

# Interventions for preventing and reducing the use of physical restraints in long-term geriatric care (Protocol)

Meyer G, Möhler R, Köpke S



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[Intervention Protocol]

# Interventions for preventing and reducing the use of physical restraints in long-term geriatric care

Gabriele Meyer<sup>1</sup>, Ralph Möhler<sup>1</sup>, Sascha Köpke<sup>2</sup>

<sup>1</sup>Institute for Nursing Science, Faculty of Medicine, Witten/Herdecke University, Witten, Germany. <sup>2</sup>Unit of Health Sciences and Education, University of Hamburg, Hamburg, Germany

Contact address: Ralph Möhler, Institute for Nursing Science, Faculty of Medicine, Witten/Herdecke University, Stockumer Straße 12, Witten, 58453, Germany. [ralph.moehler@uni-wh.de](mailto:ralph.moehler@uni-wh.de). (Editorial group: Cochrane Dementia and Cognitive Improvement Group.)

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## ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

- 1. To evaluate the effectiveness of interventions to prevent and reduce the use of physical restraints in older people who require long-term nursing care (either in the community or in nursing homes).
- 2. To evaluate the complex interventions by retrieving detailed process-related data.
- 3. To highlight the quality and quantity of research evidence available and to set an agenda for future research.

## BACKGROUND

The use of physical restraints with older people has been reported as common practice in different countries (De Vries 2004). International studies have reported prevalence between 5 and 70% (Hamers 2005, Evans 2002a, De Vries 2004). Recently, an epidemiological study on physical restraints with 2367 nursing home residents in Germany showed a prevalence of 26% (95% confidence interval (CI) 21 to 31). Centre prevalence ranged from 4 to 59%. The proportion of residents with at least one physical restraints cumulated to 40% (95% CI 33 to 46) over a 10-month mean follow-up (Meyer 2008).

Physical restraints include devices, equipment, or aids designed to confine a patient's bodily movements or free body movement to a preferred position. For example, physical restraints include bilateral bedrails, limb or trunk belts, fixed tables on a chair or chairs that prevent patients from getting up (Evans 2002a). Consistently, the claim has been made that the use of physical restraints is based on safety reasons, primarily prevention of falls. Control of disruptive behaviour, safe use of medical devices and other reasons have also been reported (Hamers 2005). On the other hand, questions have been raised about the justification for and consequences of the use of physical restraints in older people. Considering the current evidence, it is questionable whether this practice can be justified in terms of controlling psychomotor agitation and reducing the risk of falling and fall related injuries (Evans 2002a; Healey 2008). The use of physical restraints is likely to be associated with adverse outcomes (Evans 2002a). Case reports and case series have described direct injury and mortality from physical restraint use for example by falls after bedrail failure or by fatal entrapment (Healey 2008). Also, other adverse events as reduced psychological wellbeing, lower cognitive performance and decreased mobility have been attributed to the use of physical restraints (Evans 2002a; Engberg 2008), although the validity of these analyses have been questioned (Healey 2008). In residential care settings, residents with cognitive impairment and/or disrupting behaviour are more likely to be restrained than residents without cognitive problems (Evans 2002a).

A restrained-free nursing care environment has been demanded as standard of care, while anything less has been claimed as substandard (Flaherty 2004). Accordingly, in recent decades great efforts have been made to reduce the use of physical restraints. Programmes to reduce the use of physical restraints with older people were first introduced in the US in the 1980s (Castle 1998). Since then, a number of studies have been conducted in hospitals and nursing homes, the majority, however, are of inadequate methodological quality. The systematic review by Evans 2002b analysed 13 studies, including only one randomized controlled trial (RCT). Since then, further published and unpublished controlled trials have been conducted evaluating multifaceted interventions to reduce the use of physical restraints (Koczy 2005; Lai 2007; Testad

2005; Capezuti 2007; Huizing 2006; Huizing 2008). These interventions were designed as complex interventions, consisting of different components. These include, among others, educational sessions aimed at changing nurses' attitudes to physical restraint use and information about and implementation of alternatives to the use of physical restraints. Some interventions address members of different professions, e.g. physicians, nurses and social workers, most address nurses only (Evans 2002b).

## OBJECTIVES

- 1. To evaluate the effectiveness of interventions to prevent and reduce the use of physical restraints in older people who require long-term nursing care (either in the community or in nursing homes).
- 2. To evaluate the complex interventions by retrieving detailed process-related data.
- 3. To highlight the quality and quantity of research evidence available and to set an agenda for future research.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

All individual randomized controlled trials in which older adults require long-term nursing care or cluster randomized controlled trials in which groups of these older adults are allocated either to a restraint reduction programme or regular care (control group). Non-blinded studies will be included in the review as it seems unrealistic to expect blinding of the participating caregivers. The outcome assessors should be blinded to treatment allocation.

