

Effect of a Guideline-Based Multicomponent Intervention on Use of Physical Restraints in Nursing Homes

A Randomized Controlled Trial

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PHYSICAL RESTRAINTS, SUCH AS bilateral bed rails, belts, and fixed tables in a chair, are regularly applied in German nursing homes even though German legislation clearly requires that residents have free body movement¹ and despite evidence for their lack of effectiveness and safety.^{2,3} Thus, legal regulations do not appear to adequately protect nursing home residents. For US nursing homes, a recent survey reported physical restraint rates of more than 20%.⁴

Nursing home care does not necessitate the administration of physical restraints, as demonstrated by our own epidemiological research. We found pronounced center variation, with best-practice centers applying very few physical restraints.¹ Reasons for differences between centers are unclear, but the “culture of care,” as reflected in the attitudes and beliefs of nursing staff, may determine observed variation.^{1,5} Accordingly, a “culture change” has been demanded for nursing homes because avoidance of physical restraints is mandatory from a professional point of view.^{6,7}

Context Despite unambiguous legal regulation and evidence for lack of effectiveness and safety, physical restraints are still frequently administered in nursing homes.

Objective To reduce physical restraint prevalence in nursing homes using a guideline- and theory-based multicomponent intervention.

Design, Setting, and Participants Cluster randomized controlled trial of 6 months' duration conducted in 2 German cities between February 2009 and April 2010. Nursing homes were eligible if they had 20% or more residents with physical restraints. Using external concealed randomization, 18 nursing home clusters were included in the intervention group (2283 residents) and 18 in the control group (2166 residents).

Intervention The intervention was based on a specifically developed evidence-based guideline and applied the theory of planned behavior. Components were group sessions for all nursing staff; additional training for nominated key nurses; and supportive material for nurses, residents, relatives, and legal guardians. Control group clusters received standard information.

Main Outcomes Measures Primary outcome was percentage of residents with physical restraints (bilateral bed rails, belts, fixed tables, and other measures limiting free body movement) at 6 months, assessed through direct unannounced observation by blinded investigators on 3 occasions during 1 day. Secondary outcomes included restraint use at 3 months, falls, fall-related fractures, and psychotropic medication prescriptions.

Results All nursing homes completed the study and all residents were included in the analysis. At baseline, 30.6% of control group residents had physical restraints vs 31.5% of intervention group residents. At 6 months, rates were 29.1% vs 22.6%, respectively, a difference of 6.5% (95% CI, 0.6% to 12.4%; cluster-adjusted odds ratio, 0.71; 95% CI, 0.52 to 0.97; $P = .03$). All physical restraint measures were used less frequently in the intervention group. Rates were stable from 3 to 6 months. There were no statistically significant differences in falls, fall-related fractures, and psychotropic medication prescriptions.

Conclusion A guideline- and theory-based multicomponent intervention compared with standard information reduced physical restraint use in nursing homes.

Trial Registration isrctn.org Identifier: ISRCTN34974819

JAMA. 2012;307(20):2177-2184

www.jama.com

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Intervention programs developed in Europe and the United States all comprise educational approaches targeting nursing staff.^{8,9} Our recent Cochrane review⁸ did not reveal convincing evidence for the efficacy of educational approaches. However, most included studies had a high risk of bias. We developed an evidence-based practice guideline and subsequently derived a guideline-based multicomponent intervention aiming to reduce prevalence of physical restraint use. We used a cluster randomized controlled

