself.

We based the implementation strategy on the theory of planned behaviour¹⁶ to develop the nurses' professional

attitudes and change their professional behaviour in line with the intervention. Skilled nurses acted as knowledge facilitators. The standardised implementation (overview: figure 1, details: online supplemental table S2) started shortly after the randomisation with a kick-off meeting with the nursing home management and a training workshop for the facilitators. The research team provided regular guidance to the facilitators through an in-house visit and at least monthly telephone counselling. They were later trained on how to counsel their coworkers and had the opportunity to share their experiences.

We held an in-house information event for staff, residents and relatives and an information session during a regular staff meeting. Each cluster received printed materials such as flyers for different target groups, motivational posters, and brochures on various health topics.

We estimated improvements in residents' activities or participation and a reduction in the risk of future

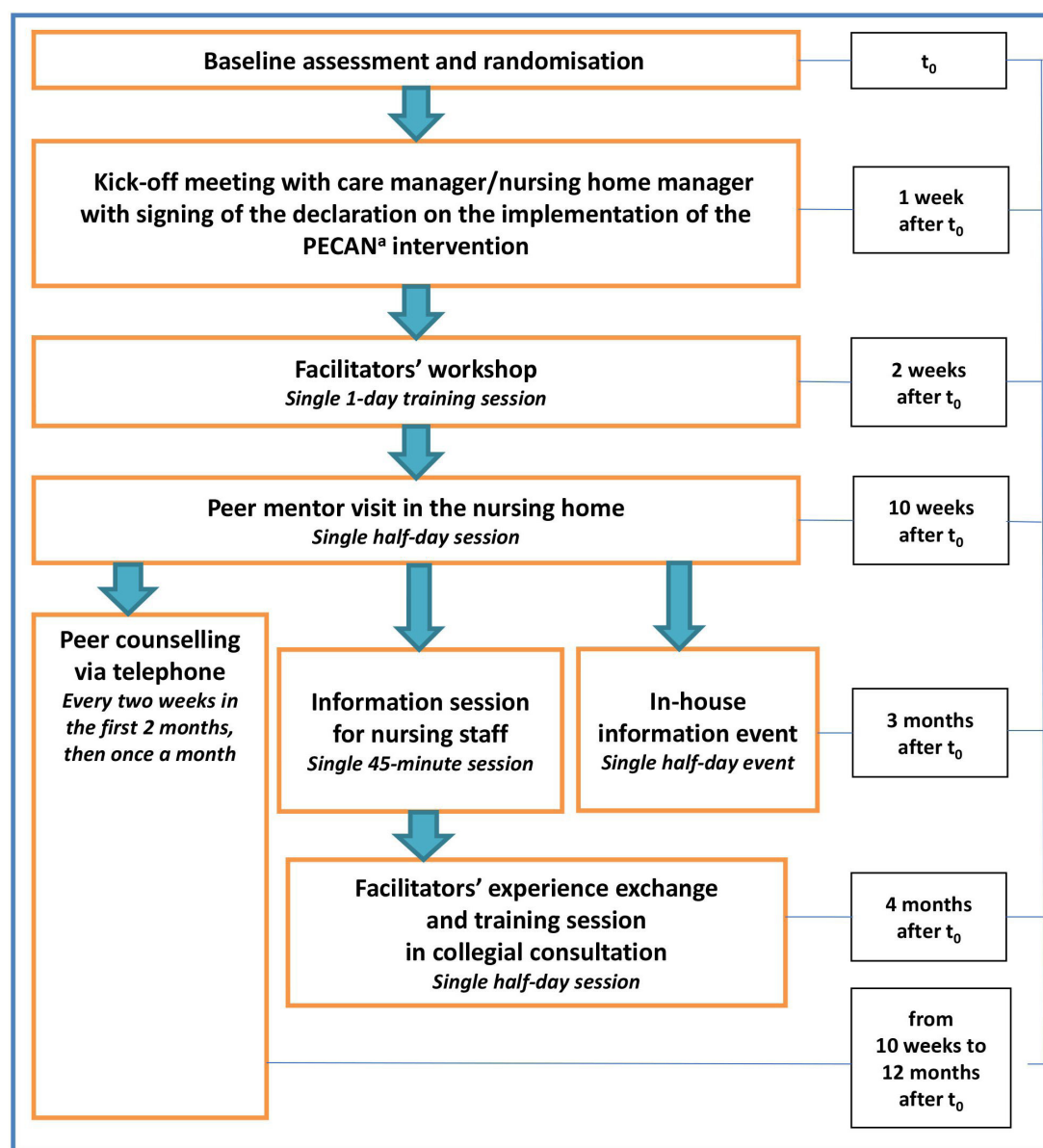


Figure 1 Overview of the implementation approach. ^aPECAN Participation Enabling Care in Nursing.

