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Prevention of physical restraints in the acute care setting (PROTECT): study protocol for a cluster-randomised controlled pilot study

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ABSTRACT

Introduction Physical restraints (PR) are regularly used in acute care settings, although evidence for their effectiveness and safety (eg, for prevention of falls) is lacking. Their use is associated with adverse events, such as decreased mobility and injuries for patients. We developed a complex intervention to prevent PR in acute care settings according to the UK Medical Research Council Framework, and investigated the feasibility. The intervention comprised the qualification of key nurses as multipliers and a short interprofessional information session. The intervention has proven to be feasible. It also became apparent that further development of the intervention and the study procedures is necessary. Therefore, this study aims to refine and pilot the complex intervention. Furthermore, the objective of this pilot study is to improve study procedures.

Methods and analysis In a preparatory phase, we will conduct focus groups and individual interviews with the target groups to explore the possibilities for adaption of the intervention and implementation strategies. Subsequently, a cluster-randomised controlled trial with a 6-month follow-up period will be conducted. It is planned to recruit eight general hospitals in Germany (area of Halle (Saale) and Leipzig) with 28 wards and 924 patients per observation period (2772 overall). Primary outcome is the proportion of patients with at least one PR after 6 months. Data will be collected by direct observation over a period of seven consecutive days and three times a day. Secondary outcomes are falls, interruptions in therapy and prescription of psychotropic medication. A comprehensive process evaluation will accompany the study.

Ethics and dissemination The Ethics committee of the Medical Faculty of the University of Halle (Saale) approved the study protocol. Results will be published in a peer-reviewed journal and presented at conferences. Study information and additional material will be freely available on an already existing website.

Trial registration number DRKS00027989.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The development of the complex intervention aimed to prevent physical restraints comprehensively follows the golden standard recommendations of the Medical Research Council Framework, also taking the involvement of target groups and stakeholders into account.
⇒ As a data collection method direct observation (which is the most valid methodological approach) throughout 1 week per measurement point will be conducted.
⇒ A comprehensive process evaluation will be conducted alongside the cluster-randomised controlled trial.
⇒ The generalisability of the study is limited as intensive care units, emergency departments, paediatric and psychiatric wards will not be included to this study.
⇒ Due to the lack of data for reasonable assumptions, no sample size calculation was performed for this pilot study. However, the planned sample of 8 hospitals and 28 wards is rather large compared with former studies in this field.

INTRODUCTION

Physical restraints (PR) such as bedrails, belts in beds or chairs and geriatric chairs with fixed tables are commonly used in general hospital settings in many countries, despite their unknown effectiveness and potential risks for harm.[1–3] Prevalence rates of PR differ widely among different hospital settings, ranging from 0% to 50%, and there is evidence for pronounced variation of prevalence rates between comparable wards across acute care institutions.[1 2 4 5] In Germany, two cross-sectional surveys revealed a prevalence of 9.3% and 11.8%, respectively.[1 6] Important risk factors for PR use in acute care settings are higher age, care dependency, increased risk of falling and cognitive impairment, that is, dementia or delirium.[2 3 7–10] Accordingly, the main reasons for using PR are safety issues, for example, to prevent falls and fall-related injuries or to ensure safe medical treatment, often in patients with dementia or delirium.[11–13] However, systematic reviews investigating the effects of PR for reducing falls and fall-related injuries in acute care settings and based on observational studies

with several methodological limitations found no or inconsistent results.[14 15]

The use of PR is associated with several adverse effects, for example, increased feelings of fear, anger and discomfort, decreased mobility, increased risk of pressure ulcers and incontinence and serious injuries.[11 12 16–23] These adverse effects may have a negative impact on patients' recovery and rehabilitation and may also increase the challenging behaviour of people with dementia.[24 25] Hence, guidelines and nurse organisations clearly recommend avoiding the use of PR in acute care settings.[26–29]

