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Implementation of a multicomponent intervention to prevent physical restraints in nursing homes (IMPRINT): A pragmatic cluster randomized controlled trial

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ABSTRACT

Background: Despite clear evidence for the lack of effectiveness and safety, physical restraints are frequently applied in nursing homes. Multicomponent interventions addressing nurses' attitudes and organizational culture have been effective in reducing physical restraints.
Objective: To evaluate the effectiveness of two versions of a guideline and theory-based multicomponent intervention to reduce physical restraints in nursing homes.
Design: Pragmatic cluster randomized controlled trial.
Setting: The study was conducted in 120 nursing homes in four regions in Germany.
Participants: All residents living in the participating nursing home during follow-up, newly admitted residents were also included. A total of 12,245 residents included in the primary analysis (4126 and 3547 residents in intervention group 1 and 2 and 4572 residents in the control group).
Methods: Intervention group 1 received an updated version of a successfully tested guideline-based multicomponent intervention (comprising brief education for the nursing staff, intensive training of nominated key nurses in each cluster, introduction of a least-restraint policy and supportive material), intervention group 2 received a concise version of the original program and the control group received optimized usual care (i.e. supportive materials only). Primary outcome was physical restraint prevalence at twelve months, assessed through direct observation by blinded investigators. Intervention and control groups were compared using baseline-adjusted linear regression on cluster level, Bonferroni-adjusted for double testing. Secondary outcomes included falls, fall-related fractures, and quality of life. We also described intervention costs and performed a comprehensive process analysis.
Results: At baseline, mean physical restraint prevalence was 17.4% and 19.6% in intervention groups 1 and 2, and 18.8% in the control group. After twelve months, mean prevalence was 14.6%, 15.7%, and 17.6%. Baseline-adjusted differences between mean prevalences were 2.0% (97.5% CI, -5.8 to 1.9) lower in intervention group 1 and 2.5% (97.5% CI, -6.4 to 1.4) lower in intervention group 2 compared to controls. Physical restraint prevalence showed a pronounced variation between the different clusters in all study groups. We found no significant differences in the secondary outcomes. According to the process evaluation, the intervention was mainly implemented as planned, but the expected change towards a least restraint culture of care was not achieved in all clusters.
Conclusions: Neither intervention showed a clear advantage compared to control. The pronounced center variation in physical restraint prevalence indicates that other approaches like governmental policies are

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needed to sustainably change physical restraint practice and reduce center variations in nursing homes.
Trial registration: ClinicalTrials.gov : NCT02341898.

What is already known about the topic?

- Physical restraints are still applied in nursing home residents despite their lack of effectiveness and safety.
- Multicomponent interventions including educational approaches targeting nursing staff seem to be effective in reducing physical restraint prevalence.

What this paper adds

- A multicomponent intervention and a concise version aimed at reducing physical restraints showed no clear advantage compared to optimized usual care.
- Multicomponent interventions might be less effective than expected in reducing centre variations and in a unselected sample with low physical restraint prevalence.

1. Introduction

Physical restraints such as bed rails, belts, and fixed tables in chairs are commonly applied in geriatric nursing care despite clear evidence showing their lack of effectiveness and safety (Köpke et al., 2012; Sze et al., 2012; Bellenger et al., 2018; Foebel et al., 2016; Goethals et al., 2012). An international consensus statement defines physical restraints as "any action or procedure that prevents a person's free body movement to a position of choice and/or normal access to his/her body by the use of any method, attached or adjacent to a person's body that he/she cannot control or remove easily" (Bleijlevens et al., 2016). The use is restricted by the law in the USA and in Germany with least restraint policies recommended as standard of care (Centers for Medicare and Medicaid Services, 2008; Registered Nurses' Association of Ontario, 2012). Most interventions aimed at reducing physical restraints are complex interventions, addressing nurses' attitudes and institution's organizational culture concerning physical restraint use as these have been shown to be strongly connected with physical restraint use (Goethals et al., 2012; Meyer et al., 2009; Möhler et al., 2012; Möhler and Meyer, 2014). However, a Cochrane Review has shown inconclusive evidence about the effectiveness of educational interventions (Möhler et al., 2012). Based on our theoretical work (Meyer et al., 2009; Möhler et al., 2012; Möhler and Meyer, 2014), we had previously developed and evaluated a guideline-based intervention applying the UK Medical Research Council's guidance for developing and evaluating complex interventions (eFig. 1) (Craig et al., 2008). In addition to the education approach, we had added components aimed at changing the organizational culture and policy regarding physical restraints (least-restraint policy). In a multi-center cluster randomized controlled trial, we had shown a statistically significant reduction of physical restraint prevalence in nursing homes. The accompanying process evaluation revealed valuable information for improving the intervention, indicating that brief education for nursing staff might not be necessary to change nurses' attitudes and practice regarding physical restraints (Köpke et al., 2012). After this study, the guideline was made publically available in Germany. In parallel, other restraint reduction activities were carried out either focusing on legal issues of requested physical restraints (Koczy et al., 2011) or on physical restraint substitution by alternative measures (Endrikat, 2012). In recent years, physical restraint prevalence declined in Germany (Foebel et al., 2016; Medical Advisory Service of the German Social Health Insurance (MDS), 2017) with some evidence for between center-variations as seen in earlier studies (Foebel et al., 2016; Meyer et al., 2009).