contractures as potential benefits. We monitored possible complications that were reported by healthcare professionals.

Control condition

The control group received a brief in-house presentation of 45 min for nursing home staff (optimised standard care) with general information about joint contractures, activities and participation.

Data collection

Blinded assessors conducted data collection through face-to-face interviews with residents or nurses acting as proxies at three measurement points: at baseline before randomisation, after 6 months and after 12 months between August 2018 and February 2020.

Primary outcome

The two-component primary outcome was assessed at baseline, 6 and 12 months. The ICF-based PaArticular Scales,¹² a standardised, contracture-specific self-reporting questionnaire, comprises two independent subscales with separate scores: (a) impairments of activities (24 items) and (b) impairments of participation (11 items) in older people with joint contractures. Response options include 0 for 'no problem', 1 for 'mild to moderate problem', 2 for 'severe problem' and 3 for 'complete problem'. The individual scores are added up to generate an ordinal raw score, which is transformed into an interval score to allow comparisons at the interval level.¹² The interval-scaled score ranges from 0 (no problem) to 100 (complete problem). A Rasch analysis of the pilot study data revealed no evidence to support a change in the rating.

We considered absolute changes in the form of a mean decrease of 10 points on the Activities Scale or the Participation Scale of the PaArticular Scales after 12 months a clinically meaningful difference in favour of PECAN.

Secondary outcome

We evaluated the residents' health-related quality of life at each time point using the German version of the generic EuroQol Five-Dimension Five-Level Instrument (EQ-5D-5L)¹⁷ for self-assessment and the proxy version 2 for nurses' proxy rating. Five dimensions of health (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) with five levels from no to most severe problems are complemented by a Visual Analogue Scale representing the self-perceived health from best to worst imaginable (range 0–100).¹⁷

Additional measures

Nurses rated the residents' cognitive status using the Dementia Screening Scale (DSS)¹⁸ to determine whether a proxy rating was required (total score 0–14; cut-off point: 3). We assessed all participants at baseline, 6 and 12 months if the cognitive status declined. Nurses also assessed the residents' behavioural symptoms at each time point using a modified German version of the Cohen-Mansfield Agitation Inventory (CMAI)¹⁹ for descriptive

and statistical purposes. The DSS and CMAI results are presented for the baseline assessment only.

Adverse events potentially associated with PECAN were extracted from the nursing records at each time point. The number of falls and fall-related consequences (fractures, injuries) were recorded retrospectively for the previous 12 months at baseline and at follow-up, physical restraints captured full-length bed rails, belts in bed or chair and fixed tables.

Health economic analysis

A cost-effectiveness analysis was not conducted due to the absence of clinical effectiveness. The cost evaluation covered the calculation of intervention-related costs and is presented in section III, online supplemental tables S3–S6.

Statistical methods

Descriptive analyses were performed for covariates at cluster and resident levels at all time points. Absolute and relative frequencies were reported for categorical; mean, SD, median, IQR, minimum and maximum figures for numeric variables; mean, SE and 95% CIs were reported for estimates. Analyses were conducted for all clusters and residents and stratified separately by intervention group.

The primary analysis used a Gaussian random effects model to compare the individual changes between treatment arms, the clusters were given random effects. The analysis was also adjusted by the individual baseline values of the outcome. Sensitivity analyses were performed to study robustness of the results. The individual changes (change between month 12 and baseline) in both scales of the primary endpoint are graphically presented as boxplots per cluster and study group.

The secondary effectiveness analysis used the same methodological approach as the primary endpoint to examine individual changes in the EQ-5D-5L index score.

To investigate the impact of other influencing factors on the effect of PECAN, planned subgroup analyses were performed with (1) ownership of nursing homes, (2) residents' cognitive status at baseline and (3) location of contracture.