With regard to acute care settings, only a small number of studies with an appropriate study design evaluated the effectiveness of intervention programmes for preventing the use of PR. The systematic literature search for our current Cochrane Review[30] resulted in only two studies[21 31] with a randomised controlled trial design. Kwok and colleagues[31] investigated the use of pressure sensors in beds and chairs as alternatives to PR in two stroke units. Enns and colleagues[21] investigated a complex intervention comprising the training of multipliers (nursing leaders), education for physicians and unit nurses and the implementation of 'least restraint rounds' and found a non-significant reduction in the use of PR, while Kwok and colleagues[31] found no differences between groups. A prospective quasi-experimental trial in two rehabilitation hospitals by Lai and colleagues[32] investigated a programme consisting of two components (staff education and the setup of an interdisciplinary restraint reduction committee) and did not find a decrease of restraint rates. Apart from these studies, some others, mostly with a pre–post design, explored the feasibility and practicability of intervention programmes for reducing PR. The interventions comprised further training for specifically selected nurses in order to promote the implementation of a policy change in the hospitals. These pilot studies showed promising results regarding the avoidance of PR without an increase of adverse events, but also a lack of methodological rigour.[33]

In our previous feasibility study,[34] we developed a complex intervention programme for acute care according to the UK Medical Research Council (MRC) framework.[35] We tested the intervention programme (comprising, eg, qualification of selected nurses as multipliers and short interprofessional information sessions) for feasibility in two wards of a university hospital with mixed methods design.[34] Overall, the intervention was feasible and the participants considered the multiplier approach as suitable and practicable. Our study[34] also revealed the need to further develop the complex intervention, the implementation strategy and some study procedures. The method for collecting the PR data via routine documentation did not prove to be practicable since the validity of the documentation was unclear. Only a specific surgical and neurological ward was included and information about the feasibility of the intervention in internal, general surgical or geriatric wards is lacking. A pilot study in different types of wards in several hospitals remains to be conducted to increase the transferability of the intervention. In summary, a modelling of the intervention and an adjustment of study procedures in a pilot study is needed before the effectiveness can be evaluated in a cluster-randomised controlled trial (cRCT) according to the UK MRC framework.[36]

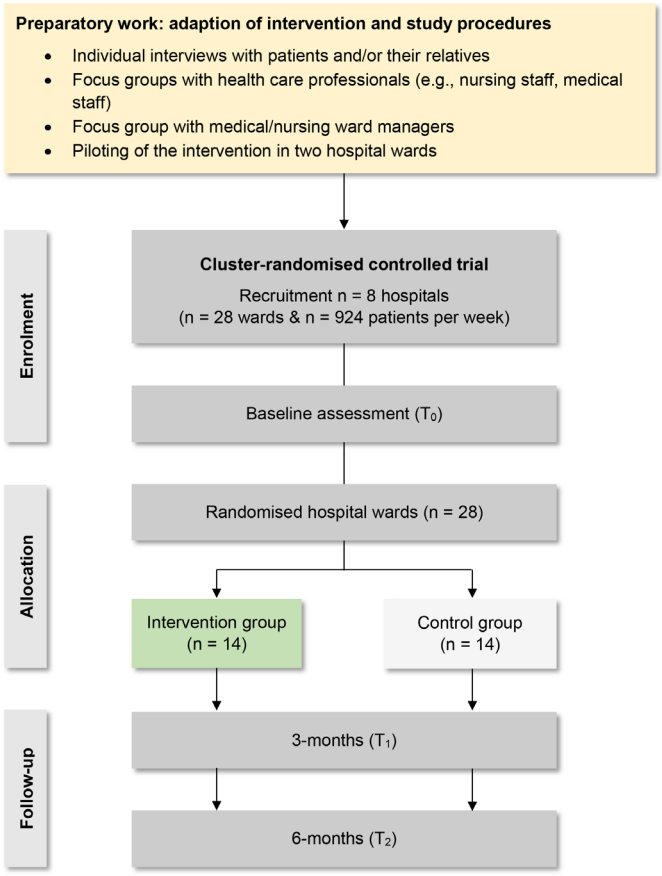

Figure 1 Flowchart of the pilot study including preparatory work and cluster-randomised controlled trial.