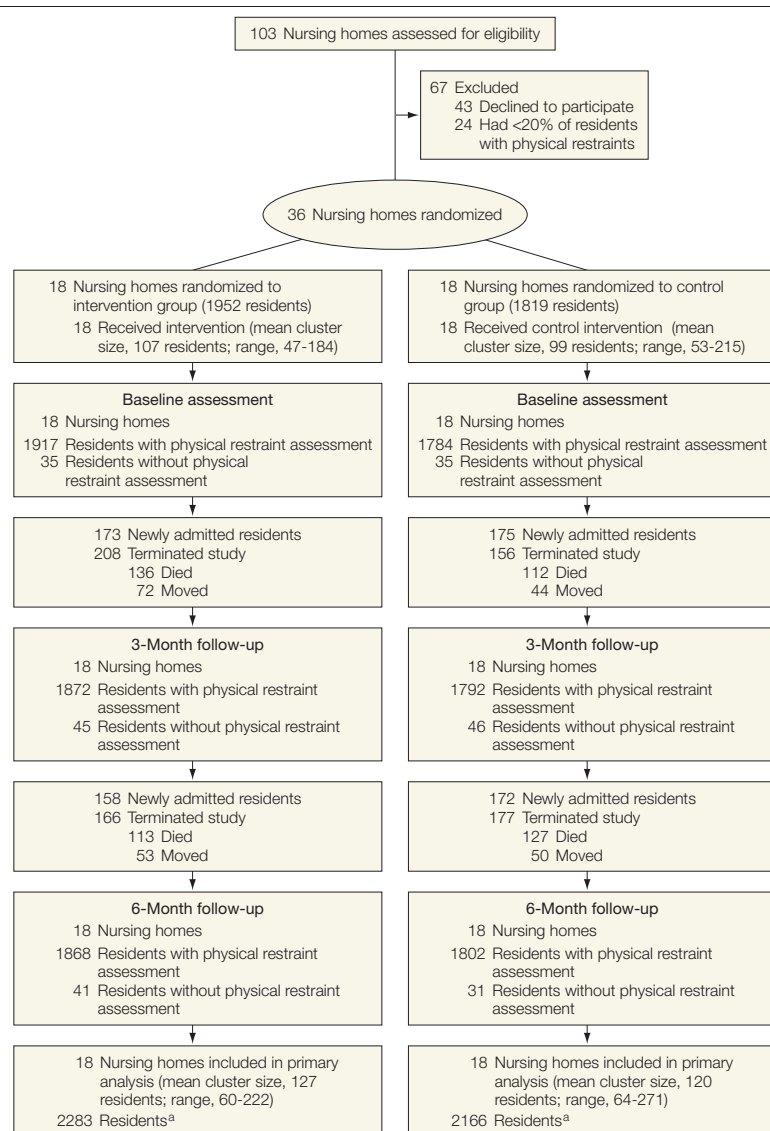
trial to test the effectiveness of the complex intervention in German nursing homes.

METHODS

Potential participating nursing homes were identified in the city of Hamburg in northern Germany and the city and region of Witten in western Germany through publicly available registers containing approximately 150 nursing homes in Hamburg and 90 in Witten and vicinity. Nursing homes were eligible if they had a self-reported rate of

at least 20% of residents with physical restraints, assessed by a short questionnaire completed by the head nurses. In Hamburg, all 19 nursing homes from an earlier epidemiological study¹ with at least 20% of residents with physical restraints were contacted first. Subsequently, 74 randomly selected nursing homes were contacted. In Witten, 10 nursing homes involved in previous research activities¹⁰ were contacted (FIGURE). Recruitment was terminated when the required sample size of 36 clusters was reached. A cluster was defined as a nursing home or an independently working unit within a large nursing home.

Figure. Flow of Clusters and Participants Through Trial



^aResidents who had at least 1 physical restraint assessment, who were present at baseline assessment, or both.

Guideline Development

The study started with the development of an evidence-based guideline. We used internationally recommended methodological procedures, published in advance.¹¹ First, representatives of 8 relevant organizations were contacted to assess possible guideline topics. Surveys were also conducted during this phase to determine the attitudes of nurses, residents, and family members.^{10,12,13}

In a next step, a multidisciplinary guideline development group of nationwide experts from all relevant fields, including a residents' representative, was convened. Group members received a 1-day introduction to evidence-based medicine and guideline development.^{14,15} The guideline development group met 5 times between October 2007 and May 2008. Based on systematic literature reviews following the GRADE framework,¹⁵ recommendations were made for 24 interventions to avoid use of physical restraints. The guideline includes only 1 strong recommendation for "educational programs for nursing staff." There are 7 weak recommendations in favor of and 2 against interventions and 14 interventions without recommendation (eTable 1, available at <http://www.jama.com>). Apart from the recommendations and comprehensive description of their evidence base, the 290-page guideline contains background informa-

tion, such as definitions of physical restraints, falls, and fall-related injuries and descriptions of legal issues. Concise versions were developed for nurses, legal guardians, relatives, and residents.