The MRC framework (Craig et al., 2008) recommends an implementation study for a successfully evaluated intervention; hence we conducted a pragmatic cluster randomized implementation trial to investigate the long-term effects of the original intervention and a newly developed concise version in a large non-selected sample of nursing home residents in four different regions of Germany. Intervention costs were described and a comprehensive process evaluation of the interventions' delivery and implementation was conducted alongside the clinical trial.

2. Methods

2.1. Study design

We conducted a pragmatic cluster randomized controlled trial with twelve-month follow-up including 120 nursing homes. Randomization was carried out on cluster level to minimize contamination; clusters were defined as nursing homes. A detailed description of the methods has been published elsewhere (Abraham et al., 2015).

2.2. Study setting and participants

All nursing homes providing care for older people were eligible for inclusion. No minimum physical restraint prevalence was required, which is in contrast to the former efficacy study, where nursing homes were only eligible if they had a self-reported prevalence of at least 20% (Köpke et al., 2012). In each study region (Hamburg and Schleswig-Holstein (Northern Germany), Halle (Saale) (Eastern Germany) and Witten (Western Germany)), all nursing homes were identified through publicly available registers. Random samples of nursing homes were invited to participate in each region and a total of 503 nursing homes were contacted (Schleswig-Holstein, n = 101; Hamburg, n = 171; Witten, n = 96; Halle (Saale), n = 135). Recruitment lasted from February to November 2015. All residents that were present in the nursing home on the day of data collection were included. Residents newly admitted during follow-up were also included.

2.3. Randomization

Clusters were randomly assigned to study groups by a person affiliated to the study center in Hamburg, but not involved in the study, using a computer-generated randomization list stratified by region with blocks of six, nine, and twelve nursing homes (generated by an independent external biometrician (BH)). One cluster at the study center Halle (Saale) that had been randomized to intervention group 1 was erroneously allocated to the control group due to miscommunication.

2.4. Intervention

First, the evidence-based guideline (Köpke et al., 2015) was updated (April to October 2014) using internationally recommended procedures (Köpke et al., 2012,2008). Five online

consensus meetings with a multidisciplinary development group were held and 22 recommendations on relevant interventions to avoid physical restraints were consented. Three external experts reviewed the updated guideline. All printed study materials were updated and piloted. Based on the in-depth analysis of the former study's process evaluation and further literature (Gerlach et al., 2012; Bleijlevens et al., 2013), the concise version of the updated program was developed. This program and the assessment instruments were piloted in two nursing homes in order to test feasibility of study procedures and materials. No major changes were necessary.

Interventions were implemented on cluster level. Intervention group 1 received an updated version of the original program (Köpke et al., 2012). In each cluster, key nurses (nominated by nursing home leaders) received an intensive training (full day training workshop and half-day counseling) with detailed information based on the updated guideline (Köpke et al., 2015) about strategies to implement a least-restraint practice, followed by structured support for three months (with at least one contact per month). A single 90-minute information session about physical restraint reduction with information e.g. on lack of effectiveness, risks and alternatives of physical restraints was offered to all nurses. A policy statement addressing a least-restraint policy was signed by the nursing home leader. Printed study materials (guideline, guideline's short version, and information brochures for nurses, residents, relatives and general practitioners) and supportive material were provided to each cluster.

Intervention group 2 received the concise version, comprising the intensive training for key nurses, the organizational component, and all supplemental materials. Intervention 2 did not comprise the single 90-minute information session for the nursing staff since this component is very time-consuming and the process evaluation of the former study (Gerlach et al., 2012) indicated only little impact. To ensure that education could be delivered if needed, we added a train-the-trainer module (advice and additional materials) for key nurses to enable the delivery of the information session to nursing staff.

