Effectiveness of a Multifactorial Intervention to Reduce Physical Restraints in Nursing Home Residents

Petra Koczy, Dr,* Clemens Becker, Dr PD,* Kilian Rapp, MPH, Dr,*† Thomas Klie, Dr Prof,‡
Denis Beische,* Gisela Büchele, MPH,† Andrea Kleiner,† Virginia Guerra,‡ Ulrich Rißmann,*
Susan Kurrle, Dr Prof,§‖ and Doris Bredthauer, Dr Prof#

OBJECTIVES: To evaluate the effectiveness of a multifactorial intervention to reduce the use of physical restraints in residents of nursing homes.

DESIGN: Cluster-randomized controlled trial.

SETTING: Forty-five nursing homes in Germany.

PARTICIPANTS: Three hundred thirty-three residents who were being restrained at the start of the intervention.

INTERVENTION: Persons responsible for the intervention in the nursing homes attended a 6-hour training course that included education about the reasons restraints are used, the adverse effects, and alternatives to their use. Technical aids, such as hip protectors and sensor mats, were provided. The training was designed to give the change agents tools for problem-solving to prevent behavioral symptoms and injuries from falls without using physical restraints.

MEASUREMENTS: The main outcome was the complete cessation of physical restraint use on 3 consecutive days 3 months after the start of the intervention. Secondary outcomes were partial reductions in restraint use, percentage of fallers, number of psychoactive drugs, and occurrence of behavioral symptoms.

RESULTS: The probability of being unrestrained in the intervention group (IG) was more than twice that in the control group (CG) at the end of the study (odds ratio = 2.16, 95% confidence interval = 1.05–4.46). A partial reduction of restraint use was also about twice as often achieved in the IG as in the CG. No negative effect was observed regarding medication or behavioral symptoms. The percentage of fallers was higher in the IG.

CONCLUSION: The intervention reduced restraint use without a significant increase in falling, behavioral symptoms, or medication. **J Am Geriatr Soc 59:333–339, 2011.**

Key words: physical restraints; elderly; nursing home; dementia

From the *Department of Clinical Gerontology, Robert-Bosch-Hospital, Stuttgart, Germany; †Institute of Epidemiology, Ulm University, Ulm, Germany; ‡Protestant University of Applied Sciences, Age Society Participation, Freiburg, Germany; §Division of Rehabilitation and Aged Care, Hornsby Kuring-gai Health Service, Hornsby, Australia; ‖Faculty of Medicine, University of Sydney, Sydney, Australia; and #Faculty of Health and Social Work, University of Applied Sciences, Frankfurt am Main, Germany.

Address correspondence to Dr. Petra Koczy, Department of Clinical Gerontology, Robert-Bosch-Hospital, Auerbachstr. 110, 70376 Stuttgart, Germany. E-mail: petra.koczy@rbk.de

The use of physical restraints for residents with dementia in long-term care facilities remains highly controversial.[1,2] Physical restraints are an interference with fundamental human rights and may be viewed as elder abuse. Despite a growing body of evidence concerning their ineffectiveness and the high rate of adverse events,[3–5] physical restraints are still widely used in nursing homes.[6] A current German study demonstrated that the prevalence of use of all physical restraints such as belts tied to a chair or bed, bed rails, or chairs with fixed tables ranges from approximately 4% to 59%.[7] Risk of falling, cognitive decline, and impaired activities of daily living are resident characteristics associated with greater use of restraints.[8–10] Furthermore, personal beliefs and staff attitudes may predict the use of physical restraints.[7,9,11] The most commonly mentioned justifications for use of physical restraints is the safety of nursing home residents. The most common argument for physical restraint use is the prevention of fall-related injuries or the control of behavioral symptoms such as agitation and wandering.[12] There is epidemiological evidence that the use of physical restraints does not prevent falls and fall-related injuries over longer time periods.[13] Several studies have observed that reduction in the use of physical restraints did not result in a greater number of falls and fall-related injuries.[14–17] Restraint-free facilities have not differed in total number of staff per resident or use of psychoactive drugs.[14,18] Different authors and legal authorities have claimed a "restraint-free environment" to be the criterion standard in long-term care.[16,19]

Only a small number of randomized controlled trials have examined the reduction of physical restraint use. The trials have come to different conclusions.[14,20–22] The quality of the studies has been limited mainly because of small sample size and methodological problems.