Intervention

A multicomponent intervention was developed based on the guideline, an exploration of best practices, and current research findings (eTable 2). To analyze best-practice strategies, we interviewed head nurses of nursing homes that had few physical restraints in our previous study.¹ The underlying theory of the intervention was the theory of planned behavior,¹⁶ which has been proven useful to explain health professionals' intentions and behavior.¹⁷ Based on earlier work on guideline implementation,¹⁸ the intervention aimed to address the 3 main components of the model: attitudes, subjective norms, and perceived behavioral control. In addition to full and concise versions of the guideline, the intervention provided information programs for all nursing staff, explicit endorsement of nursing home leaders, education and structured support of key nurses in each cluster, and support material (eTable 2).

All intervention components were pretested for feasibility and acceptability. In 3 focus group interviews, relatives of nursing home residents (n=9) and nursing home nurses (n=14) discussed the support material for the intervention (eTable 2). Participants viewed the guideline and support material as helpful and practical. A number of editorial changes were made following participants' suggestions. In 4 nursing homes not involved in the main study, the final 90-minute information program was presented to 41 nurses. Results led to minor modifications. All study procedures and instruments were pretested in 4 additional nursing homes randomly assigned to the control group (n=3) or the intervention group (n=1). Because the procedures proved feasible and no changes were made, the nursing homes were included in the main study.

In the control group, head nurses received written information about the use of physical restraints and methods to avoid physical restraints, using three 12- to 24-page brochures previously developed by a Hamburg-based multidisciplinary group. Also, the topic of physical restraints was discussed during a short presentation by one of the researchers. Apart from the experimental intervention, control group and intervention group clusters were treated equally. In Germany, nursing homes are legally required that at least 50% of nursing staff be fully trained, ie, registered, (geriatric) nurses with 3 years of vocational training. Other nursing staff have completed 1 year of training or on-the-job training.

Study Design

A detailed study protocol has been published.¹⁹ The study was a parallel-group cluster randomized controlled trial with 1:1 randomization and 6 months of follow-up. Because the intervention targeted institutions rather than individuals, randomization was carried out on a cluster level.

Computer-generated randomization lists were used for allocation of clusters in blocks of 4, 6, and 8 nursing homes. Randomization was stratified by region, ie, Hamburg and Witten. Allocation of clusters was performed by an external person not involved in the study, who informed cluster representatives about group assignment. The study ran from February 2009 to April 2010. Baseline data were assessed before randomization for all residents living in the cluster. Data on physical restraints were assessed for residents present on the day of data collection. All residents newly admitted to clusters during follow-up and present on the day of follow-up data collection were included in the study with a reduced set of baseline data. Therefore, study group sizes differ slightly between time points of physical restraint assessment (Figure). Residents were excluded if they had been admitted to nursing homes during the study but were not present on the day of physical restraint assessment.

Data on characteristics of nursing homes and residents were collected before randomization using instruments proven valid and feasible in earlier studies^{1,20} with minor adaptations. Characteristics of nursing homes were collected from head nurses. Characteristics were assessed for each resident living in the nursing home at the day of data collection. Residents received code numbers for deidentification, and nursing staff collected baseline data supported by the investigators. A validated proxy-rating tool²¹ was used to assess resident cognitive status. The scale has a maximum score of 16 (highest impairment) with a cutoff of 4 for cognitive impairment. Residents' behavioral and psychological symptoms related to dementia were determined using a modified Cohen-Mansfield Agitation Inventory,²² as used in previous studies.^{1,20} The inventory consists of 5 symptom complexes (restlessness, verbal agitation, handling things inappropriately, negative attitude, aggression), each rated on a 4-point Likert scale (never, once or twice, repeatedly, permanently), assessing symptoms within the preceding 4 weeks. All other data, including medication prescriptions, were extracted from residents' records with functional status assessed using degrees of disability of the German statutory health insurance system.²³ For feasibility reasons, a reduced set of characteristics was assessed for residents admitted during follow-up.

