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ORIGINAL RESEARCH:
EMPIRICAL RESEARCH - MIXED METHODS

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Process evaluation of a multicomponent intervention to prevent physical restraints in nursing homes (IMPRINT): A mixed methods study

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Abstract

Aims: To describe the implementation process and fidelity of two versions of a guideline-based, multicomponent intervention to reduce physical restraints in nursing homes and to identify factors that might explain the heterogeneity of effects between different clusters.

Design: Mixed methods evaluation of the implementation process (dose delivered, dose received, response, and adaption) alongside a pragmatic three-arm cluster randomized controlled trial.

Methods: Quantitative and qualitative process data were collected during the study period (February 2015–February 2017). Quantitative data from questionnaires and short surveys were analysed by descriptive statistics. Qualitative data from focus groups and semi-structured interviews were analysed using content analysis. An in-depth analysis was conducted by contrasting responding and non-responding clusters regarding the intervention goal and primary outcome.

Results: Both interventions were implemented as planned in all clusters: we found no deviations from the protocol regarding the dose delivered to and received by the clusters. Satisfaction of staff targeted by the interventions was high. The in-depth analysis did not reveal any pronounced variation in the degree of implementation or adoption in clusters with a good or nearly no response to the interventions or factors explaining different study effects.

Conclusion: Although both versions of a guideline-based multicomponent intervention to prevent physical restraints in nursing homes were implemented as planned and the response was generally acceptable, the interventions' goal to change nursing practice towards a least-restraint policy was not achieved by the entire nursing staff

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in all of the clusters. No factors could be identified that might explain the different effects of the interventions.

Impact: For some nursing homes, different approaches than addressing nurses' attitudes and institutional policies might be needed to sustainably reduce the use of physical restraints; however, the process evaluation did not reveal characteristics that might have hampered or facilitated the effectiveness of the intervention.

KEYWORDS

complex intervention, dementia, mixed methods, nursing, nursing homes, physical restraints, process evaluation

1 | INTRODUCTION

Physical restraints (PR) are commonly used in nursing homes despite clear evidence for the lack of effectiveness and safety (Bellenger et al., 2018; Foebel et al., 2016; Goethals et al., 2012; Köpke et al., 2012; Sze et al., 2012). An international consensus statement defines PR 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). Examples are bed rails, belts, and fixed tables. In many countries, the use of PR is restricted by law and least restraint policies are recommended as a standard of care (Centers for Medicare & Medicaid Services, 2008; Registered Nurses' Association of Ontario, 2012). In international studies, the prevalence of PR ranges widely from 6–35% (Feng et al., 2009; Hofmann et al., 2015; Meyer et al., 2009). The main reported reasons for PR use were to ensure residents' safety, in particular to prevent falls and to control challenging behaviour (Goethals et al., 2012; Hamers & Huizing, 2005; Möhler & Meyer, 2014). However, PR do not reduce falls or fall-related injuries, or successfully control challenging behaviour (Foebel et al., 2016; Sze et al., 2012; Hofmann & Hahn, 2014).

In 2010, we conducted a multicentre cluster randomized trial (cRCT) investigating a guideline-based intervention to prevent PR in nursing homes and found that the complex intervention was effective (difference of PR prevalence between intervention and control group after 6 months: 6.5% [95% CI, 0.6%–12.4%; cluster-adjusted odds ratio, 0.71; 95% CI, 0.52–0.97; $p = .03$]) without adverse events such as falls and fall-related fractures, or prescriptions for psychotropic medication (Köpke et al., 2012). Subsequently, we conducted a pragmatic three-arm cRCT to implement the proven multicomponent intervention and a newly developed concise version in 120 nursing homes in four regions in Germany (Hamburg and Schleswig-Holstein [Northern Germany], Halle [Saale] [Eastern Germany], and Witten [Western Germany]) (Abraham et al., 2015, 2019). In contrast to the former study (Köpke et al., 2012), both intervention versions did not significantly reduce PR. Moreover, PR prevalence still varied strongly between clusters in all study groups after 12 months (Abraham et al., 2019). Alongside this cRCT, we performed a comprehensive process evaluation to assess the implementation of both interventions and to describe the adoption of the programs in clinical practice and the barriers and facilitators. Furthermore, the aim was to explore potential explanations for the clinically non-relevant effects of both interventions and the pronounced centre variation.

2 | BACKGROUND

The guideline-based intervention was systematically developed, piloted, evaluated, and implemented according to the UK Medical Research Council's (MRC) guidance for developing and evaluating complex interventions (Craig et al., 2013). With our pragmatic, cluster randomized implementation trial (Abraham et al., 2015, 2019) we implemented two versions of the intervention in a large, non-selected sample of nursing home residents. This is an example that passed all phases of the MRC framework.

Considering the complexity of the intervention programs, we conducted a comprehensive process evaluation parallel to the cRCT as recommended by Craig et al. (2013). A process evaluation is essential to explore the implementation of the intervention and the change in processes as well as to provide insights if interventions were less effective than expected (Craig et al., 2013; Grant et al., 2013). We planned the process evaluation based on the framework for designing process evaluations of cRCTs (Grant et al., 2013). Key aspects of the framework are as follows: recruitment, delivery to and response of clusters and individuals, maintenance, unintended consequences, and context.

3 | THE STUDY

3.1 | Aims

To evaluate the implementation of two versions of a guideline-based, multicomponent intervention program to reduce PR in nursing homes. Based on the results of the trial, we also aimed to identify possible factors which might explain the ineffectiveness of the interventions.