The control group received the printed study material (optimized usual care). A detailed description of both interventions is displayed in eTables 1 + 2. Apart from the experimental interventions, control group and intervention group clusters were treated equally.

2.5. Outcome measures and data collection

Primary outcome was the proportion of residents with at least one physical restraint after twelve months. Physical restraint use was assessed through direct observation at three time points: before randomization (T_0), after six months (T_1), and after twelve months (T_2) by raters blinded to group allocation. Raters were trained using a standardized list of measures to be rated as physical restraints. In contrast to our earlier study (Köpke et al., 2012), for pragmatic reasons observations were performed twice a day (morning and evening) instead of three times a day. For the purpose of data collection, every resident was visited by an investigator accompanied by a nurse. Physical restraints were documented if they were applied at the time of visit. Residents were assessed as having a physical restraint if such a measure was applied at least on one of the two observations points. Secondary outcomes were residents' quality of life and falls and fall-related fractures.

Quality of life was assessed using the German version (Mapi Research Institute, 2008) of the validated Quality of Life-Alzheimer's Disease (QoL-AD) instrument (Logsdon et al., 1999, 2002), proxy-rated by nursing staff with direct resident contact in two independent randomly selected 10% subsamples (T_0 and T_2). Information about falls and fall-related fractures were extracted from residents' records, as in German nursing homes the documentation of any fall and fall-related injury is legally required. We also assessed residents' cognitive status (Dementia Screening Scale, DSS (Köhler et al., 2007)) and challenging behavior (modified German version of the Cohen-Mansfield Agitation Inventory, CMAI (Cohen-Mansfield et al., 1989; Cohen-Mansfield, 1991, 1996)), both rated by nursing staff. An abbreviated baseline assessment was performed for residents newly admitted during the study period.

A comprehensive process evaluation was performed to systematically document the implementation process and describe barriers and facilitators (eTable 3) (Abraham et al., 2015).

The preplanned comprehensive health economic evaluation (Abraham et al., 2015) from a German social insurance perspective was not performed due to the lack of effectiveness of both interventions and because also cost-relevant secondary outcomes as falls did not differ significantly between intervention and control group. However, we calculated the intervention costs of both interventions, considering the salary for personnel delivering the intervention components and for the participating nursing staff, and the materials. Details are provided in eTable 9.

2.6. Sample size

Based on data of the initial study (Köpke et al., 2012), a sample size of 120 clusters was needed to detect a baseline-adjusted difference of 5% in physical restraint prevalence on cluster level after twelve months with 90% power and a dropout rate of 5% using t-tests, two-sided significance levels of 2.5% (Bonferroni-adjusted for double testing) and assuming a standard deviation of 6.0% in both groups.

2.7. Statistical analysis

Statistical analyses were conducted after twelve months by the statistician (BH) blinded to group allocation of clusters. No interim analysis was performed. Data analysis followed the intention to treat principle, except one cluster erroneously allocated to control instead of the randomized intervention group 1. Both, the study team and the nursing home were not aware of the incorrect allocation and assumed that the cluster was treated in the right group until the end of the study. Therefore, the cluster was analyzed in the control group, assuming this was least biased in the sense of intention to treat. A sensitivity analysis was performed using the strict intention to treat principle and analyzing this cluster as randomized in the intervention group 1.

Baseline data on nursing homes and residents were described by treatment groups. In the primary analysis, physical restraint prevalence rates in both intervention groups were compared to controls on cluster level assuming normal distribution. A linear model was fitted using the prevalence of clusters at T_2 as dependent variable and the baseline prevalence and treatment groups as independent variables. Differences of prevalence changes between each intervention group and controls were estimated model based using a two-sided significance level of $\alpha = 2.5\%$. Within group differences between T_0 and T_2 were estimated on cluster level and compared using paired t-tests.

Data in time course (T_0, T_1, T_2) were described by treatment groups. Outcomes of residents were estimated on resident level using cluster-adjusted confidence intervals based on intra-class correlation coefficients (Donner and Klar, 2000).

Secondary outcomes were described by treatment groups and time including cluster-adjusted confidence intervals (Donner and Klar, 2000). Cluster-adjusted generalized linear mixed models were fitted. The number of falls per resident at T_2 was analyzed on

cluster level by means and 95% confidence intervals. Groups were compared using a Kruskal Wallis test on cluster level.

There were no missing values on cluster level in the primary analyses. In the secondary analyses on resident level one cluster was excluded because of residents' missing IDs in the time course. No imputation of missing values was performed.

A post-hoc subgroup-analysis was performed for nursing homes with a prevalence of physical restraints of at least 20% as this cutoff had been applied as inclusion criterion for nursing homes in our former study (Köpke et al., 2012).