#### Types of participants

The participants will be care home residents of either gender requiring long-term nursing care irrespective of their cognitive status.

#### Types of interventions

Any intervention or group of interventions were subjects or clusters are randomized to receive either a restraint reduction or prevention programme or regular care. All interventions that do not include drug therapy will be included. Studies comparing two types of programmes will also be included.

Interventions will be categorised into the following categories:

**1. Educational interventions:** These interventions include either direct-to-caregiver-programmes or programmes for disseminators who distribute the contents of the programme. We expect a range of different approaches varying for example in terms of length and content. The educational programme contents are likely to

include all or some of the following: impact of physical restraints, residents' rights and autonomy, myths and misconceptions about the use of physical restraints, ethical issues, legal aspects, restraint minimisation, dangers and adverse outcomes of physical restraint use, reasons for and management of specific behavioural problems (reasons and/or management), and alternatives to physical restraints (Evans 2002b). Following the 'framework for design and evaluation of complex interventions', it will not be possible to extract the effective or ineffective components of the educational programmes (Campbell 2000), but components of included programmes will be analysed in detail.

**2. Organisational interventions:** Organisational approaches include interventions that aim to change organisational policies, for example by introducing special 'physical restraint nurses' or clinical consultation by nurse specialists, or also by increasing family participation, or simply making equipment for physical restraints less accessible.

**3. Interventions that provide restraint alternatives:** These interventions include the provision of any device, material or other intervention to be used instead of physical restraints or to reduce the need for physical restraints. Comprehensive lists of potential alternatives have previously been published, for example by the Joanna Briggs Institute 2002.

**4. Other interventions:** All interventions that cannot be included in the above three categories will be considered.

For the purposes of this review, physical restraint is defined as: "any device, material or equipment attached to or near a person's body and which cannot be controlled or easily removed by the person and which deliberately prevents or is deliberately intended to prevent a person's free body movement to a position of choice and/or a person's normal access to their body" (Retsas 1998; Evans 2002a). While medications can also be used to control behaviour, these will not be considered for this review, because of the different modes of action of physical and 'chemical' restraints.

## Types of outcome measures

### Primary outcomes

- the prevention of physical restraints (i.e. newly introduced physical restraints)
- the number of residents or patients with at least one physical restraint
- the reduction of physical restraints (i.e. withdrawn physical restraints).

### Secondary outcomes

- type of restraint
- duration of restraint use
- prescriptions of psychoactive drugs
- residents' and nurses' quality of life
- adverse effects of the interventions employed
- duration of effect of the interventions
- injuries and deaths during the study period.

## Search methods for identification of studies

See [CochraneDementiaandCognitiveImprovementGroup](#) methods used in reviews.

The Cochrane Dementia and Cognitive Improvement Group's Specialized Register, MEDLINE, EMBASE, CINAHL, PsycINFO, LILACS, trial registries and grey literature sources will be searched. The register contains records from MEDLINE, EMBASE, CINAHL, PsycINFO, LILACS, many trial databases and grey literature sources and is updated regularly. In addition, reference lists of retrieved articles will be checked for additional trials. Experts in the field will be contacted to identify unpublished or ongoing studies.

The following search terms will be used for database searches: "restraint\*", "education", "staff training", "elderly", "old\*", "long term care", "geriatric care" and "nursing home", also the MeSH terms "restraint, physical", "education, nursing", "aged", and "residential facilities".

## Data collection and analysis

### Selection of studies

Titles and abstracts of citations obtained from the search will be examined independently by two authors and obviously irrelevant articles discarded. At this stage the authors will be overly inclusive: any article that suggests a relevant randomized controlled trial will be retrieved for further assessment. Next, the two authors will independently assess retrieved articles for inclusion in the review according to the criteria above. Disagreements will be resolved by discussion or, if necessary, referred to a third author.

### Quality assessment

Quality assessment will follow the Cochrane Handbook for Systematic Reviews of Interventions, version 5.0 (Higgins 2008). Two authors will independently assess and score the studies' methodological quality in order to identify any potential sources of systematic bias.

Criteria for appraisal of studies will be internal validity and low risk of bias through selection bias, performance bias, attrition bias, and detection bias. Study validity will be determined by categorising individual studies into low, moderate, or high risk of bias.