Data on the prevalence of physical restraint use at baseline were obtained by trained external investigators before randomization through direct observation at 3 time points during 1 day (morning, noon, evening). All residents with a physical restraint at 1 or more of the 3 time points were counted as having a restraint. For organizational reasons, assessment of baseline physical restraints took place 1 to 2 days after collection of demographic data, resulting in slightly different group sizes (Figure). To ensure resident privacy and to guarantee anonymity, the external investigators were accompanied by a

Table 1. Characteristics of Nursing Home Residents^a

	Baseline Sample		Total Sample	
	Intervention Group (n = 1917)	Control Group (n = 1784)	Intervention Group (n = 2283)	Control Group (n = 2166)
Age, mean (SD) [range], y	83 (10) [37-107]	85 (9) [38-107]	83 (10) [34-107]	85 (9) [38-107]
Women	1429 (75)	1420 (80)	1676 (73)	1677 (77)
Length of residence, median (range), mo	26 (10-57)	28 (10-56)	20 (4-50)	19 (3-49)
Degree of disability				
None	153 (8)	99 (6)	196 (9)	147 (7)
Considerable	642 (34)	642 (36)	812 (36)	833 (38)
Severe	756 (39)	721 (40)	874 (38)	835 (39)
Most severe	366 (19)	322 (18)	401 (18)	351 (16)
Residence at special dementia care unit	209/1907 (11)	213/1772 (12)	NA	NA
Legal guardian designated	885/1907 (46)	771/1772 (44)	NA	NA
≥1 Fall in preceding 12 mo	677/1835 (37)	649/1684 (39)	NA	NA
≥1 Fall-related fracture in preceding 12 mo	69/1834 (4)	84/1675 (5)	NA	NA
Cognitive impairment	1212/1905 (64)	1109/1761 (63)	NA	NA
Agitated behavior in preceding 4 wk				
Restlessness	761/1902 (40)	563/1770 (32)	NA	NA
Verbal agitation	528/1903 (28)	392/1769 (22)	NA	NA
Handling things inappropriately	529/1903 (28)	387/1769 (22)	NA	NA
Negative attitude	669/1892 (35)	464/1738 (27)	NA	NA
Aggression	432/1904 (23)	332/1769 (19)	NA	NA

Abbreviation: NA, not applicable.

^aValues are No. (percentage) or mean (SD) [range] if not indicated otherwise. In case of missing data, values are No./Total No. (percentage).

nurse who kept the code list and who also asked residents' permission for the investigator to enter their rooms. The date of data collection was only known to clusters' head nurses, who were instructed not to inform staff on the wards in order to ensure objective data assessment.

Data on prevalence of physical restraint use at the 3- and 6-month follow-ups were assessed similarly to baseline by external investigators blinded to cluster group allocation. To check for effective blinding, during the second measurement point at 3 months, external researchers were asked about their perception of the visited cluster's group allocation using a short questionnaire. If raters visited the cluster at 2 or all 3 time points, the questionnaire was completed at the last visit. After 6 months, data on medication prescriptions were again collected from residents' records. For practical rea-

sons, these were only assessed for residents present at the start of the study and still living in the nursing home at the end of follow-up. Falls and fall-related injuries were documented prospectively by nursing homes using their routine data collection systems as legally required.

Outcomes

The primary outcome was the percentage of residents with at least 1 physical restraint at the 6-month follow-up, with physical restraints defined as "any device, material, or equipment attached to or near the resident's body, which cannot be controlled easily or removed by the person and which deliberately prevents or is deliberately intended to prevent free body movement to a position of choice."²⁴ Secondary outcomes were the number of falls and fall-related fractures. Psychotropic medication data were extracted from

prescribed medications using the simple classification of the Anatomical Therapeutic Chemical Classification system,²⁵ as used in previous studies.²⁶

Different preplanned steps of process evaluation were performed to comprehensively analyze the underlying processes as well as barriers and facilitators of the multicomponent intervention (eTable 3).²⁷⁻²⁹

Cost parameters on the expenses for the implementation of the intervention were collected during and after the trial using a structured protocol. Institutional costs of the intervention's delivery were calculated based on documented real costs for materials and staff time spent.