TABLE 1 Components and methods of process evaluation

Aspects	Methods	Measurement point t_0	t_1	t_2
Recruitment procedure and drop-out	Protocol/region	x	x	x
Attitudes and knowledge towards PR use	Questionnaire (10% nurses/cluster; intervention group 1, intervention group 2, and control group)	x	x	x
Organizational culture	Questionnaire (D-OCAI) (1 leader and 10% nurses/cluster; intervention group 1, intervention group 2, and control group)	x		x
Implementation of the intervention (fidelity)	Structured documentation of each educational session (Trainer/educational session)	x		
Evaluation of the training program (attitudes, knowledge, satisfaction)	Questionnaire (all participants of educational program; intervention group 1 and intervention group 2)	x		
Evaluation of the structured support of key nurses during first 3 months (content of conversations, barriers/facilitators, and frequency/intensity of supervision)	Structured documentation of all key nurses' contacts and conversations (study nurses/study centre)	x		
Description of crucial structure and process-related factors on cluster level and changes during study period (e.g., regulations for approaching challenging behaviour of residents with dementia, specific strategies to reduce PR)	Short survey (1 leader/cluster; intervention group 1, intervention group 2, and control group)	x	x	x
Barriers and facilitators	Focus groups (8–12 key nurses; intervention group 1 and intervention group 2/region)			x
	Semi-structured interviews (1 leader/cluster; intervention group 1 and intervention group 2)			x
Awareness of the intervention	Focus groups (8–12 relatives, legal guardians, members of the board of residents; intervention group 1 and intervention group 2/region)		x	x
	Short survey (all key nurses and 3 randomly selected nurses/cluster; intervention group 1 and intervention group 2)			x
Attitudes of nurses towards the intervention	Focus groups (1 nurse/cluster; intervention group 1, intervention group 2/region)			x

Abbreviations: D-OCAI, German version of the "Organizational Culture Assessment Instrument" derived from the "Competing Values Framework"; PR, Physical restraint.

Measurement points; t_0 = baseline; t_1 = after 6 months; t_2 = after 12 months.

3.2 | Design

The process evaluation used a convergent mixed methods design (Creswell & Plano Clark, 2018). Various qualitative and quantitative process data on cluster and individual level were assessed alongside a three-arm cRCT with equal emphasis on qualitative and quantitative methods (Abraham et al., 2015). This process evaluation was conducted between February 2015-February 2017.

3.3 | Interventions

A detailed description of the interventions has been published elsewhere (Abraham et al., 2019). In summary, intervention group 1 received an updated version of the original guideline-based intervention comprising a training for key nurses (multipliers; 1.5 days comprising information about PR reduction and workshops on strategies to reduce PR including case discussions and best-practice examples) and 3 months structured support by the research team, a 90-min information session about PR reduction for all nurses and the distribution of a policy statement from nursing home leaders supporting a least-restraint policy. In addition, the nursing homes received printed study material. The main messages of the evidence-based guideline were the apparent lack of evidence for the effectiveness and safety of PR, the need for individual risk-specific interventions rather than using PR, and the implementation of least-restraint policies. The guideline's recommendations on the avoidance of PR are shown in Table S1. Intervention group 2 received the concise intervention program without the information session for all nurses but with an additional train-the-trainer module for key nurses to enable the delivery of the information session to the nursing staff. The control group received optimized usual care (provision of printed study material).

3.4 | Sample/Participants

All participants were recruited from the nursing homes included in this study. Target groups for the process evaluation were all nurses that attended the information session, key nurses, and leaders (directors of nursing homes and nursing managers), as well as residents' relatives and representatives. For the focus groups, we recruited convenience samples of 8–12 participants per group, no further inclusion or exclusion criteria were applied. We also randomly selected a subgroup of 10% nurses per cluster for a written survey at all three data collection times (baseline, after 6, and after 12 months). After the 12 months' follow-up, we conducted structured interviews with all leaders of both intervention groups. Furthermore, all key nurses and three randomly selected nurses from each intervention cluster were recruited for a short survey.

3.5 | Data collection

An overview about methods, participants, and time points is presented in Table 1.

The recruitment procedure, reasons for non-participation, and dropouts were documented on a cluster level by the study coordinators at each study centre. Crucial structure and process-related information (e.g., change in staffing levels, restraint policies) were collected for participating nursing homes at baseline, after 6, and after 12 months using a short survey. Organizational culture was assessed at baseline and after 12 months in a random sample of 10% of nurses and one leader per cluster, using the German version of the "Organizational Culture Assessment Instrument" (D-OCAI; Strack, 2012). The D-OCAI comprises four components (dominant characteristics, organizational coherence, dealing with the employees, and success criteria), each with four items rated on a 5-point scale.

Implementation fidelity was determined by structured documentation of the delivery of all intervention components, for example, for each educational session and for the support of the key nurses during the first 3 months. Attitudes and experiences of different target groups regarding the adoption of the intervention were collected in both intervention groups through separate focus groups each with: (a) key nurses (seven focus groups); (b) nurses (two focus groups); and (c) residents' relatives, legal guardians, and members of the board of residents (seven focus groups). Focus groups were chaired by researchers with a Master of Nursing degree from the four study centres. A flexible interview guide was used focusing on the experiences with the role of the key nurses, experiences with, and barriers and facilitators of the interventions' implementation. Semi-structured interviews were conducted with key nurses and one leader per cluster after 12 months. We used a flexible interview guide with open questions addressing the experiences, additional strains, and unintended consequences of the interventions' implementation. All interview guides are available from the authors on request. Focus groups and semi-structured interviews were audio recorded.