The significance level is 5% if not stated otherwise, e.g. 2.5% in the Bonferroni-adjusted primary analysis. Statistical analyses were performed using SAS version 9.4 and SAS/STAT version 14.2.

2.8. Ethical and legal considerations

The data protection strategy was reviewed by a commissioner for data protection (federal state Saxony-Anhalt, Eastern Germany). The protocol was approved by the ethics committees of the Universities of Lübeck (January 2015, reference no. 14-251) and Halle (Saale) (March 2015, reference no. 2015-02). Leaders of participating nursing homes gave written informed consent. A waiver of written informed consent from residents or their legal guardians was granted as the investigators had no direct access to the residents' data, including their names. According to data protection regulations, nursing staff members accompanied the investigators during data collection.

3. Results

Overall, 120 nursing homes (Schleswig-Holstein, n = 39; Hamburg, n = 23; Witten, n = 29; Halle (Saale), n = 29) with 9012 residents were included at baseline (n = 3039 intervention group 1, n = 2593 intervention group 2, n = 3380 control group). During the study period 3409 residents were newly admitted and 3351 residents were lost to follow-up (n = 2653 died, n = 628 moved, n = 70 with unclear reasons). All clusters completed the study, but two clusters (in Halle (Saale) and Witten, respectively) declined data collection at T_1. Data on the primary outcome were available for n = 8800 residents at baseline, n = 8745 after six months and n = 8841 after twelve months. In total n = 12,245 residents were included in the primary analysis (Fig. 1).

The interventions were implemented as planned with exception of the one cluster discussed above. A total of 184 key nurses attended the full-day session (at least one key nurse per intervention cluster) and 722 nurses attended the single education session offered in intervention group 1. A detailed overview of the dose delivered for each component is displayed in eTable 4.

At baseline, residents had a mean age (SD) of 83.2 (10.1) years, 6454 residents (73.5%) were women. The mean cluster size ranged from 68 (intervention group 2) to 84 residents (control group). Baseline characteristics of clusters and participants were comparable between groups (Table 1, eTable 5).

The primary outcome (mean physical restraint prevalence on cluster level) was 17.4% at baseline in intervention group 1, 19.6% in intervention group 2 and 18.8% in the control group. After twelve months, prevalence declined in all study groups (14.6% intervention group 1, 15.7% intervention group 2, 17.6% control group) (Table 2).

The baseline-adjusted difference between intervention group 1 and control group was -2.0% (97.5% CI, -5.8 to 1.9; P = .25) and between intervention group 2 and control group -2.5% (97.5% CI, -6.4 to 1.4; P = .14). Both differences were not significant on the level of 0.025 (Bonferroni-adjusted). Physical restraint prevalence decreased statistically significant within both intervention groups from baseline to follow-up (intervention group 1: -2.8; 95% CI -5.5 to -0.01; P = .042 and intervention group 2: -3.9; 95% CI -6.8 to -1.0; P = .009). The reduction in the control group (-1.2; 95% CI -0.04 to 0.11; P = .294) was not statistically significant (eTable 6). A sensitivity-analysis using the allocation as randomized resulted in similar effects for the primary outcome (data not shown). A further sensitivity analysis in the subgroup including only nursing homes with physical restraint prevalences $\geq$ 20% at baseline (intervention group 1: n = 13, intervention group 2: n = 16, control group: n = 15) did not show a significant reduction (significance level of 0.025, Bonferroni-adjusted) comparing intervention groups versus control group as well. The baseline-adjusted difference between intervention group 1 and control group was -4.4% (97.5% CI, -12.1 to 3.2; P = .18) and between intervention group 2 and control group -1.0% (97.5% CI, -8.3 to 6.3; P = .75) (eTable 7).

We assessed blinding of research assistants at T_2 with 53.7% (95% CI, 45.5 to 63.6) of correct ratings indicating successful blinding.

The number of residents with at least one fall or fall-related fracture during the study period did not differ statistically significant between groups (Table 3). There was also no statistically significant difference in the mean number of falls per resident and in the mean number of falls per resident with at least one fall (eTable 8).

Residents' quality of life was slightly lower after twelve months in all study groups with no statistically significant differences between groups (eTable 9). No adverse effects were observed in any study group.