Sample Size Calculation

Based on previous study data, we expected the control group to be mostly stable throughout the intervention with an assumed prevalence of physical restraint use of 33%.¹ The study design was planned to detect a reduction of physical restraint use in the intervention group to a rate of 21% at 6 months with a power of 90% and a significance level of 5% using a 2-sided cluster-adjusted χ^2 test.³⁰ The anticipated effect was assumed to exceed previously reported results of interventions aiming to reduce physical restraints.^{9,31,32} An intraclass correlation coefficient (ICCC) of 0.034 and a design factor of 5.0 were assumed based on published estimations under comparable circumstances.¹ Therefore, a sample of 2824 residents in 34 nursing homes with a mean cluster size of 83 residents was planned. Presuming a drop-out rate of 5% of nursing homes and 2% of residents (excluding residents with early study termination through death or moving), 36 nursing homes with a mean cluster size of 85 residents were needed.³⁰

Statistical Analyses

Statistical analyses were conducted after the end of follow-up by the statistician (B.H.), who was unaware of group allocation of clusters. No interim analyses were performed. Analyses were by intention to treat; no participants or clusters changed groups and

no cluster dropped out during follow-up. There were no missing data for the primary outcome after 3 and 6 months. Frequencies of missing data for baseline characteristics are presented in TABLE 1.

Baseline data for the 3 measuring points were analyzed descriptively for control group and intervention group without statistical testing or cluster adjustment except physical restraints and psychotropic medication prescriptions, which were adjusted for cluster.

The population analyzed for the primary end point consisted of participants seen at least once during physical restraint assessment after 6 months. The main outcome, ie, prevalence of residents with at least 1 physical restraint, was analyzed using a 2-sided cluster-adjusted χ^2 test at a level of significance of $\alpha = .05$.³⁰ Additionally, corresponding cluster-adjusted 95% confidence intervals of prevalence and nonadjusted odds ratio (OR) differences were calculated³⁰ and estimations of pooled ICC reported. Cluster-adjusted 95% confidence intervals of prevalence data were estimated corresponding to the cluster size weighted prevalence estimation from cluster means taking into account variance of cluster means.^{30,33} Cluster size weight

refers to the proportion of the cluster to the specific analysis population, and only confidence intervals had to be adjusted for cluster correlation.

Further outcome measures, ie, prevalence of different physical restraints at different measurement points, falls, fall-related fractures, and psychotropic medication prescriptions, were analyzed using the same methods.³⁰ Statistical tests and confidence intervals were calculated for separate populations at baseline, after 3 months, and after 6 months. In a post hoc analysis, we completed a repeated-measures analysis as well (eAppendix). Statistical analyses were performed using SAS version 9.3 TS1M0 (on Windows 7, 64 bit; SAS Institute).

Ethical Considerations

The protocol was approved by the ethics committees of the School of Nursing Science at Witten/Herdecke University (April 24, 2009) and the Hamburg Chamber of Physicians (April 8, 2009; reference No. PV3165) as well as the Hamburg data protection office. Head nurses or managers of participating nursing homes gave written informed consent. As successfully applied in an earlier study,¹ a waiver of consent from participating residents

was obtained from the data protection officer and the ethics committees. To protect resident privacy, investigators had no direct access to resident data, and all resident-related data were de-identified. Investigators were unaware of residents' data, including their names.

RESULTS

Thirty-six nursing homes were included with 3771 residents at baseline: 18 nursing homes with 1952 residents in the intervention group and 18 nursing homes with 1819 residents in the control group. Three clusters (all in Hamburg and all in the control group) were independently working units within a large nursing home; 33 were entire nursing homes. Clusters were of variable size (eTable 4). Thirty nursing homes were located in Hamburg and 6 in the city or the area of Witten. The number of residents differed between measurement points: 3701 at baseline assessment, 3664 after 3 months, and 3670 after 6 months, resulting in 4449 residents assessed at least once during the study (Figure). Six hundred seventy-eight residents were included after initial baseline assessment in their nursing home. Overall, 707 residents terminated the study early