Knowledge and attitudes concerning PR use were assessed by a self-developed standardized questionnaire based on a previously applied questionnaire (Köpke et al., 2012) in a randomly chosen subgroup of 10% nurses per cluster at all three data collection times. Attitude was assessed using the theory of planned behaviour (TPB) (Ajzen, 1991) with 11 items deriving from three concepts. The first TPB concept is the "attitude towards the behavior", which refers to the degree to which performance of the behaviour, that is, the use of PR, is appraised positively or negatively. The second concept "subjective norm" describes the perceived social pressure, for instance, by colleagues, to perform or not perform a behaviour. The third concept "perceived behavioral control" refers to the ease or difficulty to conduct a certain behaviour, that is, the avoidance of PR (Ajzen, 1991). The items were rated using 4-point Likert scales (1 = strong disagreement - 4 = strong agreement), lower scores indicating more negative attitudes towards PR use. Two of the eleven items are formulated positively and were inverted for the analysis. For all three TBP concepts, mean values were calculated. Two items were not included in the calculation of the total mean score ("I would need the support of my nursing home manager to avoid PR" and "The opinion of my colleagues is important to me") because they were too unspecific in relation to the overall concept. All participants of the educational program also completed this questionnaire and an additional questionnaire on satisfaction with the educational program.

Awareness of the intervention was assessed by a short survey with three randomly selected nurses from each cluster in both intervention groups. Information about the activities of the key nurses was collected in the 3 months' structured support and in the interviews at follow-up.

3.6 | Ethical considerations

The Ethics Committees of the University of Lübeck (No. 14-251, January 2015) and the Martin Luther University Halle-Wittenberg (No. 2015-02, March 2015) approved the process evaluation as a part of the cRCT (Abraham et al., 2019). Participants of written surveys gave their consent by returning the questionnaires. Written informed consent was obtained from all the participants in the individual interviews and focus groups.

3.7 | Data analysis

Audio recordings of all interviews and focus groups were transcribed verbatim according to the transcription rules (Dresing & Pehl, 2013) and analysed using qualitative content analysis (Mayring, 2014). Initially, a set of preliminary categories derived from the research question and the interview guide were applied to each interview and inductively redefined during the coding process by two independent researchers (BBH, RK). Subsequently,

TABLE 2 Knowledge of participants after educational program

	Nurses (*N* = 662)	Key nurses (*N* = 153)
The aim of the program was to impart that…		
… PR should be avoided as much as possible	96.8% (*N* = 629)	99.3% (*N* = 151)
… Sophisticated measures are necessary to avoid PR	40.2% (*N* = 250)	21.1% (*N* = 31)
… Too many PR are used in nursing homes	74.4% (*N* = 472)	77.7% (*N* = 115)
… Nurses can avoid physical restraint use if they find individual solutions	97.2% (*N* = 635)	97.3% (*N* = 146)
… PR have a considerable risk potential	86.3% (*N* = 549)	87.7% (*N* = 128)

Abbreviation: PR, physical restraint.

the researchers discussed the categories regarding clarity, comprehensiveness, and coherence. One researcher (BBH) coded all interviews using these categories and discussed the results with two other members of the study team (RM, JA). The final categories were described by paraphrasing, generalizing, and reducing the coded text passages. All quantitative data were analysed descriptively.

The in-depth analysis, aimed at identifying factors or characteristics that might explain the lack of effectiveness of both interventions, was conducted by contrasting responder clusters and non-responder clusters regarding the intervention goal and primary outcome. Responders/non-responders were defined as clusters with a relative reduction/increase in PR of about 50% and an absolute reduction/increase of at least 10% (in case of a baseline prevalence of less than 10%, the absolute reduction or increase was set at 5%). We included various process data in this analysis, for example, all information collected from key nurses, the structural changes and modifications, and the interviews with leaders after 12 months.

3.8 | Validity and reliability/Rigor

To ensure credibility and dependability of qualitative analyses, coding was verified by two members of the study team. Transferability was supported by sampling different relevant target groups regarding PR use and implementation of the study interventions. Furthermore, focus groups and individual interviews were conducted in all four study regions.

The instruments for collection of quantitative data were pilot tested in two nursing homes prior to the start of the study. Furthermore, rigor in the collection of quantitative data was promoted by using structured protocols. Organizational culture was assessed with the validated questionnaire (D-OCAI; Strack, 2012). Attitudes, knowledge, and satisfaction were assessed using a self-developed questionnaire based on a previously applied questionnaire with proven feasibility and acceptability (Köpke et al., 2012).

4 | RESULTS

4.1 | Recruitment procedure

Clusters were recruited between February and November 2015. Overall, 503 nursing homes in four regions were invited to participate (Lübeck: *N* = 101, Hamburg: *N* = 171, Witten: *N* = 96, Halle (Saale): *N* = 135). Despite great efforts, Hamburg (*N* = 23), Halle (Saale) (*N* = 29), and Witten (*N* = 29) could not recruit the pre-planned number of 30 clusters each. The study region in Lübeck instead recruited 39 clusters, resulting in a total of 120 nursing homes as planned.

Main reasons for non-participation were lack of time, structural changes in nursing homes, and participation in other projects or studies. There were no differences between characteristics of the non-participating nursing homes in the four study regions. Information about the characteristics of the nursing homes and residents has been published elsewhere (Abraham et al., 2019).

4.2 | Delivery to clusters and response of clusters and individuals

Both interventions were delivered as planned; a detailed description has been published elsewhere (Abraham et al., 2019).