The study presented here was conducted between 2004 and 2006 and investigated the effect of a multifactorial cluster-randomized intervention to reduce the need for physical restraints (belts tied to a chair or bed and chairs with fixed tables) for the residents of 45 nursing homes in Germany. Bed rails were not included in the study. It was hypothesized that the intervention would reduce the use of restraints without increasing risks to residents.

METHODS

Study Population

After a written proposal to 308 German nursing homes, 123 expressed interest in participating in the intervention study (Figure 1). The only inclusion criterion for nursing homes was the use of physical restraints on at least five residents to target facilities with a major problem regarding restraint use. Seventy-eight homes did not meet the inclusion criterion or withdrew from participation after an initial information meeting, leaving 45 nursing homes in the study. At the start of the intervention, 5,561 residents lived in these homes. Before the start of the study, each nursing home was asked to identify all residents who were currently being restrained. Four hundred thirty (7.7%) residents were restrained at some time during the 3 days immediately before the start of the intervention (T1). During the 3-month intervention period, 60 (22.4%) restrained residents in the intervention group (IG) and 37 (22.8%) in the control group (CG) were lost to follow-up because of death, discharge, or missing data. Three hundred thirty-three residents remained for final analysis. No nursing homes dropped out of the study.

Ethical approval was obtained from the Ethics Committee of the State Board of Physicians. Informed consent was given from all nursing homes with restrained residents. Individual consent was not obtained from residents.

Randomization

An independent organization performed randomization according to nursing home after baseline assessment of all restrained residents. In the randomization, 23 nursing homes with an average of 112 (range 60–317) residents each were assigned to the IG, and 22 nursing homes with an average of 100 (range 50–282) residents each were assigned to the CG. The final study population assessed at T1 and at the end of the 3-month intervention period (T2) consisted of 208 residents from intervention homes and 125 residents from control homes.

Intervention

One person responsible for the intervention from each of the participating homes (change agent) was appointed. These change agents served as the main contact persons for the research team. More than 90% were registered nurses, and 40% also had a management role in their homes. Only two had a different professional background (social work).

They received one 6-hour mandatory training course and were asked to introduce and implement the content of the intervention package in their care homes. The 23 change agents were trained in groups of four to eight people each. The intervention period was 3 months.

Four members of the research team led the training course: one nurse scientist (U.R.), one lawyer (T.K.), one gerontopsychiatrist (D.B.), and one social worker (V.G.).

Increasing Awareness

To demonstrate and emphasize the risk of side effects and the perception of being restrained, one of the change agents was voluntarily restrained.

Education

The training course included state-of-the-art information on epidemiology and the side effects of restraint use.[23] The research team provided information about legal aspects and possible alternatives for restraint use from the perspective of the nurse scientist and gerontopsychiatrist The change agents were educated as to how to adapt or modify environmental and organizational factors to encourage the well-being of residents with dementia. Examples of medical causes of agitated behavior were given, and different strategies to assist staff in managing dementia were discussed. The overall intention of the training course was to improve the change agents' knowledge regarding fall prevention and behavioral symptoms.

Technical Aids

To prevent fall-related injuries, the change agents were encouraged to use assistive devices such as sensor mats, hip protectors, and antislip socks. As part of the intervention, each restrained resident could receive up to three hip protectors and five pairs of antislip socks. In addition, each nursing home was supplied with at least one sensor mat to identify the intention of residents to leave the bed unassisted.