Table 2. Prevalence of Physical Restraint Use

	Baseline		3-Month Follow-up		6-Month Follow-up	
	Intervention Group (n = 1917)	Control Group (n = 1784)	Intervention Group (n = 1872)	Control Group (n = 1792)	Intervention Group (n = 1868)	Control Group (n = 1802)
Any physical restraint, No.	604	545	447	546	423 ^a	525 ^a
% (95% CI) ^b	31.5 (26.1-37)	30.6 (25.6-35.5)	23.9 (19.3-28.5)	30.5 (26.6-34.4)	22.6 (18.5-26.8)	29.1 (25.0-33.3)
Restrictive bed rails, No.	559	505	406	490	379	472
% (95% CI) ^b	29.2 (22.7-35.6)	28.3 (23.1-33.5)	21.7 (16.9-26.5)	27.3 (22.7-32)	20.3 (16-24.6)	26.2 (21.7-30.7)
Any waist belt, No.	53	51	42	56	31	54
% (95% CI) ^b	2.8 (1-4.5)	2.9 (1.2-4.5)	2.2 (0.6-3.9)	3.1 (1.7-4.5)	1.7 (0.7-2.6)	3.0 (1.9-4.1)
Waist belt in bed, No.	12	17	13	16	17	19
% (95% CI) ^b	0.6 (0.2-1.1)	0.9 (0.06-1.9)	0.7 (0.3-1.1)	0.9 (0.2-1.6)	0.9 (0.4-1.4)	1.1 (0.07-2)
Waist belt in chair, No.	47	40	35	42	20	41
% (95% CI) ^b	2.5 (0.8-4.1)	2.2 (0.9-3.6)	1.9 (0.4-3.3)	2.3 (1.2-3.5)	1.1 (0.2-1.9)	2.3 (1.3-3.2)
Fixed table, No.	40	29	31	33	8	30
% (95% CI) ^b	2.1 (0.7-3.5)	1.6 (0.6-2.6)	1.7 (0.7-2.6)	1.8 (0.9-2.8)	0.4 (0.1-0.7)	1.7 (0.6-2.8)
Other physical restraint, No.	71	70	49	82	67	78
% (95% CI) ^b	3.7 (1.9-5.5)	3.9 (1.7-6.2)	2.6 (1.5-3.8)	4.6 (2.1-7.1)	3.6 (1.5-5.7)	4.3 (1.6-7.1)

^aPrimary end point.

^bAll percentages and CIs are adjusted for cluster.

due to death (n=488) or moving (n=219). No nursing home dropped out of the study.

Baseline characteristics of clusters and participants, including physical restraints, were generally comparable between study groups (eTable 4, Table 1, and TABLE 2). Five nursing homes had lower than the self-reported prevalence of 20% of residents with physical restraints (eFigure), most likely a result of usual fluctuations.

Results for the primary outcome, ie, prevalence of physical restraint use at 6 months, are displayed in Table 2 and the eFigure. At baseline, prevalence of physical restraint use was comparable between groups: 31.5% in the intervention group vs 30.6% in the control group. After 6 months, physical restraint prevalence was significantly lower in the intervention group, 22.6%, vs 29.1% in the control group (difference, 6.5%; 95% CI, 0.6% to 12.4%; cluster-adjusted OR, 0.71; 95%

CI, 0.52 to 0.97; $P=.03$; ICC, 0.029). The eFigure provides a graphical illustration of the results. All physical restraints were used less frequently in the intervention group compared with the control group. Results at 3 months showed similar results: intervention group: 23.9%, vs 30.5% in the control group, a difference of 6.6% (95% CI, 0.6% to 12.6%; OR, 0.72; 95% CI, 0.53 to 0.97; $P=.03$; ICC, 0.029) (Table 2).

Results for falls, fall-related fractures, and prescriptions of psychotropic medication showed no statistically significant differences between groups (TABLE 3 and TABLE 4).