OBJECTIVES

In this study, we aim to refine and pilot our complex intervention[34] to prevent PR in acute care hospitals and to evaluate the intervention in a cRCT. Furthermore, the objective of this pilot study is to improve the study procedures (eg, recruitment strategy, data collection method) and collect data needed to determine a sample size in preparation of a future cRCT designed to evaluate the effectiveness of the intervention.

METHODS AND ANALYSIS

Study design

In the preparatory phase of the PROTECT study, the intervention will be redefined and improved. Subsequently, we will conduct a cRCT with two parallel groups and a 6-month follow-up comprising three measurement points (baseline, after 3 months, after 6 months) (see figure 1). A comprehensive process evaluation with quantitative

and qualitative methods will be carried out alongside the cRCT. The recruitment of hospitals started in April 2022. The study will be completed in summer 2023.

Preparatory work

In our previous study,[34] we identified important barriers regarding the implementation of the intervention and some study procedures. These aspects will be further explored in the preparatory phase before the cRCT starts. Focus groups and individual interviews will be conducted with the target population (eg, nurses, physicians, physiotherapists, nursing and medical ward managers, patients and their relatives). This aims to determine the possibilities needed for improvement of the intervention (eg, content of educational programmes, transferability to different departments, strategies for integration of other healthcare professionals), potentially suitable intervention components as well as implementation strategies. One focus group with participants from different healthcare professions will be conducted to get deeper insights in the interprofessional decision-making processes regarding PR use. Additionally, one focus group with nursing and medical ward managers will be conducted. Based on the results, the intervention and study procedures will be revised. The individual interviews with patients and/or their relatives are planned to get deeper insights into the experiences of being physically restrained. The results of these interviews will be considered in the educational session. Furthermore, we will explore the specific need of intervention components for this target group, for example, written information material including contents and design. Participants will be recruited from wards not being included in the main study. The adapted intervention programme and the instruments for data collection will be pretested. Therefore, two wards (not included in the cRCT) will be recruited to evaluate the feasibility of study procedures and materials. The intervention and study procedures will be adapted, if necessary.

Participants and recruitment

Inclusion and exclusion criteria

Cluster level: Clusters are defined as individual, independently operating wards or multiple, highly interconnected wards (departments) with common organisational structure and staff. Internal medicine, surgery, trauma surgery, neurology and general acute care hospital wards will be included. Emergency departments, intensive care units, paediatric wards and psychiatric wards will be excluded, since the rationale for and nature of PR use strongly differs from the targeted acute care settings in this study.

Individual level: All adult patients (18 years and older) who are being treated in the participating wards and present at the data collection period will be included. Patients who are primarily treated due to a psychiatric illness who are actually assigned to a psychiatric ward (regardless of the diagnosis) and paediatric patients who are actually assigned to a paediatric ward, but are treated on the study ward (eg, due to lack of available beds in other wards) will be excluded.

Recruitment of study centres

For the purpose of this pilot study, we plan to recruit eight hospitals in the catchment areas of Halle (Saale) and Leipzig (both Eastern Germany). The hospitals will be contacted in a random order selected from a publicly available online hospital register. The nursing directors of the hospitals will be invited to take part in the study via mail, email and a subsequent telephone call. The study will be presented personally on-site to nursing/medical directors or others designated by the facility. Nursing directors of each hospital will select the participating wards.

Intervention

Intervention group

The intervention programme will be based on the complex intervention developed in the previous feasibility study.[34] The intervention programme follows a multiplier approach and short interprofessional information sessions. The intervention programme will be adapted according to the results of the preparatory work, but the intensive training sessions for multipliers and the short interprofessional information sessions as described below will remain as main components.