Problem-Solving Tools

Alternatives for restraint use were discussed using a prepared case report. An important aspect was to address the process of decision-making regarding the use of physical restraints, which included the legal guardian, family caregivers, and staff members. The change agents then had the opportunity to discuss alternatives to restraint use using their own cases.

Implementation of Course Contents

The change agents were instructed to perform in-house teaching sessions to improve the knowledge of their colleagues and to implement the course contents in their nursing home over a 3-month period. They were equipped with training material including leaflets, a training manual, and a PowerPoint presentation for their own in-house teaching sessions. A further suggestion was to initiate case consultations for restrained residents.

Support

Advice by telephone from the research team was available during the entire 3-month intervention period. An in-house visit by a member of the research team was offered on request, and 22 nursing homes took advantage of this.
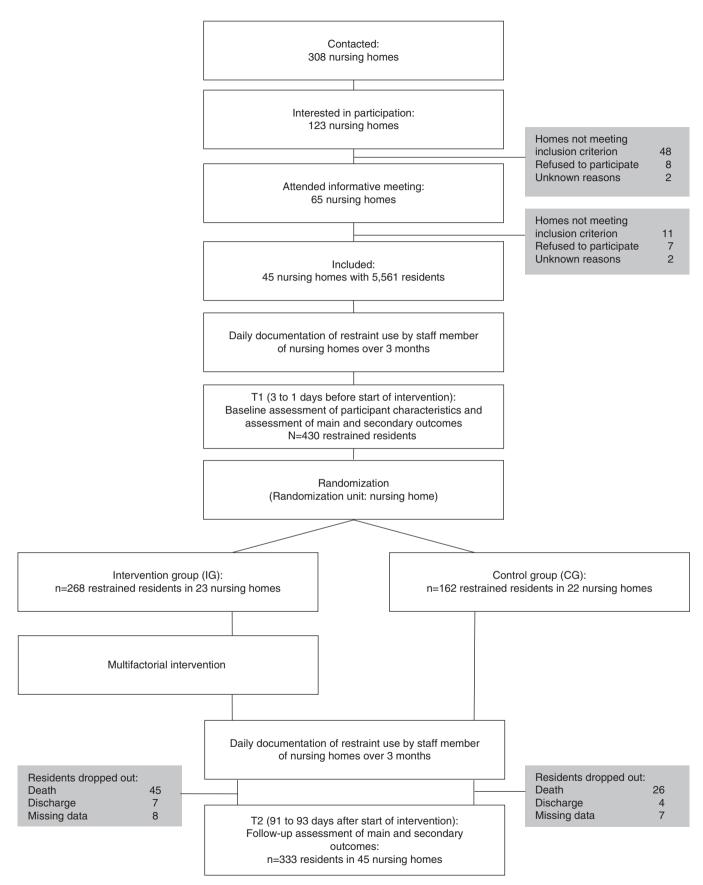
Figure 1. Flow chart.

Nursing homes assigned to the CG received the training program after the intervention period (waiting-list control design).

Baseline Variables

Information on baseline characteristics of restrained residents (age, sex, level of care, mobility, and cognition) was obtained before randomization at T1 (Table 1). An independent rater of the long-term care insurance organization assessed the level of care according to the German national long-term care insurance rating.[24] To claim long-term care benefits, people must require assistance with basic activities of daily living every day. The level of care is, therefore, a measure of the need for care and a proxy for the degree of functional limitation; a higher level indicates greater requirement for nursing assistance. A modified Rivermead Mobility Index,[25] which assesses a range of activities from turning over in bed to running, was used as a measure of physical mobility. The original Rivermead Mobility Index contains 15 items, but because of the reduced mobility of residents, only items 1 to 10 were assessed. The Dementia Screening Scale[26,27] was used to describe cognitive status.

Staff nurses assessed components of residents' behavior over the previous 4 weeks.

A member of the research team assessed all items at T1 and T2 in cooperation with a staff member in the participating homes.