Results of the process evaluation (eTable 2) will be published in detail elsewhere and are therefore only presented in brief. Overall, 50 information programs were administered to the 18 intervention group clusters with 569 nurses participating. Directly after the course, the majority (74.5%) under-

stood at least 4 of the 6 questions concerning the program's main messages. A short survey at the end of the study with 1 randomly chosen staff nurse in each nursing home revealed that nurses found the intervention to have changed "institutional cultures" and nurse attitudes toward physical restraints. The qualitative analysis of 40 in-depth interviews with nominated key nurses and head nurses identified important facilitators of and barriers to reducing prevalence of physical restraint use. Potential facilitators were supportive attitudes among head nurses; in-house quality circles with case discussion; counseling and education of relatives; and explicit and qualified information for judges, legal guardians, and physicians. Important barriers were negative experiences of nurses, concerns and uncertainties of relatives and legal guardians, and organizational problems (eg, staff fluctuation).

Resource use due to the implementation of the multicomponent intervention yielded total costs of \$36 838 (€27 288) in the intervention group (eTable 5).

The survey of external researchers' perception of visited clusters' group allocation indicated successful blinding. During 69 visits at the 3-month follow-up, 37 ratings (53.6%; 95% CI, 41.2%-65.7%) were correct in identifying clusters as an intervention group or control group cluster.

Table 3. Falls and Fall-Related Fractures During the Study Period

	Intervention Group (n = 2283)	Control Group (n = 2166)	Difference, % (95% CI)	OR (95% CI)
Residents with ≥1 fall, No.	528	565		
% (95% CI) ^a	23.1 (19.1 to 27.2)	26.1 (21.1 to 31.1)	3.0 (−3.5 to 9.4)	0.85 (0.60 to 1.21)
Residents with ≥1 fall-related fracture, No.	32	40		
% (95% CI) ^a	1.4 (0.8 to 2.0)	1.9 (1.1 to 2.6)	0.5 (−0.5 to 1.4)	0.76 (0.42 to 1.38)

Abbreviation: OR, odds ratio.

^aPercentages and CIs are adjusted for cluster.

Table 4. Psychotropic Medication Prescriptions

	Baseline			6-Month Follow-up		
	Intervention Group (n = 1917)	Control Group (n = 1784)	Difference, % (95% CI)	Intervention Group (n = 1562) ^a	Control Group (n = 1485) ^a	Difference, % (95% CI)
Any psychotropic drug, No.	1052	966		854	802	
% (95% CI) ^b	54.9 (51.6 to 58.2)	54.1 (49.8 to 58.5)	−0.7 (−6.2 to 4.7)	54.7 (51.1 to 58.3)	54.0 (50.1 to 57.9)	−0.7 (−6.0 to 4.6)
Antipsychotics, No.	593	505		478	419	
% (95% CI) ^b	30.9 (27.5 to 34.4)	28.3 (24.0 to 32.6)	−2.6 (−8.1 to 2.9)	30.6 (26.4 to 34.8)	28.2 (23.3 to 33.1)	−2.4 (−8.8 to 4.0)
Anxiolytics, No.	224	206		186	162	
% (95% CI) ^b	11.7 (9.3 to 14.0)	11.5 (8.6 to 14.5)	−0.1 (−3.9 to 3.6)	11.9 (9.2 to 14.6)	10.9 (8.0 to 13.8)	−1.0 (−5.0 to 3.0)
Hypnotics, No.	165	161		133	130	
% (95% CI) ^b	8.6 (6.5 to 10.7)	9.0 (7.0 to 11.1)	0.4 (−2.5 to 3.3)	8.5 (6.2 to 10.9)	8.8 (7.3 to 10.2)	0.2 (−2.5 to 3.0)
Antidepressants, No.	464	476		402	410	
% (95% CI) ^b	24.2 (20.3 to 28.1)	26.7 (22.9 to 30.4)	2.5 (−2.9 to 7.9)	25.7 (21.7 to 29.8)	27.6 (23.6 to 31.6)	1.9 (−3.8 to 7.6)

^aResidents assessed at both baseline and 6 months.

^bPercentages and CIs are adjusted for cluster.