The original programme comprised the following components:

- An *intensive training session* (3 hours) on the prevention of PR for key nurses (nominated by nursing ward managers; the key nurses were supposed to be registered nurses, otherwise no further requirements, eg, years of professional experience, were predefined) as multipliers with the following function: contact person dealing with all measures avoiding the use of PR (eg, for medical colleagues, relatives, legal guardians); coordination of all activities for a change in practice; support all stakeholders during decision-making regarding the use of PR; critical review of the PR used and development of an agenda with prevention strategies,
- *Short interprofessional information sessions* (45 min with the following target groups: nurses, medical staff, physiotherapists) on the prevention of PR. Content was definition of PR, lack of effectiveness, risks of using PR, legal aspects, strategies to avoid PR, patient-centred approaches in dealing with patients with challenging behaviour, prevention and management of delirium and prevention of falls,
- Regular *multidisciplinary audit and feedback sessions* (at least once per month) in practice conducted by the key nurses, nursing staff and medical staff (including self-assessment on the use of PR and discussion of challenging cases),
- *Structured informational discussions* conducted by the study team in order to involve leaders from different professions in implementing changes in practice.

The intervention in our current pilot study will be flexible, allowing tailoring for specific acute care settings and different structures of participating general hospitals (eg, in terms of time point and place, where the educational sessions will be conducted). The intensive training sessions and short interprofessional information sessions will be standardised based on a teaching concept. However, the training and short interprofessional information session will also be flexible to a certain degree depending on the respective needs of the participants in the different departments, for example, in terms of the scope of some topics or the case studies and specific strategies.

Control group

The control group will receive the standard care (care as usual) provided in the respective hospital wards. Apart from the experimental intervention, the control group and intervention group clusters will be treated equally.

Randomisation

The complex intervention targets the ward or department level of hospitals rather than individuals. Therefore, randomisation will be performed on a cluster level.

For the random assignment, computer-generated lists will be used, stratified by prevalence of PR (≤12% and >12%) with blocks of two or four clusters in random order. An independent external biometrician (BH) will generate the randomisation lists. The assignment of clusters will be conducted consecutively after completion of baseline measurements. An external independent researcher will inform the clusters about the group assignment via email and phone call.

Outcome measures and data collection

The primary outcome is the proportion of patients with at least one PR after 6 months. Data will be collected through direct observation at three measurement points: before randomisation (T_0), after 3 months (T_1) and after 6 months (T_2). To minimise bias due to daily patient flow the data will be collected over a period of 1 week. The observation will occur on seven consecutive days, three times each day, morning (08:30 to 10:30), noon (13:00 to 15:00) and evening (19:00 to 21:00). The direct observations at T_0 will be conducted by two researchers (JA and SG) and trained research assistants before randomisation, and by blinded trained research assistants at follow-up. All the data collectors will receive a comprehensive introduction in data collection procedures and will practice these procedures. All of them will be accompanied at first by experienced researchers before they conduct data collection on their own.

Physical restraint use will be documented during the observation using a standardised protocol. A patient will be considered to be a 'PR case', if at least one PR was documented during the observation period. If this PR or other types of PR are applied once more to the same patient during the observation week, this will be documented, but not taken into account with regard to the primary outcome.

We define PR in accordance to an internationally consented research definition: '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 that is attached or adjacent to a person's body and that he/she cannot control or remove easily'.[37]

The following types of PR will be considered: restrictive bedrails; belts of various types; fixed tables/chair tables; chairs preventing rising and other PR such as fixation vests.

A nurse, who will be appointed as a contact person for all study-related questions on-site for the respective ward will accompany the study staff during the direct observation. The patients' rooms will only be entered after the nurse has asked the patients whether they agree to the visit. If someone refuses, the accompanying nurse will carry out the observation. Only patients present in their rooms or on the ward will be included in the data collection. To prepare and explain the upcoming in-house data collection, the contact nurses will distribute laminated information sheets for the patients and their relatives placed in the patients' rooms.

Secondary outcomes are defined as accidental falls, treatment interruptions (eg, removal of medical devices) and prescriptions of psychotropic medication (a list of active ingredients and drug names has been prepared and can be found as online supplemental file 1). These will be assessed as safety parameters and extracted from routine documentation. In addition, other variables relevant to the study, such as sociodemographic and clinical data (referral diagnosis, cognitive status (dementia syndrome, delirium)) of patients, will be removed from the routine documentation by the contact nurses using a standardised form at the beginning of the observation week and for all newly admitted patients.

Hospital and ward characteristics will be collected at baseline by nursing ward managers. All data collection sheets will be piloted for feasibility and acceptability.