Supplementary analyses investigated the robustness of the results regarding the primary endpoint by additionally adjusting for the cluster-specific and individual-specific baseline variables like age, gender, length of stay and care dependency level at the individual level, as well as ownership, number of residents and staff-resident ratio.

The model²⁰ used for the primary analysis imputes automatically missing values at month 12 assuming missing at random. The impact of missing values was examined in sensitivity analyses. Details about assumptions made were documented in the statistical analysis plan which is available on request. We performed longitudinal analyses for the primary and secondary endpoints over the three time points using linear mixed effect models based on the following main effects: intervention group, linear and quadratic time and random effects (intercept) for

cluster and resident as well as random effects (time) for residents. These models provide robust results even when the data deviates from the ideal situation.^{20 21} All analyses were performed using the statistical software R, V.4.0.2 (R Core Team, 2020) and the respective packages: ggplot2, plyr, tidyr, dplyr, openxlsx, table1, foreign, mice, mitml, micemd, lme4 and hmisc.

RESULTS

Participants flow

The study comprised 35 nursing homes (Halle (Saale), n=18; Rosenheim, n=17) and 562 residents were allocated at baseline (n=303 intervention group, n=259 control group, see figure 2). Since the required number of participants was not achieved in most of the clusters, four more nursing homes were enrolled. We achieved 97.2% of the calculated sample size. All the clusters completed the study, 138 residents (24.6%) terminated the study early (n=124 died, n=12 moved, n=2 withdrew). Data on the combined primary outcome were available for 560 residents at baseline (except 2 residents who withdrew consent; n=356 self-reported; n=204 proxy-reported), 483 residents (n=271 self; n=212 proxy) after 6 months and 424 residents (n=211 self; n=213 proxy) after 12 months.

The baseline characteristics of participants and clusters were comparable between the groups (table 1; online supplemental table S7). The cluster size ranged from 44 to 196 residents (mean 94.7). At baseline, residents had a mean age of 85.4 (SD 7.2) years, and the majority were women (73.4%). The overall proportion of residents with contractures was 39.3% with a range from 9.7% to 78.0% (available data from 25 clusters). Joint contractures were most frequently located in the upper and lower extremities (48.4%).

Implementation of the intervention

The intervention was delivered to the clusters and their facilitators as planned according to early results of the process evaluation but not all clusters used the training and support (details: online supplemental table S8). We did not modify PECAN or the implementation strategy as no side effects, risks or complications were reported. Interventions are summarised in online supplemental table S9 (individual level) and online supplemental table S10 (organisational level). The most frequently cited reasons (multiple answers) for no or partial implementation were lack of time and staff (39%), that residents saw no need for action (35%), staff considered the intervention to be irrelevant (29%) or not suitable (11.7%) (online supplemental tables S11 and S12). Results of the process evaluation indicate that staffing, workload, team spirit and leadership were essential for implementation.

Maintenance of blinding

Data collection was conducted by blinded researchers for 464 residents (96.5%) after 6 months and 417 residents (98.5%) after 12 months. The interviewers' estimation

of cluster allocation did not reveal any evidence for unblinding. Only three events of unblinding occurred. In two cases, unblinded researchers could be replaced with blinded personnel.

Primary and secondary outcomes

The comparison of the intervention and control group did not reveal a statistically significant effect in favour of PECAN after 1 year (table 2). Residents in the intervention group reported a slight reduction of their limitations on the Activities Scale compared with a mild increase in the control group. For the Participation Scale, both the intervention and the control group showed a small reduction in their limitations.

The estimated ICC is 0.156 for the Activities Scale and 0.073 for the Participation Scale, which indicates a small cluster effect.²² The individual changes in the Activities score and the Participation score per cluster and study group are shown in boxplots (online supplemental figures S1 and S2). The comparison of changes in health-related quality of life showed no statistically relevant differences after 1 year between the intervention group and the control group (table 2). Residents in both groups reported a slight decrease in the index score. The self-perceived health status increased slightly for the intervention group and decreased for the control group.