4.2.1 | Knowledge of participants after educational program

Key nurses and other nurses received a questionnaire to evaluate the educational program. Most of the participants made correct statements regarding the content and aim of the educational program (Table 2). About two thirds of participants also agreed that too many PR are used in nursing homes and most were convinced that no sophisticated measures (e.g., permanent observation, one-to-one care) are necessary if PR are to be avoided (which is the correct answer).

4.2.2 | Participants' satisfaction with educational program

In general, participants were satisfied with the educational program (see Table 3). Most of the nurses and key nurses judged the timeframe, comprehensibility of the content, and educational level of the program as appropriate, and on the whole agreed that the chosen methods were suitable.

4.2.3 | Attitudes of participants towards PR use after educational program

Participants' attitudes towards PR use were evaluated at baseline, after 6, and after 12 months using a standardized questionnaire. Overall, the key nurses showed more negative attitudes towards PR use compared with the nurses who attended the information session. Figure 1 shows all 11 items with assignment to the TPB concepts. We found differences for some items between the rating by key nurses and other nurses (e.g., "Without more nursing staff, there is no point in discussing the removal of PR").

We also found differences between key nurses and nurses in the total mean scores in two concepts of the instrument ("attitudes towards the behavior" and "perceived behavioral control"), indicating more positive attitudes of key nurses regarding the goal of the intervention (to avoid or reduce PR) and a higher perceived behavioural control to put this goal into clinical practice (see Figure 2).

4.2.4 | Attitudes of nursing staff towards PR use during study period

We also assessed nurses' attitudes towards PR use in an independent, randomly selected 10% subsample of nurses per cluster during the study period. Figure 3 shows the total mean score of the three TPB concepts for the three study groups and the different measurement points. In general, nurses in intervention group 1 showed a more negative attitude towards PR use compared with nurses in the other study groups. The total mean scores of the concepts "attitudes towards the behavior" and "perceived behavioral control" decreased at each measurement point in all the study groups, whereas the total mean score for the concept "subjective norm" at each measurement point was relatively similar between the groups.

TABLE 3 Participants' satisfaction with educational program (single 90-min information session for all of the nurses and intensive full-day training for key nurses)

	Nurses ($N = 662$)	Key nurses ($N = 153$)
Adequacy of timeframe		
High	83.8% ($N = 539$)	96.1% ($N = 147$)
Low	16.2% ($N = 105$)	3.9% ($N = 6$)
Adequacy of method		
High	91.1% ($N = 579$)	94.2% ($N = 143$)
Low	8.9% ($N = 57$)	5.8% ($N = 10$)
Comprehensibility of content		
High	93.8% ($N = 606$)	96.1% ($N = 146$)
Low	6.2% ($N = 40$)	3.9% ($N = 7$)
Educational level of the program		
Too low	7.3% ($N = 47$)	3.3% ($N = 5$)
Just right	77.1% ($N = 496$)	83.7% ($N = 128$)
Too high	15.6% ($N = 100$)	13.0% ($N = 20$)

4.2.5 | Activities of key nurses

Table 4 shows all activities regarding PR reduction implemented by the key nurses throughout the 3 months' support period documented with structured protocols. Conversations with colleagues and relatives were most frequently applied. More key nurses in intervention group 2 in comparison to intervention group 1 reported that they offered information sessions for colleagues, that alternatives for PR have been acquired more often, and that the existing PR were currently being reviewed.

In addition, the activities of key nurses were assessed in a short survey at the end of the study (see Table 5). Most key nurses stated that they conducted case conferences (intervention group 1:72.4%, intervention group 2:81.8%) and adapted internal activities to avoid PR (intervention group 1:82.7%, intervention group 2:65.9%). More than half of the key nurses (intervention group 1:58.6%, intervention group 2:61.4%) mentioned conversations with their leaders as one way to improve structures and processes. A smaller proportion of key nurses reported that they organized and implemented training sessions for colleagues (intervention group 1:41.4%, intervention group 2:43.2%).

4.2.6 | Role of the key nurses

Almost all of the key nurses (intervention group 1: 89.6% ($N = 26$), intervention group 2: 95.4% ($N = 42$)) stated during the 3 months' structured support that they were satisfied with their role as key nurse. In general, they indicated that they usually had an advisory function. They were mainly contacted or consulted in complex cases of PR use or for conversations with relatives and colleagues, meetings, and new admissions of residents. They often attended case conferences to solve problems regarding PR use. Most of the key nurses indicated that they had enough scope for action (e.g., they were released from other responsibilities by leaders), but some mentioned that they had not enough time for their role as key nurses.

The statements made by leaders at the final semi-structured interviews are largely consistent with those of the key nurses. In addition, the leaders stated that key nurses were widely accepted by the nursing staff.

4.2.7 | Use of materials

The use of materials was assessed during the 3 months' structured support of key nurses and at the final semi-structured interviews with