Process evaluation

A comprehensive process evaluation based on international recommendations[38] will be conducted using mixed methods in order to assess the implementation process and describe barriers and facilitators. The process evaluation will address the underlying contextual factors as well as the processes of recruitment and implementation of the intervention at the cluster and individual level. Therefore, different process parameters will be assessed (see table 1). At the cluster level, contextual factors such as existing standard operating procedures, in-house education regarding the use of PR as well as staff turnover during the study period will be collected from the nursing ward managers using a structured questionnaire at the three measurement points. The recruitment process will be documented at cluster level (eg, dates and

Table 1 Aspects and methods of accompanying process evaluation

Focus	Assessment/documentation	Measurement point
Recruitment procedure (eg, dates and kind of contact, content of study presentations, conduct of personal study presentations)	**Protocol** (by study team)	Before baseline data collection
Reasons for non-participation or drop-out of clusters	**Structured inquiry and documentation** of reasons (by study team)	Continuous
Description of crucial structure and process-related factors on cluster level (eg, SOP or introduction of specific strategies to reduce physical restraints; staff turnover fluctuation)	**Structured questionnaire** for nursing ward management	T_0, T_1, T_2
Conveyance of the intervention (intervention fidelity) (eg, duration, number of participants, deviations from the schedule)	**Structured protocol** of each educational session (training for key nurses and short interprofessional information sessions) (by study team)	After T_0 (immediately after the educational programme)
Evaluation of the education programme (eg, satisfaction with duration, knowledge transfer, methods)	**Standardised questionnaires** for participants	After T_0 (immediately after every educational programme)
Experiences, barriers and facilitators (how/to what extent was the intervention programme implemented), and activities on physical restraint prevention Changes in daily routine? Attitude towards the intervention? Influence of key nurses, managers and other medical staff on the reduction of physical restraints	**Focus groups** with key nurses (about three to four mixed focus groups with participants from different hospitals) **Semi-structured interviews** with nursing and medical ward managers **Structured short questionnaires** for all nurses and physicians from every interventional clusters	T_2
Experiences and attitudes of patients and relatives regarding physical restraints	**Semi-structured interviews** with patients who experienced physical restraints themselves during their hospital stay, and/or their relatives (n=10)	T_2
Context and contextual factors, which could influence the intervention (eg, progress of SARS-CoV-2 pandemic and related political measures; scientific and other developments (eg, guidelines, laws) that could influence the intervention)	**Structured inquiry and documentation**	Continuous

Measurement point: T_0=baseline; T_1=3-month follow-up; T_2=6-month follow-up.
SARS-CoV-2, severe acute respiratory syndrome coronavirus type 2; SOP, standard operating procedures.

kind of contact, content of study presentations, conduct of personal study presentations). The trainers will document all educational sessions (eg, duration, number of participants, deviations from the planned schedule) using a structured protocol. The participants will be asked to fill out a standardised questionnaire after each session to evaluate the educational programme. The questionnaires are based on a self-developed questionnaire used in our previous studies[34 39] and are available as online supplemental file 2.

At the end of the 6-month follow-up period, the barriers and facilitators of the implementation process and activities on physical restraint prevention will be assessed within three to four focus groups, set up with multipliers (key nurses) from the various intervention clusters. Semi-structured interviews will be conducted with the nursing and medical ward managers. The experiences of nursing and medical staff from each intervention cluster will be assessed with a short questionnaire. The views and attitudes of patients and/or relatives will be evaluated through semi-structured interviews with a sample of patients who experienced physical restraints during their hospital stay and/or their relatives. We expect important insights in patients' and relatives' specific needs and acceptance of alternative strategies to avoid PR use. We aim to include ten patients and/or relatives for participation.

The SARS-CoV-2 pandemic may have an impact on patient care and may lead to increased use of PR[40] and we will address this aspect specifically in our interviews and short questionnaires. Furthermore, for example, increased staff shortage and political measures could be a barrier for the implementation of the intervention. Continuous documentation of the course of the SARS-CoV-2 pandemic and related (political) measures will be carried out.