### Data extraction

Data extraction will be performed using a standardised data collection form and entered in the current version of RevMan. Data from included studies will be extracted independently by two reviewers, using a standardised form and checked for accuracy. Study names will not be masked. The results will be discussed. In case of disagreement a third reviewer will be called in to reach consensus. Authors of primary studies and experts in the field will be contacted to check for ongoing or unpublished studies. A hand search for abstracts of the following scientific congresses will be performed in order to retrieve unpublished studies: IAGG World

Congress of Gerontology & Geriatrics, The Gerontological Society of America's Annual Scientific Meeting, Congress of the European Union Geriatric Medicine Society, European Congress of Gerontology, and Asia/Oceania Regional Congress of Gerontology and Geriatrics.

### Data analysis

First, we will check data for clinical homogeneity. If clinical homogeneity is present, raw data will be used for meta-analysis. If it is not possible to acquire raw data, data extraction will follow the Cochrane Collaboration Handbook for Systematic Reviews of Interventions, version 5.0 (Higgins 2008).

Summary statistics will be required for each trial and each outcome. For dichotomous data (as the primary endpoint), the effect measure will be odds ratio (OR). The numbers in each group (restraint reduction programme or regular care) and the numbers experiencing the outcome of interest will be sought and recorded. For continuous data (duration of restraint use), the effect measure will be the weighted mean difference (WMD). The mean change from baseline, the standard deviation of the mean change, and the number of patients for each treatment group at each assessment will be extracted. Where changes from baseline are not reported, the mean, standard deviation and the number of participants for each group at each time point will be extracted, if available.

The amount and kind of missing data related to participants' dropout that cannot be retrieved from the original authors will be described in the 'Characteristics of Included Studies' table and the impact will be discussed. The potential impact of the missing data on the results will depend on the extent of missing data, the pooled estimate of the treatment effect and the variability of the outcomes. Variation in the degree of missing data may also be considered as a potential source of heterogeneity. Intention-to-treat analyses will be conducted by imputing outcomes for the missing participants using the last observation carried forward approach. Recognizing that statistical analysis cannot reliably compensate for missing data (Unnebrink 2001), the impact of any assumption will be assessed by trying more than one method as a sensitivity analysis. For example, for dichotomous data, it will first be assumed that all missing participants in the first group incurred the event and those in the second group did not, after which the opposite will be assumed. When missing data are common, these worst-case/best-case scenarios will cover a very wide range of possible treatment effects and thus the analysis will not be very informative. However, when missing data are not common and this procedure is done across all trials in the review with little impact on the results, it can

be concluded that the missing data will not affect the outcome of the review.

Pooling of data from individually randomized and from cluster randomized studies for which the intra-cluster correlation coefficient (ICCC) is known or could be calculated will be conducted using generic inverse variance (Higgins 2008). Heterogeneity between trials included in each analysis will be tested using  $I^2$  with 95% CI (Ioannidis 2007). In the case of evidence for statistical heterogeneity, this will be explored by identifying any results with non-overlapping 95% CI, creating a subgroup analysis, and seeking to confirm any statistically significant differences between subgroups by comparing the ratio of the difference in the natural logarithm of the relative risks and the standard error of the difference in log relative risks to the standard normal distribution (test for interaction).

Meta-analysis will be conducted for interventions of the same category. It is likely that some interventions will include elements of more than one category. In this case comparable interventions (e.g. including educational and organisational elements) will be considered for meta-analysis. Presentation of meta-analysis will be carried out in forest plots. If it is not possible to pool the data, we will present the results in a descriptive review of different interventions and effects.

Data from all identified trials for each analysis will be entered into a funnel plot to investigate the likelihood of overt publication bias. If appropriate, other statistical methods e.g. Egger's regression method or Begg's rank correlation method will be used to estimate publication bias (Sterne 2005).

Depending on availability of sufficient data, the following subgroup analyses will be undertaken:

#### Severity of dementia at baseline:

- Mild: Mini Mental State Examination (MMSE) with > 17-26 points out of 28 or comparable scale
- Moderate: MMSE with 10 to 17 points or comparable scale
- Severe: MMSE with < 10 points or comparable scale (Feldman 2005)

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\* Indicates the major publication for the study

## **HISTORY**

Protocol first published: Issue 1, 2009

## **CONTRIBUTIONS OF AUTHORS**

GM and SK initially planned the study; GM, RM and SK have written the study protocol.

## **DECLARATIONS OF INTEREST**

None known.

## **SOURCES OF SUPPORT**

### **Internal sources**

- Faculty of Medicine, Institute for Nursing Science, Witten/Herdecke University, Germany.
- Unit of Health Sciences and Education, University of Hamburg, Germany.

### **External sources**

- Ministry of Education and Research, Germany.