Supplementary analyses

The results of sensitivity analyses (reflecting different assumption for missing mechanisms as well as the subgroup analyses) provided a robust and consistent picture regarding the primary endpoints. Missing rates in the primary endpoint (depending on specific subgroups and assumptions) ranged between 24.3% and 24.6%. There was one (possibly random) finding where the 95% CI is left of 0: the differences between changes in the Activities Scale in privately owned institutions (-7.936; 95% CI (-15.278 to -0.594)). The 95% CI of the corresponding effect in the Participation Scale only marginally overlap with 0 (-8.766; 95% CI (-17.813 to 0.281)). For publicly owned institutions, the Participation Scale shows a tendency for the intervention to worsen the score: the difference between changes is 13.324 with 95% CI (-0.323 to 26.972). All other supplementary analyses show no evidence of a difference between the changes. Sensitivity analyses did not indicate any impact of different missing mechanisms on the significance of effects.

Safety of the intervention

There were no relevant differences between the study groups in terms of the frequency of falls and fall-related fractures or injuries (table 3). The number of physical restraints was comparable between the groups, with a tendency towards less use in the intervention group. Full-length bed rails were used in both groups. Adverse effects were not reported in any study group.

CONSORT 2010 Flowchart

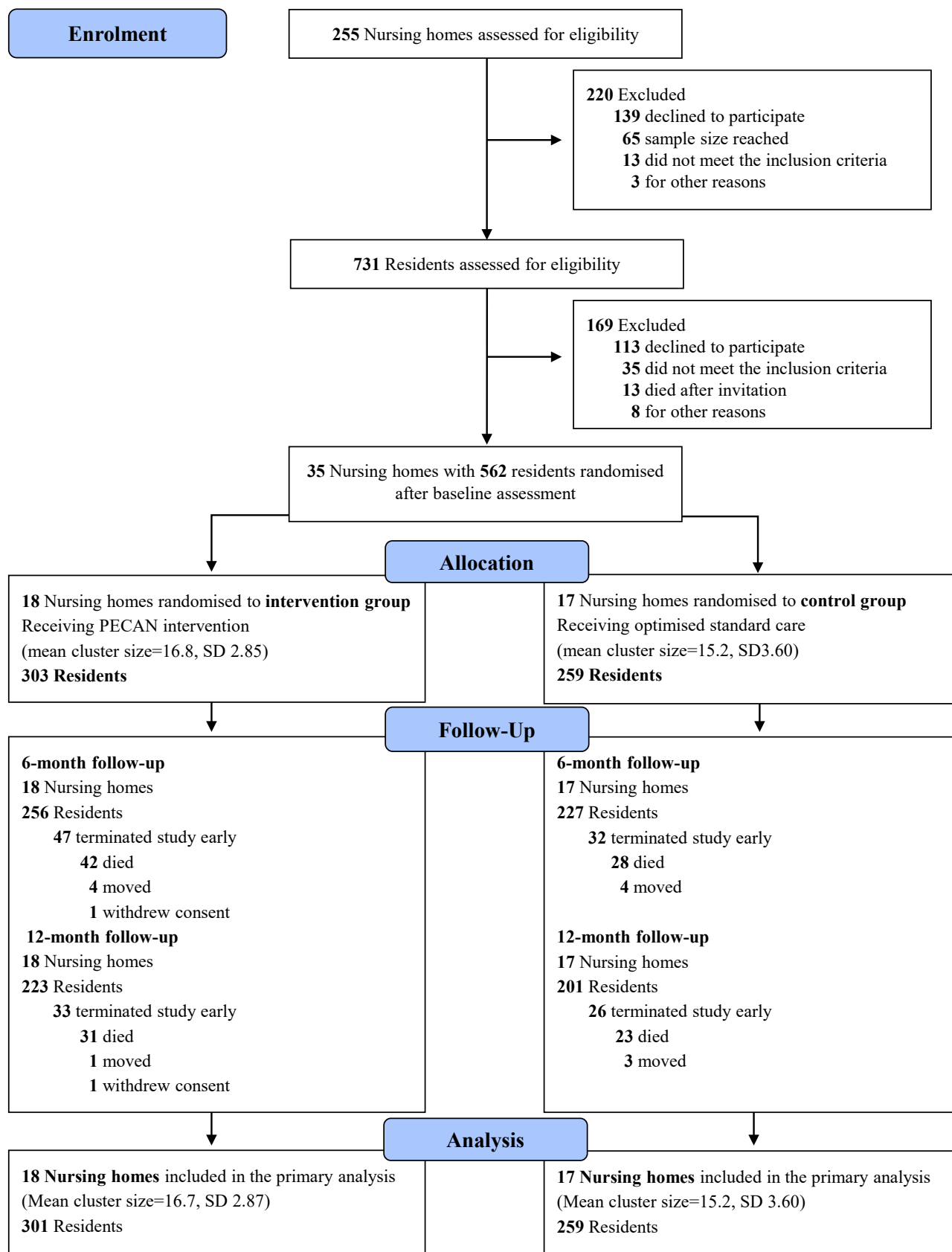


Figure 2 Flow of clusters and participants through the cluster-randomised trial. PECAN, Participation Enabling Care in Nursing. CONSORT, Consolidated Standards of Reporting Trials

Table 1 Baseline characteristics of nursing home residents

Characteristics*	Intervention group n=301	Control group n=259
Women	227 (75.4)	184 (71.0)
Age (years), mean (SD)	85.6 (7.2)	85.0 (7.2)
Length of residence (years), mean (SD)	3.61 (4.5)	3.29 (4.0)
Care dependency level†		
≤1	3 (1.0)	4 (1.6)
2	74 (24.6)	64 (24.7)
3	111 (36.9)	88 (34.0)
4	71 (23.6)	64 (24.7)
5	42 (14.0)	39 (15.1)
No of affected joints, mean (SD)	6.97 (3.4)	6.30 (3.7)