COMMENT

Our cluster randomized controlled trial demonstrated that a guideline-based multicomponent intervention significantly reduced prevalence of physical restraint use. The basis for the intervention was a carefully developed evidence-based guideline on the avoidance of physical restraints that followed recent methodological standards of guideline development. However, the guideline in our study was merely the basis for the intervention, not its central component. As opposed to other guideline-based interventions, the central recommendation is not to perform a certain action, ie, not to apply physical restraints. Therefore, the main message of the guideline and the related intervention is that it is possible to refrain from using restraints. It is also made clear that implementing a certain set of “alternatives” is not an adequate strategy, as there is no strong evidence that these help avoid use of restraints.

Our study results extend the small body of evidence on interventions aiming to reduce prevalence of physical restraint use. Earlier controlled trials reported complex interventions with inconsistent results. However, their methodological quality was limited and process evaluation explaining barriers and facilitators had not been reported.^{8,34,35}

In our recent Cochrane review,⁸ we summarized 5 randomized controlled trials aiming to reduce prevalence of physical restraint use. In contrast to these previous studies, the present intervention was rigorously based on relevant theory and extensive preparatory work. The intervention also comprises different components targeting all relevant persons, aiming to implement a “practice culture” without physical restraints. It therefore goes beyond other approaches that were restricted to nurse education and counseling.^{31,32,36,37}

We developed our intervention according to the UK Medical Research Council's methodological guidance for the development and evaluation of

complex interventions.²⁸ Our process evaluation, for example, shows the important role of head nurses in nursing homes with marked reduction in the prevalence of physical restraint use. However, because of the exploratory nature of the process evaluation, findings should not be overinterpreted. In particular, associations between single process measures and outcomes might not be causally related.

Our study has important strengths. All study procedures were transparently reported in advance.^{11,19} Study procedures ensured a low risk of bias. We used direct observation to assess prevalence of physical restraint use. The study also has potential limitations. Head nurses of control and intervention clusters had to be informed about the dates for assessing prevalence of physical restraint use. Although they had agreed not to communicate the dates to their staff, information leakage cannot be ruled out. However, we had investigated this methodological problem in a preparatory study and found comparable results for scheduled and unannounced visits.¹ The analysis of psychotropic medication use was limited to residents present both at baseline and at 6 months. Furthermore, concerning physical restraint use, 6 months may appear to be a short time period in which to judge the sustainability of a fundamental change in practice. Nevertheless, considering the consistent effects after 3 and 6 months, we are confident that a “culture change” has been achieved, resulting in a continuing avoidance of physical restraints. As it seems infeasible to further optimize the intervention with justifiable effort, more pronounced reduction or even complete prevention of physical restraint use may require more stringent implementation of legal regulations with clear penalties. The results of this study are likely generalizable to countries with comparable legal and professional conditions.

Author Contributions: Drs Köpke and Meyer had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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Critical revision of the manuscript for important intellectual content: Gerlach, Haut, Haastert, Möhler.

Statistical analysis: Haastert.

Obtained funding: Köpke, Mühlhauser, Meyer.

Administrative, technical, or material support: Gerlach, Haut, Möhler.

Study supervision: Köpke, Mühlhauser, Meyer.

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and none were reported.

Funding/Support: The study was funded by a grant from the German Federal Ministry of Education and Research within the Nursing Research Network Northern Germany (projects 01GT0606 and 01GT0608).

Role of the Sponsor: The funding body approved the design of the study but had no role in the conduct of the study; in the collection, management, analysis, and interpretation of the data; or in the preparation, review, or approval of the manuscript.

Disclaimer: The opinions, results, and conclusions reported in this article are those of the authors and are independent of the funding source.

Online-Only Material: eTables 1 through 5, the eFigure, and the eAppendix are available at <http://www.jama.com>.

Additional Contributions: We thank the study coordinators, nursing staff, and participating residents of 36 nursing homes and the members of the guideline development group. We also thank research assistants Britta Blotenberg, BScN (Witten/Herdecke University), Christiane Brinkmann (University of Hamburg), Pia von Lützu, MScN (Witten/Herdecke University), and Eva Schmidt (University of Hamburg), whose work was funded by the German Ministry of Education and Research, for assistance in data collection and administration. None of the practice partners received compensation for the contributions.

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