Definition of Physical Restraints

Restraints were defined according to the Joanna Briggs Institute definition 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."[23] Only the use of belts tied to a chair or bed and chairs with fixed tables were used for the outcome evaluation. Bed rails were not included.

Main and Secondary Outcome

Every study participant had to be restrained at some time during the 3 days before the start of intervention (T1). The

Table 1. Characteristics of All 333 Restrained Residents at Baseline (T1)

Characteristic	Intervention Group (n = 208)	Control Group (n = 125)	P-Value
Age, n (%)			.23[a]
<69	26 (12.5)	8 (6.4)	
70–79	44 (21.1)	24 (19.2)	
80–89	80 (38.5)	60 (48.0)	
≥90	58 (27.9)	33 (26.4)	
Sex, n (%)			.02[b]
Female	148 (71.2)	103 (82.4)	
Male	60 (28.8)	22 (17.6)	
Level of care, n (%)[c]			.01[a]
1	8 (3.8)	9 (7.2)	
2	88 (42.3)	65 (52.0)	
3	112 (53.9)	51 (40.8)	
Fallers, n = 320 (96.1%)[d]			.18[b]
No	187 (93.0)	115 (96.6)	
Yes	14 (7.0)	4 (3.4)	
Rivermead Mobility Index, median (range)[e]	1.0 (0–10)	2.0 (0–10)	.29[f]
Cognition, median (range)[g]	11 (2–15)	10 (2–15)	.10[f]
Cohen-Mansfield Agitation Inventory, median (range)			
Agitated and inappropriate behavior[h]	15.0 (10–41)	15 (10–43)	.56[f]
Verbally agitated behavior[i]	10 (6–28)	11 (6–34)	.13[f]
Aggressive behavior[j]	7 (7–31)	7 (7–32)	.09[f]
Number of psychoactive drugs	1.5 (1–5)	2.0 (1–5)	.08[f]
Duration of restraint use during T1, hours[k]	28 (1–72)	30 (1–72)	.52[f]

[a] Cochrane-Armitage test for trend.
[b] Chi-square test.
[c] Level of care according to the German national long-term care insurance rating: 0 (no help needed) to 3 (extensive help needed).
[d] Residents with one or more falls 4 weeks before T1; n = 320, data were only available for 96.1% of the restrained residents.
[e] Range 0 (low mobility) to 10 (high mobility).
[f] Mann-Whitney U test.
[g] 0 (no cognitive impairment) to 16 (severe cognitive impairment).
[h] Range 10 (no behavioral disorder) to 70 (severe behavioral disorder).
[i] Range 6 (no behavioral disorder) to 42 (severe behavioral disorder).
[j] Range 7 (no behavioral disorder) to 49 (severe behavioral disorder).
[k] 72-hour period.

Table 2. Effects of the Intervention

	n (%)		
Effect	Intervention Group (n = 208)	Control Group (n = 125)	Odds Ratio (95% Confidence Interval)*
Reduction of duration of restraint use			
Duration of reduction			
100% (not restrained)[†]	35 (16.8)	11 (8.8)	2.16 (1.05–4.46)
≥75%	45 (21.6)	13 (10.4)	2.45 (1.26–4.77)
≥50%	56 (26.9)	18 (14.4)	2.25 (1.25–4.05)
≥25%	69 (33.2)	27 (21.6)	1.87 (1.11–3.14)
Percentage of fallers during the intervention period[‡]	34 (16.3)	10 (8.0)	2.08 (0.98–4.40)

* Adjusted for sex.
[†] Main outcome.
[‡] Residents with one or more falls during the 3-month intervention period.

main outcome was the complete cessation of physical restraint use in residents at Days 91 to 93 after the start of the intervention (100% reduction at T2). The assessment dates used for the analysis of restraint duration were unknown to the nursing homes. Daily documentation of restraint use began 3 months before randomization to ensure the quality of the documentation process and continued until after the end of the intervention. The duration per day for which restraints were used was documented in a daily calendar, together with any falls and fractures. A staff member in the participating homes completed the daily documentation for each resident. Once a month, the calendar was sent to the research team. Missing data or mistakes in the documentation were clarified over the telephone.