Location of joint contracture		
Upper extremities	15 (5.0)	26 (10.0)
Lower extremities	38 (12.6)	55 (21.2)
Both	156 (51.8)	115 (44.4)
Spine and any extremities	92 (30.6)	63 (24.3)
Accidental falls in the preceding 12 months		
Mean no (SD)	1.12 (2.1)	1.25 (2.4)
Residents with at least one fall	130 (43.2)	107 (41.3)
Residents with cognitive impairment		
DSS‡≥3	103 (34.2)	91 (35.1)
Mobility aids and other devices	280 (93.0)	239 (92.3)
Urinary and/or faecal incontinence	217 (72.1)	185 (71.4)
Challenging behaviour in the preceding 4 weeks (modified version of CMAI§)		
Restlessness	51 (16.9)	41 (15.8)
Verbal agitation	27 (9.0)	27 (10.4)
Handling things inappropriately	29 (9.7)	24 (9.3)
Negative attitude	35 (11.7)	31 (11.9)
Aggression	14 (4.6)	31 (11.9)
Residents with any physical restraint	33 (11.0)	24 (9.3)
Physiotherapy	141 (46.8)	80 (30.9)
Occupational therapy	49 (16.3)	31 (12.0)

*Values are absolute numbers (percentages) unless stated otherwise.

†Five levels of care dependency from 1 to 5, a higher level translates to a more severe care dependency; the resident's need for care was assessed by expert raters from the German health insurance medical service.

‡DSS¹⁸: Total score ranges from 0 to 14; higher scores indicate more severe cognitive impairments

§CMAI¹⁹: Modified German version rating five symptoms complexes within the preceding 4 weeks on a 4-point Likert scale: never, once or twice, repeatedly, permanently

CMAI, Cohen-Mansfield Agitation Inventory; DSS, Dementia Screening Scale; SD, standard deviation.

DISCUSSION

This c-RCT evaluated the effectiveness of PECAN to improve activities and participation of nursing home residents with joint contractures through individually tailored care planning using the WHO's ICF model. PECAN implemented in 35 nursing homes by a structured facilitation approach did not significantly reduce the residents' self-reported impairment in activities and participation after 12 months. We found no relevant differences in the

secondary outcome health-related quality of life. PECAN had no negative impact on residents' safety in terms of falls, fractures or physical restraints.