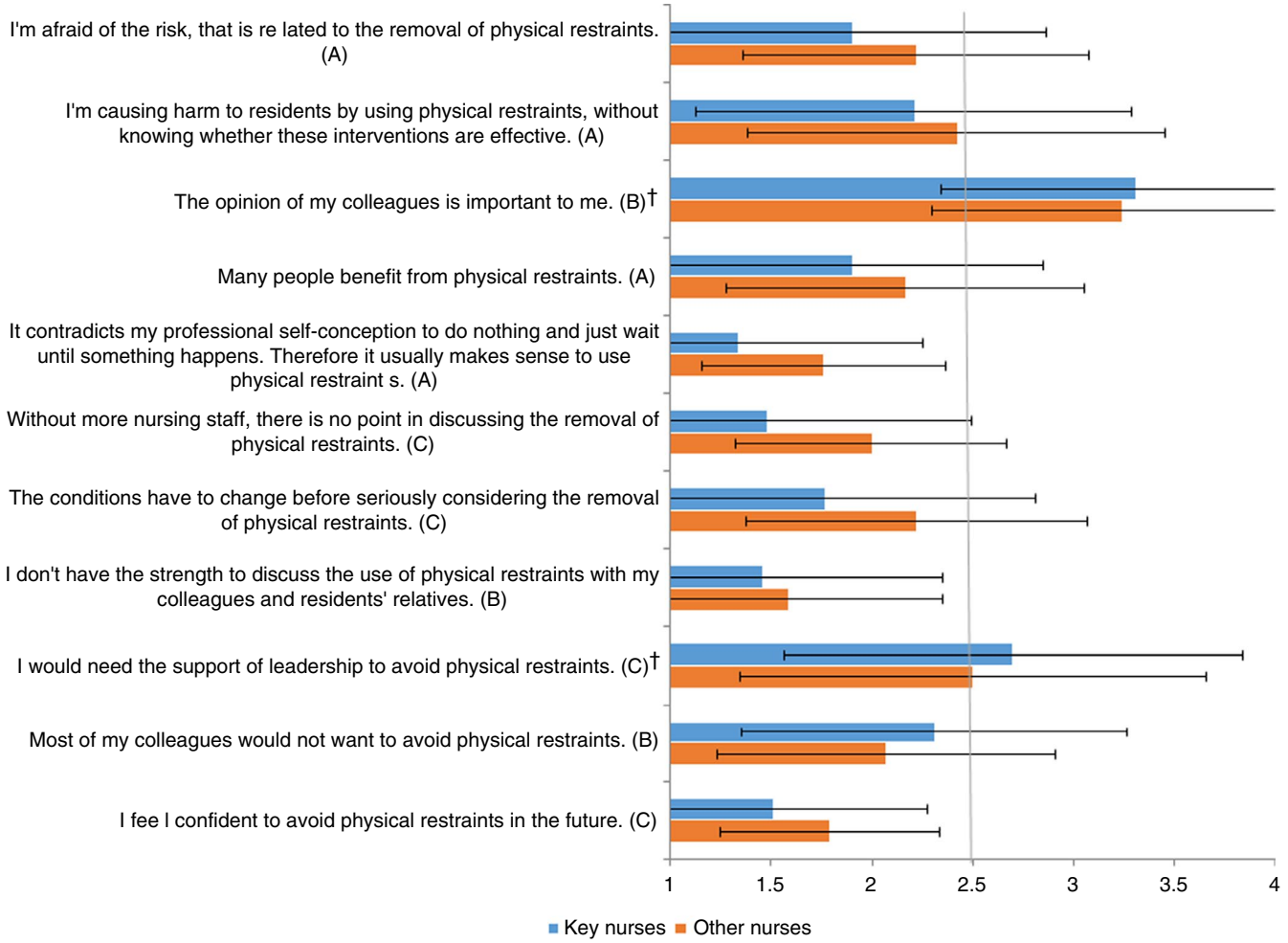

FIGURE 1 Mean score and standard deviation for single items of attitudes of participants towards physical restraint use after the educational program (A = attitudes towards the behavior, B = subjective norm, C = perceived behavioral control; 1 = strongest disagreement, 4 = strongest agreement; †item formulated positively and inverted for the analysis) [Colour figure can be viewed at wileyonlinelibrary.com]

leaders. Overall, the key nurses and leaders judged the study material positively. The information material was considered as useful and informative: they reported that information material was actively distributed and frequently used in admission interviews, at the induction of new nurses or during conversations with relatives. Additionally, there was a high demand for brochures in the residential units. Key nurses and leaders also predominantly judged the image material as being positive.

4.2.8 | Structural changes/modifications

Structural changes and modifications on cluster level during the study period were assessed by short surveys with leaders. There were no clear differences between study groups regarding architectural modifications, introduction of specific strategies for addressing challenging behaviour of residents with dementia, new regulations or policies for PR use, or purchase of new equipment. For instance, the control group acquired a comparable number of technical aids as alternatives to PR (e.g., low beds, walking aids) or new regulations/procedures for dealing with PR (e.g., standard of care, specific documentation forms).

4.2.9 | Barriers of PR reduction

An overview about the barriers of PR reduction is provided in Table 6, a detailed description has been published elsewhere (Abraham et al., 2019).

4.2.10 | Perspectives and attitudes of nursing home residents' advocates

After 6 and 12 months, perspectives and attitudes of residents' advocates were evaluated through focus groups. In every group of residents' advocates, that is, relatives, legal guardians, and members of the board of residents, we found a lack of knowledge and uncritical attitudes towards PR. Additionally, residents' advocates judged the use of PR to prevent falls and to control challenging behaviour