Sample size

Based on the results of our previous feasibility study[34] and other published studies in this area,[21 31] a valid sample size calculation is not possible due to a lack of information regarding expectable prevalence reduction and intraclass

correlation coefficients (ICCC). For the purpose of this pilot study, we plan to recruit eight hospitals. Taking the experiences of the feasibility study into consideration, we expect in overall 28 wards and 33 patients per ward and observation period (2772 overall). As in the preliminary feasibility study, no cluster dropout is expected. We will spend a lot of effort to avoid cluster dropouts. We will openly communicate the time and personnel requirements related with participation in the study to all the hospitals and wards. In addition, we will explain in detail all the study procedures with all the relevant stakeholders and will coordinate deadlines early and closely with the hospitals and wards during the entire study. The results of this pilot study will be used for determining the sample size (ICCC, expectable treatment effects) for a subsequent confirmatory trial.

Data analysis

The statistical analysis will follow Good Clinical Practice standards and will be carried out by a blinded biostatistician (BH) after follow-up, data cleansing and database locking. No interim analyses are planned. Data analysis will be performed using the intention-to-treat population considering the cluster structure.

Characteristics of wards and patients will be described by frequency tables, means, standard deviation (SD) or percentiles, depending on their distributions without cluster adjustment.

PR prevalence will be estimated in both groups with cluster-adjusted 95% confidence intervals (CIs) and ICCC will be calculated.[41] In the primary analysis, the proportion of patients with at least one PR within 1 week after 6 months will be compared between the intervention and control group using mixed logistic regression that is cluster-adjusted by including clusters as random effects. A secondary per-protocol analysis of the primary outcome after exclusion of protocol deviation clusters will serve as a sensitivity analysis. Supplementary secondary analyses of the course of PR prevalence over the three measurement points (T_0, T_1, T_2) are planned, using mixed logistic regression models at the patient level cluster-adjusted by random effects[41] and including adjustment for repeated measurement with fixed effects treatment groups, measurement point (T_0, T_1, T_2) and interaction group × measurement point. In these models, additional patient characteristics might be included as independent variables to investigate the role of a different patient mix in the wards. Initial value adjustment for PR prevalence at T_0 in the clusters will be performed using mixed linear models on cluster level considering repeated measurement with fixed effects PR prevalence at T_0 treatment group, measurement point (T_1, T_2) and interaction group × measurement point. No imputation of missing values is planned. The use of different types of PR will be described by frequency tables.

Secondary outcomes will be analysed over time and cluster-adjusted. The analysis of all secondary outcome measures will be interpreted in an exploratory manner. Data analysis will be performed using SAS statistical analysis software.

The process evaluation will be exploratory. All quantitative data will be analysed descriptively. Qualitative data from recorded focus groups and individual interviews will be transcribed using the transcription rules according to Dresing and Pehl[42] and analysed using content analysis.[43] The qualitative data will be tagged, sorted and synthesised by two independent researchers, and initial themes will be identified. All initial themes will be coded and based on these categories and subcategories were developed. The categories will be developed in inductive and deductive manner. The researchers will constantly discuss coding and analysis. Any disagreements will be resolved in discussion. The content will be summarised and narratively described.[43]

Data management

The primary outcome, secondary outcomes and baseline characteristics of participating hospitals, wards and patients will be collected paper-based by study members (JA and SG) and trained research assistants. All cluster-related data will be pseudonymised by using numeric codes according to cluster affiliation. The code lists will be stored on local servers. Only the study members (JA and SG) will have access to the code lists of clusters. The patient-related sociodemographic and clinical data will be collected and anonymised. Only the patient-related data for PR use and safety parameters will be pseudonymised using a patient numeric code number to avoid multiple data collection of the same patients. The patient code list remains locked on the wards for the observation period. Only the ward staff will have access to these lists and will update it before each observation. After the respective measurement period, the patient code list will be destroyed. Research assistants or study members (JA and SG) will not have direct access to patients' names and records.

All the data collection sheets will be checked by researchers (JA and SG) for completeness and plausibility immediately after the data are collected and implausibility will be clarified between the data collector and the researcher. Due to data protection rules, it is not possible to check specific patient data. Therefore, if implausibility cannot be clarified, we will handle this as missing data.