The secondary outcomes were partial reductions of restraint use, the percentage of fallers at T2, the number of psychoactive drugs used, and the occurrence of behavioral symptoms in the IG and the CG. Fallers were defined as restrained residents with one or more falls 4 weeks before T1 or within the 3-month intervention period. The falls definition of the Prevention of Falls Network Europe consortium was used. The use of psychoactive drugs, including antidepressants and neuroleptics, was recorded. Patterns of behavioral symptoms were evaluated using the Cohen-Mansfield Agitation Inventory.[28] Three modified clusters of observed behavior were analyzed: agitated and inappropriate behavior, verbally agitated behavior, and aggressive behavior.[29]

The Cohen-Mansfield Agitation Inventory and number of psychoactive drugs were assessed during visits of research team members at T1 and again at T2. Main and secondary outcomes were defined before the start of the study. A post hoc secondary outcome was change in the behavior measured.

Statistical Analyses

Restraint use during a 3-day period (days 91–93) was defined as the main outcome. The reduction of restraint use was expressed as the percentage of the reduction of restraint use between T1 and T2: hours of restraint use at T1 minus hours of restraint use at T2/hours of restraint use at T1. The categorized percentages of the reduction of restraint use

served as outcomes (100% (unrestrained), ≥75% and <75%, ≥50% and <50%, ≥25% and <25%).

Logistic regression models were applied to test the effect of the intervention on restraint use and on percentage of fallers. For number of psychoactive drugs used and the Cohen-Mansfield Agitation Inventory, differences between baseline assessment and follow-up assessment were calculated.

Cluster randomization led to differences in the characteristics of the IG and CG residents in terms of sex, age, and level of care. The sex difference between the groups (71.2% vs 82.4% female) mainly explained the imbalance in these baseline characteristics, so all models were adjusted for sex.

Before definitive analyses, potential cluster effects were estimated for all models. For all analyses, cluster (nursing home) effects of nursing homes accounted for approximately 1.5% of the total variance and individual effects for more than 98%, so clusters were not considered in the final analysis. All calculations were performed with SAS version 9.2 (SAS Institute, Inc., Cary, NC).

RESULTS

Nearly 70% of the 333 restrained residents were aged 80 and older. The median score of between 10 and 11 (of 16) on the Dementia Screening Scale indicated the presence of severe cognitive impairment in the study population. The restrained residents were considerably limited in physical mobility (median 1–2 out of 10 on the Rivermead Mobility Index) (Table 1).

The randomization procedure did not eliminate all differences between study groups at baseline. Restraint use at the start of the intervention was somewhat higher in the IG (7.2%) than in the CG (5.0%). In addition, the percentage of women was lower in the IG (71.2%) than in the CG (82.4%). In both groups, women represented the majority of restrained residents. The percentage of fallers in the month before the start of the intervention was twice as high in the IG (7.0%) as in the CG (3.4%). More than 90% of the study population was categorized at level of care 2 or 3, indicating a medium or high need for care. The IG needed more nursing assistance than the CG. Mobility (Rivermead Mobility Index), cognition (Dementia Screening Scale),

Table 3. Changes in Number of Psychoactive Drugs and Behavioral Symptoms

Changes Between Baseline and 3-Month Follow-Up	Mean ± Standard Deviation		β Estimate (95% Confidence Interval)*
	Intervention Group (n = 208)	Control Group (n = 125)	
Number of psychoactive drugs	− 0.04 ± 0.64	− 0.08 ± 0.51	− 0.04 (− 0.2–0.11)
Cohen-Mansfield Agitation Inventory			
Agitated and inappropriate behavior	− 0.5 ± 6.29	− 0.88 ± 7.31	− 0.44 (− 1.94–1.06)
Verbally agitated behavior	− 0.15 ± 4.88	− 0.74 ± 4.92	− 0.57 (− 1.67–0.54)
Aggressive behavior	− 0.07 ± 4.38	− 0.12 ± 4.05	− 0.03 (− 0.99–0.93)

* Adjusted for sex.

behavior (Cohen-Mansfield Agitation Inventory), and number of psychoactive drugs taken were similar between the groups (Table 1).