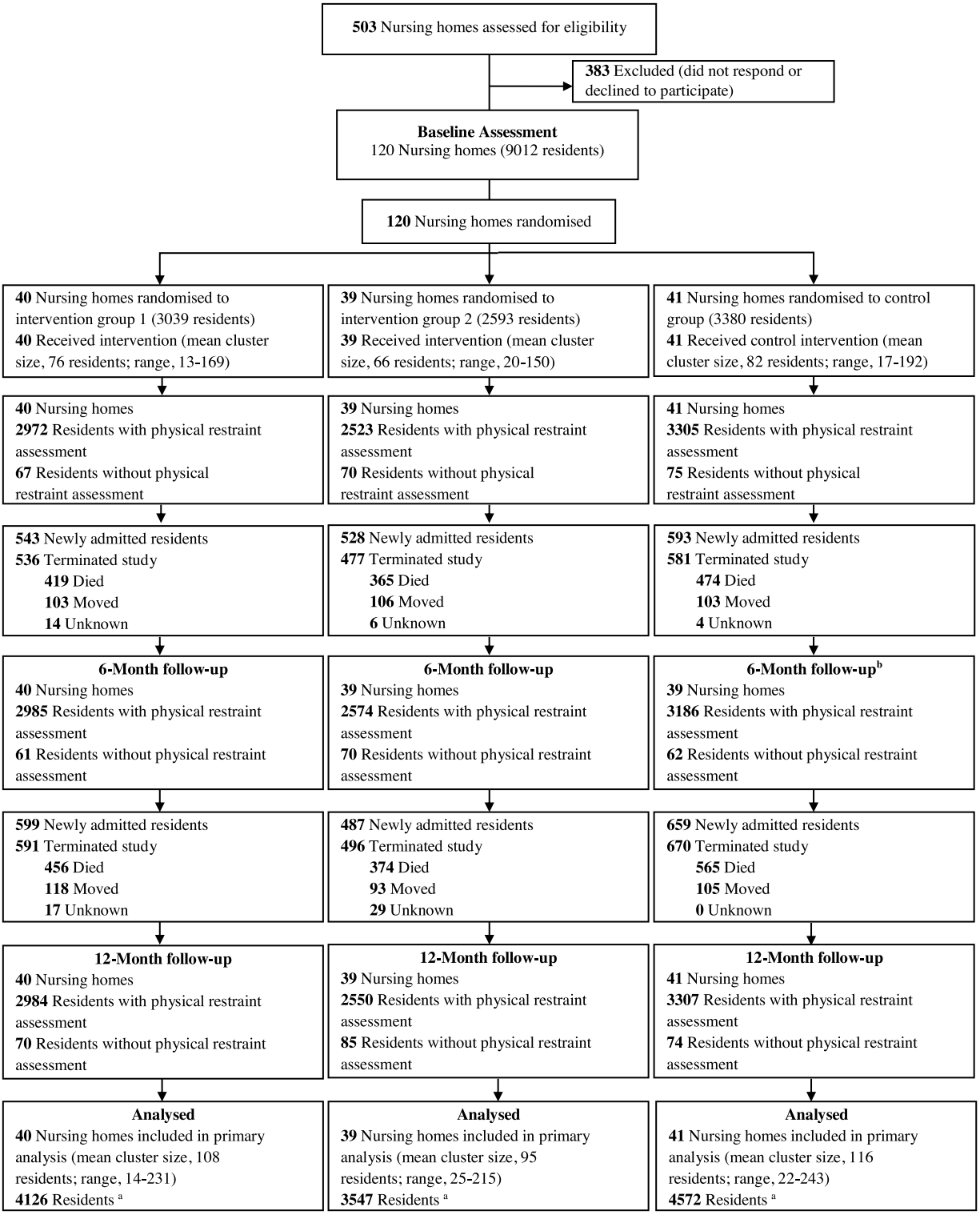
The results of the process evaluation confirmed that the intervention was predominately implemented as planned (the dose delivered is displayed in eTable 4 for all components). We identified facilitators and barriers of physical restraint reduction from interviews with leaders, key nurses, randomly selected nursing staff, and protocols of the structured support for key nurses. The different groups described comparable topics, depending on the context (eTable 10). Both, key nurses and leaders described positive attitudes towards the intervention and its principle goal and most key nurses described being satisfied with their role and felt accepted by their colleagues. However, we found that a certain number of nurses in both intervention groups still believed that physical restraints are effective measures to prevent falls and injuries. Accordingly, several key nurses did not notice a cultural change regarding physical restraint reduction in their nursing home or described that nursing staff discontinued reducing physical restraints. Another important barrier was the partly uncritical attitudes of residents' relatives and legal guardians regarding physical restraints. Key nurses described challenges in trying to convince relatives or legal guardians about the need to avoid or reduce physical restraints. Other barriers were time constraints and lack of equipment, e.g. low beds. A detailed description of the facilitators and barriers described by the different groups of staff are displayed in eTable 10.