Trained research assistants will enter the data into the statistical analysis software IBM SPSS V.28. Blinded information on group allocation will be transferred to the biometrician (BH) only after the blinded review.

At the latest 1 month after the end of the respective measurement period, data entry and plausibility checks (primary and secondary outcomes; 10% of baseline data) will be conducted by two independent members of the research team. After data freezing, any further changes to the database will be impossible.

The data of all the participants in the focus groups and individual interviews will be pseudonymised for transcription and analysis. The audio data will be deleted after

transcription and the code list after analysis. MAXQDA will be used for data management of the qualitative data. IBM SPSS V.28 will be used for the descriptive data of participants. All electronic data and case report forms will be archived securely for 10 years at University of Halle (Saale).

PATIENT AND PUBLIC INVOLVEMENT

We are aiming to investigate an interdisciplinary complex intervention programme. Therefore, the perspectives of nurses, physicians, physiotherapists, nursing and medical ward managers will be considered during the preparatory focus groups. Patients and their relatives recruited at the participating hospitals will be directly involved in the preparation phase of the study and in process evaluation. We have established an external advisory board with a heterogeneous skill mix and perspectives, which also includes their experiences in clinical practice. This advisory board consists of a researcher with expertise in the field of PR prevention and methodological expertise as well as members who are able to consider the ethical and legal perspectives, nurses' perspective, nursing leader's perspective and clinical medical perspective. Additionally, we included a patient advocate (legal guardian), and patients who have had the experience of a PR use and/or their relatives.

ETHICS AND DISSEMINATION

The Ethics Committee of the Medical Faculty of the University of Halle (Saale) has approved the study protocol in January 2022 (no. 2021–216). If necessary, additional approval will be obtained from the local ethics committees of the participating hospitals. All study procedures will be in accordance with Good Clinical Practice (ICH-GCP) and the Declaration of Helsinki.[44]

Written informed consent will be obtained from the managers of each participating hospital before the study starts. As was carried out in previous trials,[34 45] no written informed consent for study participation from patients or their legal guardians/representatives will be required (waiver of informed consent). A large proportion of the patients affected by PR are older people with dementia and/or delirium. For these people, written consent would have to be obtained predominantly from legal guardians, if they are available or even known at all. This procedure would not be feasible, particularly in view of the sometimes short lengths of stay, and would lead to a large proportion of the relevant target group being excluded from the study. Apart from that, the intervention is located at the level of wards or departments and is intended to optimise the standard (nursing) care processes. The PR-data will be collected by direct observation and additional information will be derived from routine documentation. The investigators will have no direct access to patients' data. According to data protection regulations, a member of the nursing staff will accompany the investigators. Patients' rooms will only be entered after the nurse has obtained the consent of the patients. All patient-related data will be anonymised for the investigators. No risks for the patients (such as increased falls and therapy interruptions) are to be expected and there will be no additional burden, for example, due to data collection.[21 31–33] Written informed consent will be obtained from all participants of individual interviews and focus groups in advance. An example of study information (online supplemental file 3) and consent form (online supplemental file 4) can be found as supplementary material. Participating hospitals, wards and interviewees may withdraw their consent at any time.

We plan to publish the main study results in an international, peer-reviewed and open access journal. All data will be reported in accordance with the Consolidated Standards of Reporting Trials-Statement extension to cluster-randomised trials.[46 47] The study results will be presented at scientific conferences. All trial information (eg, procedures, material and results) and different information material, addressing researchers, clinicians, nursing staff and healthcare providers will be freely available via an already existing website (http://www.leitlinie-fem.de). Furthermore, the programme will be offered to relevant healthcare providers, and policy makers in Germany will be informed about the study by letter.

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Contributors JA and GM developed the conception and design of the initial protocol and obtained funding. JA and SG were responsible for the conception and design of the final study protocol. BH was responsible for the statistical planning of design and analyses of the study. SG drafted the manuscript supervised by JA and GM. All authors contributed, critically appraised, reviewed and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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