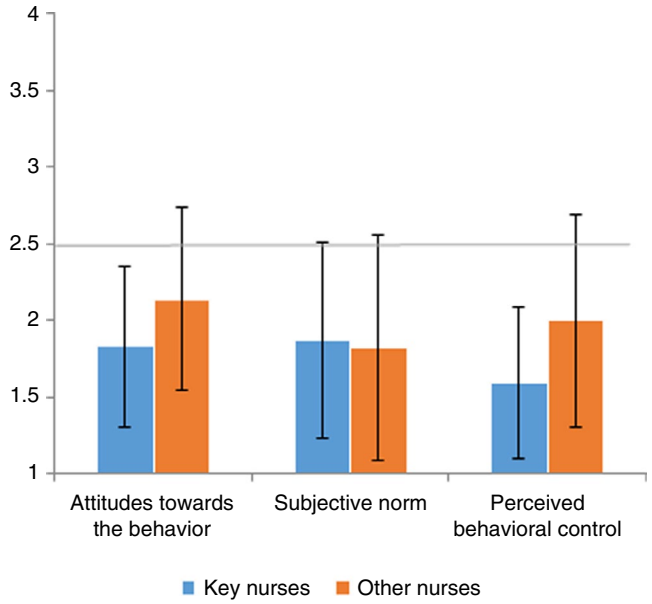

FIGURE 2 Total mean score and standard deviation for the three constructs of the theory of planned behavior of participants after educational program (1 = strongest disagreement, 4 = strongest agreement) [Colour figure can be viewed at wileyonlinelibrary.com]

as being necessary. Detailed results have been published elsewhere (Nordhausen et al., 2019).

4.3 | Maintenance of processes

At the end of the study, a short survey was conducted with a random sample of nursing staff who had been employed in the nursing home since baseline (intervention group 1: $N = 67$, intervention group 2: $N = 59$). Nursing staff mostly stated (intervention group 1: 73.1%, intervention group 2: 81.3%) that the intervention had been successfully implemented. They perceived a change in attitudes and thinking of nurses, increased awareness and knowledge about PR due to the educational sessions, increased safety for residents, and an increased use of alternatives for PR. In addition, most nurses (intervention group 1: 80.6%, intervention group 2: 86.4%) expected that the implemented interventions would have an impact even after the completion of the study. They were mostly positive about the interventions' goal to avoid PR, described peer support and peer control within the nursing team, and a change in the culture of PR use in their nursing homes. However, this was not the experience in all the clusters.

4.4 | Context

4.4.1 | Organizational culture

Analysis of the organizational culture in a 10% random sample of nurses and one leader per cluster using the standardized questionnaire D-OCAI (Strack, 2012) revealed no differences between study groups and there were no changes during study period (data not shown).

4.5 | Additional analysis

The additional analysis revealed no clear differences between responding and non-responding nursing homes. The number of responding and non-responding clusters was comparable in intervention group 1 and intervention group 2.

The degree of the interventions' implementation was similar in both intervention groups, we found no differences in structural and conceptual issues and the described barriers and facilitators were comparable. Key nurses in the non-responding clusters did not describe more or stronger barriers towards the interventions' implementation and the key nurses in the responding clusters also described several barriers. Summing up, we did not find characteristics or process-related issues that were likely to explain the pronounced variation between clusters with large reduction and clusters without a change or even an increase in PR.

5 | DISCUSSION

The process evaluation of the IMPRINT study revealed that both versions of a guideline-based complex intervention aimed at reducing the use of PR in nursing homes were predominantly implemented as planned and we found no deviations from the protocol in the dose delivered to the clusters. Only a small number of key nurses asked for additional advice. Regarding the dose received, we found differences between the study regions in the number of key nurses attending the training. All the nursing home leaders were recommended to have a minimal number of two key nurses per cluster and this was fulfilled for most clusters. As in our former study (Köpke et al., 2012), the training for key nurses resulted in a better knowledge of the facts and myths about PR use. Key nurses' satisfaction with the training session and with their role as a key nurse was high throughout both intervention groups. Compared with the nursing staff attending the brief information session, key nurses' attitudes towards using PR were more negative, indicating that the intervention goal (changing nurses' attitudes) was more successfully reached by the intensive training for key nurses compared with the brief information session for all the nurses. This is confirmed by the barrier described by key nurses that some of the nursing staff still believed that PR are adequate measures to prevent falls. Most key nurses and leaders judged the information material to be beneficial and used them in daily practice.

With regard to the maintenance of the change processes, the assessment of nurses' attitudes towards PR use indicated less positive attitudes after 6 months in two of three concepts ("attitudes towards the behavior" and "perceived behavioral control") and remained stable after 12 months. We found similar changes in the control group, albeit