The economic evaluation showed that implementing intervention 1 yielded total costs of $44,509 (38,081€), total costs of intervention 2 were $19,688 (16,844€). Costs for the materials used in the control group were $48 (41€). Details are displayed in eTable 11.

4. Discussion

In this pragmatic cluster randomized controlled trial both intervention variants did not significantly reduce physical restraints in nursing home residents compared to optimized usual care. Physical restraint reduction was smaller than expected in both intervention groups. The reduction in the control group was comparable to the former efficacy trial (Köpke et al., 2012).

One reason for the lack of effectiveness of the successfully evaluated intervention might be the lower baseline physical



[a]Residents who had at least one physical restraint assessment.
[b]Two nursing homes (n=144 residents) declined data collection at six-month follow-up.

Fig. 1. Flowchart for the cluster randomized controlled trial.
[a]Residents who had at least one physical restraint assessment.
[b]Two nursing homes (n = 144 residents) declined data collection at six-month follow-up.

Table 1
Baseline characteristics of nursing home residents.

Characteristics	Intervention Group 1 (n = 2972)	Intervention Group 2 (n = 2523)	Control Group (n = 3305)
Age, mean (SD) [range], years (11 missings)	83.7 (9.7) [34-108]	83.5 (10.0) [25-106]	82.5 (10.5) [24-105]
Female sex, No. (%) (18 missings)	2110 (71)	1936 (77)	2408 (73)
Length of residence, mean (range), months (30 missings)	36 (0-363)	40 (0-546)	39 (0-495)
Care dependence category[a] (35 missings)			
None	31 (1)	67 (3)	32 (1)
Level 0	122 (4)	83 (3)	107 (3)
Level 1 (considerable)	1164 (39)	944 (37)	1293 (39)
Level 2 (severe)	1146 (39)	940 (37)	1194 (36)
Level 3 (most severe)	489 (17)	484 (19)	669 (20)
Residence at special dementia care unit 293 missings	244 (9)	272 (11)	458 (14)
≥ 1 Fall in preceding 12 months (1192 missings[b])	1051 (41)	840 (37)	1116 (40)
≥ 1 Fall-related fracture in preceding 12 months (8 missings)	106 (4)	85 (3)	79 (2)
Cognitive impairment (375 missings[b])	1683 (60)	1401 (58)	1957 (61)
Challenging behavior in preceding 4 weeks			
Restlessness (356 missings[b])	814 (29)	595 (25)	915 (29)
Verbal agitation (363 missings[b])	570 (20)	429 (18)	635 (20)
Handling things inappropriately (364 missings[b])	511 (18)	422 (17)	636 (20)
Negative attitude (390 missings[b])	718 (26)	572 (24)	853 (27)
Aggression (361 missings[b])	460 (16)	420 (17)	560 (17)

[a] Residents' need for care assessed by the medical service of the German social care insurance; Need for care in performing activities of daily living, household tasks: Level 0: less than 90 min/day, Level 1: at least 90 min/day, Level 2: at least 3 h/day, Level 3: at least 4 h/day.
[b] Including the category 'not applicable', e.g. when residents lived only for a short time in the nursing home and this information was not available.

restraint prevalence with less than 20% in all groups compared to more than 30% in our previous study (Köpke et al., 2012). In the previous study, nursing homes were included if they had a self-reported prevalence of at least 20%, but we did not apply such an inclusion criterion in this study since we aimed to recruit an unselected population.

In the last years several projects and initiatives aimed at reducing physical restraints in nursing homes, resulting in a trend

Table 2
Prevalence of physical restraint use.