This study has several strengths, including complete cluster retention and two drop-outs overall, indicating a low risk of attrition bias. Data quality is strong since each cluster participated in all follow-up visits. We are confident in the appropriateness of the assumptions as well as the robustness of the results due to a high degree of

Table 2 Primary and secondary outcomes, mean (SD) and estimate (CI)

	Score at baseline		Score at 12-month follow-up		Change*		Having intervention†
	Intervention group (n=301)	Control group (n=259)	Intervention group (n=223)	Control group (n=201)	Intervention group	Control group	
Primary outcomes‡							Estimate (97.5% CI)
Activities scale	53.9 (14.3)	53.7 (15.9)	50.7 (13.9)	52.8 (16.9)	-1.47 (12.2)	0.196 (12.5)	-1.72 (-6.05; 2.61)
Participation scale	42.2 (17.4)	41.1 (20.8)	36.3 (21.9)	37.0 (23.1)	-3.87 (19.7)	-3.18 (20.8)	-1.24 (-7.02; 4.54)
Secondary outcome							Estimate (95% CI)
EQ-5D-5L Index§	0.534 (0.3)	0.524 (0.3)	0.576 (0.3)	0.564 (0.3)	0.011 (0.3)	0.014 (0.3)	-0.001 (-0.06; 0.06)
EQ-5D-5L VAS Score	58.4 (21.5)	55.9 (20.3)	61.2 (22.7)	54.2 (22.0)	2.54 (24.1)	-3.17 (23.1)	5.34 (-0.63; 11.31)

*Weighted mean differences between baseline and after 12 months calculated from the Gaussian random effect model.

†Overall mean difference between changes of control and intervention group calculated from the Gaussian random effect model.

‡Score ranges between 0 (no problem) and 100 (complete problem).

§Index ranges between 0 (worst possible state of health) and 1 (best possible state of health).

EQ-5D-5L, EuroQol Five-Dimension Five-Level Instrument; VAS, Visual Analogue Scale.

agreement among various sensitivity analyses. Performance bias can be largely ruled out as deviations from protocol were not detected.

Our intervention underwent a careful development process⁷ that included some newly proposed core elements in the updated MRC Framework²³ such as identifying the context, creating and adapting a logic model and including the cost perspective.

We assume a good fit of the primary outcome, the contracture-specific PaArticular Scales,¹² because both the assessment and the intervention are based on the ICF.¹⁵ The Rasch-validated outcome measure provides a score on an interval level and is highly eligible for parametric statistics as implemented in our study.²⁴ The risk of detection bias is deemed low as the PaArticular Scales were designed specifically for blinded raters to assess the primary outcome. Quality of life measured with EQ-5D-5L seems appropriate as it is associated with the activities of nursing home residents.²⁵

This study has potential limitations. Despite adjusting the recruitment procedure after the pilot study,⁸ nursing home staff handled inclusion criteria differently as residents with few impairments due to contractures

were also enrolled. This highlights the need for a standardised definition and assessment of joint contractures. Our outcomes focus on limitations rather than positive aspects of health. Activities and participation are not only influenced by access to services and involvement in life situations but also by a person's sense of inclusion or satisfaction.¹⁵ Addressing well-being or satisfaction with relationships, meaningful activities and autonomy would broaden the perspective.²⁶ A lack of congruence between proxy-reported and self-reported outcomes has been frequently reported.^{27–29} Only half of the assessments (49.8%) were completed as self-report at the 12 months follow-up. However, adequate feasibility and validity were shown in the proxy use of the EQ-5D-5L by nurses in nursing homes.³⁰

No precise information on effectiveness (changes in the Activities Scale and the Participation Scale) can be drawn from the wide confidence intervals. Regarding the generalisability, we expect similar results in other samples due to the precarious situation in the nursing homes and the high internal validity. The sample characteristics of residents are similar to those of German nursing home residents in general. Female residents in full inpatient

Table 3 Safety measures during the study period at the resident level

Variables	Intervention group (n=301)		Control group (n=259)	
	No (%) of participants	No of events	No (%) of participants	No of events
Fall	102 (33.9)	286	104 (40.2)	344
Fall-related fracture	13 (4.3)	14	7 (2.7)	8
Fall-related injury	23 (7.6)	28	25 (9.7)	33
Physical restraints	21 (7.0)	32	25 (9.7)	35

care account for 69.7% (73.4% in our study). The care dependency level is greater than 2 in 79% of nursing home residents overall,³¹ 74.1% in our study. An improvement in activities and participation was visible in both study groups. Subjective attention in the control group³² may apply, as some clusters revised standard operating procedures on joint contractures during the study period. The nursing homes' preparation for new quality audits by the health insurance medical service with focus on mobility and individual day structuring went into effect during recruitment, may have had an impact. We attribute little impact to the implementation of the nursing practice guideline on mobility since only three facilities in the intervention and one in the control group implemented the guideline during the study period (online supplemental table S8).