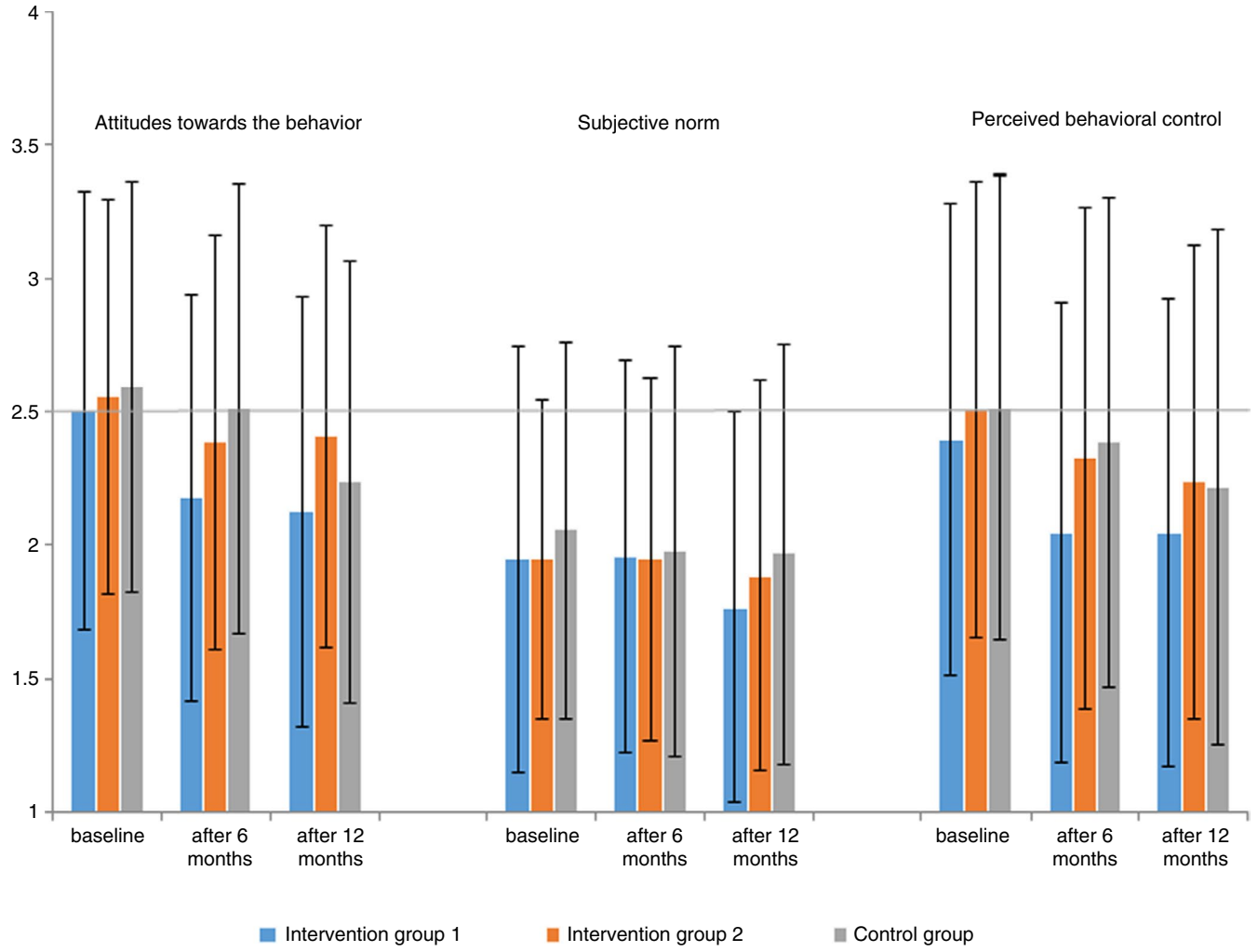

FIGURE 3 Total mean scores and standard deviation for the three constructs of the theory of planned behavior of nursing staff towards physical restraint use during study period (1 = strongest disagreement, 4 = strongest agreement) [Colour figure can be viewed at wileyonlinelibrary.com]

to a lesser extent, indicating that a Hawthorne effect might have occurred. Some key nurses did not perceive a cultural change towards a least-restraint culture or described that nursing staff discontinued reducing PR. This indicates that changes in (key) nurses' attitudes did not affect the clinical practice as expected in all the clusters.

Several studies have been conducted investigating programs to reduce PR use (Gulpers et al., 2011; Möhler et al., 2012) but very few studies conducted a detailed process evaluation. Apart from the former study evaluating our intervention (Köpke et al., 2012), only the EXBELT study (Bleijlevens et al., 2013), investigating a belt reduction program in psychogeriatric nursing homes, reported process data. In the line with our previous study (Köpke et al., 2012) and other studies (e.g., Haut et al., 2010; Moore & Haralambous, 2007), we identified uncritical attitudes of relatives, legal guardians, and residents' representatives regarding PR use as an important barrier. Key nurses described challenges in convincing relatives of some residents regarding PR reduction. In contrast, two thirds of the relatives in the EXBELT study were satisfied with the withdrawal of belt restraints (Bleijlevens et al., 2013). However, belt restraints are the most restrictive type of PR and relatives were strongly involved in the decision-making processes, which might lead to a more positive attitude of relatives towards restraint reduction. The opinion that PR are effective to prevent falls was also prevalent with some of the nursing staff in our study, irrespective of the attempts to address this topic in our intervention and has also been described in other studies (Goethals et al., 2012; Möhler & Meyer, 2014).

The intervention implemented in intervention group 1 had been proven effective in our former cRCT and the concise intervention implemented in intervention group 2 was revised according to the results of the process evaluation and the experiences collected in this study (Köpke et al., 2012). Despite the predominantly successful implementation and the positive experiences described by the key nurses, nurses, and leaders, both versions of the intervention did not significantly reduce the use of PR compared with the control group. One reason was the pronounced difference of the effects in the different regions. We found nearly no reduction or even an increase in PR use in about one third of the 79 intervention clusters after 12 months. Other clusters showed a stronger reduction. These differences led to the small effect of both interventions (Abraham et al., 2019).

TABLE 4 Activities of key nurses during the 3 months' support

Task[a]	Intervention group 1 (*N* = 84)	Intervention group 2 (*N* = 73)
Conversations with colleagues	*N* = 41	*N* = 44
Conversations with relatives	*N* = 29	*N* = 31
Information sessions for colleagues	*N* = 6	*N* = 18
Review of existing PR	*N* = 8	*N* = 13
Case conferences	*N* = 12	*N* = 11
Acquirement of alternatives (e.g., low beds, fall mats, sectional bed rails)	*N* = 2	*N* = 7
Conversations with residents	*N* = 7	*N* = 4
Other (e.g., change in regulations)	*N* = 8	*N* = 5

Abbreviation: PR, physical restraint.

[a]Multiple choices possible.