	Baseline			6-Month Follow-up			12-Month Follow-up		
	Intervention Group 1 (n = 2972)	Intervention Group 2 (n = 2523)	Control Group (n = 3305)	Intervention Group 1 (n = 2985)	Intervention Group 2 (n = 2574)	Control-Group (n = 3186)	Intervention Group 1 (n = 2984)	Intervention Group 2 (n = 2550)	Control-Group (n = 3307)
Residents with any physical restraint, No.[a]	470	513	575	415	429	568	385	382	546
Mean prevalence % (95% CI)[b]	17.4 (13.9-20.9)	19.6 (15.3-23.9)	18.8 (15.0-22.6)	15.6 (12.9-18.3)	17.2 (12.9-21.4)	19.8 (16.2-23.3)	14.6[c] (11.8-17.4)	15.7[c] (10.9-20.5)	17.6[c] (14.1-21.1)
Restrictive bed rails, No.[a]	403	452	474	303	336	430	299	311	420
Mean prevalence % (95% CI)[b]	15.0 (11.5-18.6)	17.1 (12.6-21.6)	15.8 (12.2-19.4)	11.6 (9.2-13.9)	13.3 (9.2-17.5)	15.0 (11.7-18.3)	11.1 (8.5-13.7)	12.6 (8.0-17.2)	13.8 (10.6-16.9)
Any belt, No.[a]	17	35	20	10	27	37	12	20	36
Mean prevalence % (95% CI)[b]	0.6 (0.1-1.1)	1.2 (0.7-1.8)	0.5 (0.2-0.8)	0.5 (0.1-1.0)	1.1 (0.4-1.9)	1.1 (0.5-1.8)	0.4 (0.1-0.8)	0.7 (0.3-1.2)	1.0 (0.4-1.6)
Belt in bed, No.[a]	2	2	3	4	3	1	3	2	4
Mean prevalence % (95% CI) [b]	0.1 (0.0-0.2)	0.0 (0.0-0.1)	0.1 (0-0.1)	0.1 (0.0-0.3)	0.1 (0.0-0.2)	0.0 (0.0-0.1)	0.1 (0.0-0.2)	0.1 (0.0-0.2)	0.1 (0.0-0.2)
Belt in chair, No.[a]	16	34	18	6	25	36	10	19	32
Mean prevalence % (95% CI)[b]	0.6 (0.1-1.1)	1.2 (0.6-1.8)	0.5 (0.2-0.8)	0.4 (0.0-0.8)	1.1 (0.3-1.9)	1.1 (0.5-1.8)	0.4 (0.0-0.7)	0.7 (0.3-1.1)	0.9 (0.4-1.4)
Fixed table, No.[a]	18	15	19	14	12	22	12	10	29
Mean prevalence % (95% CI) [b]	0.7 (0.3-1.0)	0.6 (0.2-0.9)	0.9 (0.1-1.7)	0.5 (0.1-0.9)	0.5 (0.2-0.8)	1.0 (0.4-1.5)	0.4 (0.1-0.7)	0.6 (0.0-1.1)	1.1 (0.4-1.8)
Other physical restraints, No.[a]	91	72	103	136	113	184	93	93	154
Mean prevalence % (95% CI)[b]	3.1 (1.8-4.4)	2.9 (1.8-4.1)	3.0 (1.8-4.3)	5.2 (3.2-7.1)	4.7 (3.1-6.3)	5.8 (4.2-7.5)	3.8 (1.9-5.6)	3,4 (1.9-5.0)	4.6 (3.1-6.0)

[a] No. on resident level.
[b] Percentages are mean prevalences on cluster level.
[c] Primary endpoint.

Table 3
Falls and fall-related fractures during the study period (resident level).

	Intervention Group 1 (n = 4315)		Intervention Group 2 (n = 3712)		Control Group (n = 4740)		OR (95% CI) Intervention Group 1 vs. Control Group	OR (95% CI) Intervention Group 2 vs. Control Group
	No.	% (95% CI)[a]	No.	% (95% CI)[a]	No.	% (95% CI)[a]		
Residents with ≥1 fall	1467	34.0 (30.4 to 37.6)	1223	32.9 (29.0 to 36.9)	1505	31.8 (27.8 to 35.7)	1.17 (0.89-1.53)	1.03 (0.79-1.35)
Residents with ≥1 fall-related fracture	104	2.4 (1.8 to 3.0)	73	2.0 (1.3 to 2.7)	87	1.8 (1.3 to 2.4)	1.31 (0.87-1.97)	1.11 (0.73-1.71)

[a] Cluster-adjusted CIs.

of lower prevalence in Germany (Foebel et al., 2016; Medical Advisory Service of the German Social Health Insurance (MDS), 2017; Feng et al., 2009). From the 120 clusters, 22 (18%) had a baseline prevalence lower than 10% and a decreased or unchanged prevalence after twelve months; it might be more difficult to reduce physical restraints in a population with low prevalence. Although the sensitivity analysis including only clusters with a baseline prevalence of at least 20% also did not show statistically significant differences between the study groups, this might be due to lack of power as only 44 clusters could be included. Since the control group also received the guideline and the materials (optimized usual care) and there was significant public attention on physical restraint use in German nursing homes, as described above, it might be possible that some clusters in the control group used these materials for own restraint reduction approaches without the structured implementation. Considering the negative impact of physical restraints on residents' health, providing the guideline to all clusters was required for ethical reasons.