After 3 months, the probability of being free of restraints was more than twice as high in the IG as in the CG (odds ratio (OR) = 2.16, 95% confidence interval (CI) = 1.05–4.46). A reduction of restraint use of at least 75%, 50%, or 25% was also achieved approximately twice as often in the IG as in the CG. The influence of the intervention on factors potentially caused by restraint use is reported in Tables 2 and 3. The percentage of fallers during the intervention period was higher in the IG (OR = 2.08, 95% CI = 0.98–4.40). Two fractures were documented, one in each group. No effect was observed on the number of psychoactive drugs taken or in change of behavior.

DISCUSSION

This study in long-term care facilities demonstrates that a short-term multifactorial intervention significantly reduced the need for physical restraints (belts tied to a chair or to bed and chairs with fixed tables). It also shows that the duration of physical restraint could be reduced in residents for whom physical restraint was still used. No major disadvantages occurred for residents in the IG. The percentage of fallers in the IG remained higher during the intervention period. This has to be interpreted with caution because of the difference in fall incidence at baseline, although it is possible that residents increased their level of activity and thereby had a higher risk of falling. Furthermore, frail older adults who have been immobilized for some time may have a greater risk of falling. The incidence of fractures was too small to give conclusive results. A greater number of psychoactive drugs did not replace physical restraints. The amount of behavioral symptoms did not differ between groups.

The decision to restrict the intervention to 3 months was made to avoid contamination and high drop-out rates in this frail group. The trade-off was a short time frame to implement the intervention. This pragmatic approach with limited time and effort in training of change agents was chosen to increase the chance of dissemination of the program after the end of the study.

There are several limitations of the study that have to be considered. The staff members of the nursing homes performed the daily documentation of physical restraints and falls. A member of the research team conducted the

assessments at T1 and T2 in cooperation with staff members. Data collection was, therefore, unblinded.

Despite the randomization, there were differences in baseline characteristics of participants between the two groups. The sex ratio was unbalanced, and the number of restrained residents differed between the IG and the CG.

No information was available about the way in which the change agents shared their knowledge with their colleagues. The number of in-house teaching sessions or case consultations was not documented. There was no qualitative or quantitative evaluation of the quality improvement process. Because of the design of the study, it is not possible to identify the most-effective or the least-successful components of the intervention. The selected components of increasing awareness, improving knowledge, clarifying legal arguments, demonstrating alternatives, providing related equipment and supplies, and empowering staff members to participate in the decision-making process seem to be reasonable choices. Because of financial constraints data were not collected on beliefs, attitudes, and knowledge about the use of restraints before or after the intervention.

The findings of the study might differ if the intervention is applied in other countries[14,20–22] because of, for example, differing legal requirements, organizational prerequisites for nursing homes, and working conditions for staff members. In a recent study,[30] as well as in other successful trials, it was demonstrated that organizational characteristics, staff attitudes, specific care concepts, environmental characteristics, clinical practice guidelines, and protocols influence the success or failure of multifactorial interventions to reduce restraint usage.

In summary, this study is another step to build evidence that the reduction of restraints is feasible in long-term care. An interdisciplinary approach based on medical and nursing science including ethical and legal aspects is likely to yield the greatest benefits. Further studies should include implementation research and process evaluation. The results from this study, together with other efforts, have prompted the government at the federal and state level in Germany to initiate similar programs in an attempt to achieve, as quickly as possible, a restraint-free environment in long-term care.

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