Our in-depth analysis of nursing homes with a pronounced reduction in PR (responders) and those with no reduction or even an increase in PR (non-responders) did not reveal any clear explanations for the different response. Changing an institutional policy and culture is a difficult task that affects different groups of stakeholders and hierarchies as well as individual and organizational behaviours. Barriers towards the implementation of a least restraint policy might occur on each level and behaviour. Accordingly, a meta-synthesis on barriers of PR reduction in long-term care identified barriers on both individual and institutional level (Kong et al., 2017). Different strategies seem to be needed for different institutions; however, we did not find characteristics to determine institutions that respond to our interventional approach. More research is needed to identify predictive characteristics and assessments.

Another explanation for the partly small effect might be the lower PR baseline prevalence, compared with our previous study (Köpke et al., 2012). In recent years, there was a general tendency towards less PR use in German nursing homes (Feng et al., 2009; Foebel et al., 2016; Medical Advisory Service of the German Social Health Insurance (MDS), 2017). This is also consistent with the results of another cRCT from Norway (Testad et al., 2016), although this study has to be interpreted with caution due to its methodological limitations as, for example, unclear randomization and allocation concealment procedures. However, there was a more significant reduction in control group (from 18.4% to 8.8%; $p < .001$). However, it might be more difficult to reach a substantial reduction if the use of PR declined in this population and therefore other approaches such as governmental policies are needed to sustainably change PR practice and reduce regional disparities in nursing homes (Abraham et al., 2019).

5.1 | Limitations

This process evaluation was planned and conducted according to established frameworks (Craig et al., 2008; Grant et al., 2013), using qualitative and quantitative methods on both cluster and individual levels. We collected data from the target groups directly addressed in the interventions (i.e., key nurses and nurses attending the educational components), from nursing home leaders (who were expected to have a strong influence on contextual factors and resources available for the behavioural and organizational changes), and from other stakeholders (e.g., residents' representatives and families) but with exception of the residents. A pre-planned nested case study (Abraham et al., 2015) was not conducted since the recruitment of residents and their family members was not successful. We also collected data on contextual aspects, for example, the organizational culture and information about changes regarding equipment that can be used as an alternative to PR. We collected comprehensive data to describe the degree of implementation (i.e., the dose delivered and the dose received by the target groups) and to some extent the change processes, but we were unable to monitor the success of the intended organizational change in all of the clusters and for the

TABLE 5 Activities of key nurses during the study period

Task[a]	Intervention group 1 (*N* = 29)	Intervention group 2 (*N* = 44)
Case conferences	72.4% (*N* = 21)	81.8% (*N* = 36)
Adaptation of internal activities to avoid PR	82.7% (*N* = 24)	65.9% (*N* = 29)
Conversations with leaders to improve structures and processes	58.6% (*N* = 17)	61.4% (*N* = 27)
Organization and/or implementation of training for colleagues	41.4% (*N* = 12)	43.2% (*N* = 19)
Other (e.g., conversation with relatives or colleagues)	41.4% (*N* = 12)	61.3% (*N* = 27)

Abbreviation: PR, Physical restraint.

[a]Multiple choices possible.

TABLE 6 Barriers of PR reduction from the perspective of nursing home leaders, key nurses, and nursing staff

Barriers	Described by: Nursing home leaders	Key nurses	Nursing staff
Leadership			
Leaders' negative attitudes regarding PR reduction		x	
Role and function of key nurses			
Lack of support from nursing home leaders		x	
Negative experiences of restraint reduction	x	x	
Low reputation of key nurses by nursing staff	x		
Limited resources, e.g., time constraints	x	x	
Clinical practice			
Negative experiences regarding PR reduction	x	x	
Lack of knowledge of nursing staff (e.g., nursing staff partly believed that PR are effective in preventing falls)	x	x	
Lack of interest and motivation to change daily routines (nursing staff)	x	x	x
Different attitudes towards PR of newly employed or temporary staff (e.g., based on different cultural backgrounds or former restraint policies)	x		
Uncritical attitudes of relatives and legal guardians towards PR		x	x
Institutional level and structures			
Resignation of key nurses from the nursing home	x		
Simultaneous structural changes (e.g., implementation of electronic nursing documentation)	x		
Staff fluctuation	x		
Lack of care equipment, e.g., low beds	x	x	x
Inadequate resources/staffing to provide care that meets the specific needs of residents with dementia			x

Abbreviation: PR, Physical restraint.

complete study period. We did not systematically record the number of key nurses who left the nursing homes before the end of the study; however, in all the clusters at least one trained key nurse was available for the complete study period. It was also not possible to quantify the information about the processes and activities initiated by the key nurses (e.g., the number of information sessions delivered to the nursing staff) because the key nurses did not complete the documentation diaries as planned (Abraham et al., 2015).

6 | CONCLUSION

The two versions of a guideline-based complex intervention for preventing PR in nursing homes were implemented as planned and the response was generally positive, but the interventions' goal to significantly change nurses' attitudes and practice towards a least-restraint policy was not achieved in the complete nursing staff in all the clusters. We found pronounced heterogeneity in the effects of the intervention but not in the degree of implementation. This indicates that for some nursing homes other approaches are needed to sustainably change the practice regarding PR use, for example, legal or governmental policies. However, we were not able to identify characteristics predicting the responsiveness of nursing homes towards our guideline-based approach.

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CONFLICT OF INTEREST

No conflict of interest has been declared by the authors.

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 centre in Lübeck and Hamburg. GM was the responsible coordinator of the study centre in Halle (Saale) and Witten. SK was responsible for implementation of the interventions and data collection in Lübeck, JA and GM in Halle (Saale), RK in Hamburg, and RM in Witten. BBH performed the analysis of the qualitative process data. JA, MB, and RM drafted the manuscript. All authors commented on the manuscript drafts and read and approved the final manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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