In 25 (32%) intervention clusters we found nearly unchanged or increased physical restraint prevalence after twelve months and we also found baseline prevalences higher than 30% in 16 clusters (13%) after 12 months (e Figure 2), indicating that there are still pronounced center differences across nursing homes as identified in earlier studies (Foebel et al., 2016; Meyer et al., 2009; Hofmann et al., 2015). Therefore, we did not reached the aim of the study to change the nursing home culture towards a least-restraint policy and to reduce the center variations. However, the statistically significant reduction within both intervention groups from baseline to follow-up indicates that the guideline-based intervention was supportive in reducing physical restraints in some nursing homes, but the effect was smaller than expected and not observed in all intervention clusters.

The results of our process evaluation revealed some important barriers for changing the culture of care regarding physical restraints use: nursing staff still showed positive or uncritical attitudes towards using physical restraints to some extent despite clear evidence of the lack of effectiveness and the strong ethical implications of physical restraints against residents' dignity and freedom (Köpke et al., 2012; Foebel et al. 2016; Goethals et al. 2012; Sze et al. 2012; Bellenger et al. 2018; Gastmans and Milisen, 2006), This is confirmed by other studies (Möhler and Meyer, 2014; Kong et al., 2017). However, key nurses from several clusters showed positive attitudes towards the aim of the intervention and described that a policy change could be established. It was not possible to perform an analysis of our process data on cluster level and therefore we did not identify characteristics associated with a greater reduction of physical restraint prevalence. Our hypothesis based on our Cochrane Review and further studies (Möhler and Meyer, 2014; Möhler et al., 2012; Gulpers et al., 2011) that a strong focus on policy change seems necessary to reach a change in clinical practice was not confirmed. A study that included a strong policy component (prohibiting the use of belt restraints in the intervention group) found a statistically significant reduction of belts but prevalence of all types of physical restraints was still high at follow-up (54% in the intervention group and 69% in the control group) (Gulpers et al., 2011). Based on the results of our study, complex interventions aiming at reducing physical restraints by changing the culture of care regarding physical restraints seem to be less effective as expected in a large unselected sample. Other approaches are needed to reduce physical restraint prevalence in nursing homes, i.e. legal or governmental policy changes making clear that physical restraints are inadequate measures in the care of nursing home residents (Möhler and Meyer, 2014; Kong et al., 2017).

This study had several strengths. This is one of the first examples completing all stages of the UK Medical Research Council's guidance for the development and evaluation of complex interventions (Craig et al., 2008), demonstrating the applicability of the framework in health services research (eFig. 1). Including 120 nursing homes and more than 12,000 residents, our study is the largest in this field and all clusters completed the twelve months follow-up period. The rigorous study procedures ensured the validity of the results. For instance, physical restraint use was assessed by direct observations by blinded raters. The study also has potential limitations. Due to the large sample some study procedures were pragmatic, e.g. proxy ratings of residents' quality of life in two randomly selected subsamples. One cluster was inadvertently allocated to another group as randomized but a sensitivity-analysis of the primary outcomes showed comparable results and we did not expect that this introduced a risk of bias. Differences in standard deviations of physical restraint prevalence were higher than assumed in all groups (7.3% to 9.0%), resulting in a reduced power: Assuming a standard deviation of 8%, a difference of 5% could be detected by a power of 66%, a difference of 6% by a power of 83%. Increased heterogeneity of data compared to our previous study (Köpke et al., 2012) yielded further power reduction.

5. Conclusion

Neither version of a guideline-based multicomponent intervention was effective in reducing physical restraints in a large unselected sample of nursing home residents. We found more pronounced reductions of physical restraints in the intervention groups, but these were lower than expected and of unclear clinical relevance due to the resources needed to implement the guideline. Other approaches, like legal or governmental policies, seem to be necessary to sustainably change physical restraint practice and reduce center variations in nursing homes.

Author contributions

SK and GM developed the conception and design of the initial protocol and obtained funding. SK was the responsible coordinator of the study center in Lübeck and Hamburg. GM was the responsible coordinator of the study center in Halle (Saale) and Witten. SK and AB were responsible for implementation of the interventions and data collection in Lübeck, GM and JA in Halle (Saale), RK in Hamburg, and RM in Witten. BH conducted the sample size calculation and was responsible for statistical planning and data analyses. AI was responsible for the health economic

evaluation. BBH performed the analysis of the process data. JA and RM drafted the manuscript. All authors commented on the manuscript drafts and read and approved the final manuscript.

Conflict of interest disclosures

The authors declare that they have no competing interests. All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.ijnurstu.2019.03.017.

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