Overall, the head nurses and facilitators were able to adapt PECAN to their context, but delivery varied between clusters. Leadership, teamwork and adequate resources as key determinants for effective change³³ influenced implementation according to the initial findings of the process evaluation. We assume that the study's overall findings do not apply to all clusters. Individual benefits for residents cannot be ruled out, and the intervention does not impair their safety.

The prescribing physicians' perspectives and resources hampered the prescription in both the pilot trial⁸ and this study. We provided argumentation templates and discussed the topic in counselling, but prescriptions only increased slightly (baseline: 46.8%; after 12 months: 47.5%). Addressing the influences on prescribing seems to be essential to provide the required support to residents.

A key component of PECAN is individualised care planning based on the residents' goals. Meaningful tailored activities, particularly those that take on a functional role, can improve health, well-being, quality of life and perceived quality of care.^{34 35} Exploring individual preferences proved difficult in our study since some residents were unable to provide information and nurses had to rely on statements from relatives. Goal-setting to tailor occupational therapy proved similarly difficult for stroke-impaired residents.³⁶ However, early assessment and regular updating of biographical data might be beneficial. Research is still needed on how to effectively tailor meaningful activities for residents with dementia.³⁷ Activities are usually tailored to the majority of residents³⁸ which posed a problem in our study as well. The recommended formation of small groups based on interests and abilities was frequently not possible due to a lack of resources. The need for meaningful social interactions is thought to be essential for residents' self-worth and sense of belonging, but can be difficult to meet due to differences in residents' communication skills.^{34 38} Some head nurses dismissed the facilitators' efforts to assist residents in establishing social relationships, such as changing the seating arrangement in the dining room.

Implementation proved to be comparably difficult in studies dealing with the prevention of physical restraints³² and antipsychotic drug use in nursing homes³⁹ due to the organisational context. Professional provision of care is systematically considered to be at risk, due to the consistently low staffing levels in German nursing homes.³¹ To facilitate the provision of individualised care, stakeholders must foster a caring culture through increased staffing.³⁸ The residents' participation needs should be addressed by well-trained nursing staff rather than social care assistants supported by adaptable routines and procedures within the organisation.⁴⁰ Further research should broaden the understanding of participation according to the ICF and to implement social participation as a fundamental care goal. The psychosocial component should be incorporated into the quality assessment of the health insurance medical service.

Conclusions

PECAN was not effective in improving activities and participation of nursing home residents with joint contractures after 12 months compared with optimised standard care. No adverse effects have been reported. We consider implementation feasible, as some clusters have successfully implemented PECAN. However, we note that such individually tailored interventions are difficult to implement under current circumstances due to significant organisational barriers in nursing homes.

Author affiliations

¹Medical Faculty, Institute of Health and Nursing Sciences, Martin Luther University Halle-Wittenberg, Halle, Germany

²Faculty of Applied Health and Social Sciences, Rosenheim Technical University of Applied Sciences, Rosenheim, Germany

³Faculty of Medicine, Institute for Medical Information Processing, Biometry and Epidemiology, Ludwig Maximilians University Munich, Munich, Germany

⁴Faculty of Medicine, Centre for Health and Society, Institute for Health Services Research and Health Economics, Heinrich Heine University Düsseldorf, Düsseldorf, Germany

⁵Institute for Health Services Research and Health Economics, German Diabetes Center, Leibniz Institute for Diabetes Research at Heinrich Heine University Düsseldorf, Düsseldorf, Germany

⁶Medical Faculty Heidelberg, Department for Primary Care and Health Services Research, Nursing Science and Interprofessional Care, Heidelberg University, Heidelberg, Germany

Twitter Natalie Nguyen @_natalie_nguyen

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ORCID iDs

Natalie Nguyen <http://orcid.org/0000-0003-0243-6994>

Ulrich Mansmann <http://orcid.org/0000-0002-9955-8906>

Katrin Beutner <http://orcid.org/0000-0001-5265-6501>

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