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Restraint use among nursing home residents: cross-sectional study and prospective cohort study

Gabriele Meyer, Sascha Köpke, Burkhard Haastert and Ingrid Mühlhauser

Aims and objectives. To investigate (1) the prevalence of physical restraints and psychoactive medication, (2) newly administered physical restraints, frequency of application of the devices and frequency of psychoactive medication on demand during 12-month follow-up and (3) characteristics associated with restraint use in nursing homes.

Background. High quality data on restraint use in German nursing homes are lacking so far. Such information is the basis for interventions to achieve a restraint-free care.

Design. Cross-sectional study and prospective cohort study.

Setting and subjects. Thirty nursing homes with 2367 residents in Hamburg, Germany.

Methods. External investigators obtained prevalence of physical restraints by direct observation on three occasions on one day, psychoactive drugs were extracted from residents' records and prospective data were documented by nurses.

Results. Residents' mean age was 86 years, 81% were female. Prevalence of residents with at least one physical restraint was 26·2% [95% confidence interval (CI) 21·3–31·1]. Centre prevalence ranged from 4·4 to 58·9%. Bedrails were most often used (in 24·5% of residents), fixed tables, belts and other restraints were rare. Prevalence of residents with at least one psychoactive drug was 52·4% (95% CI 48·7–56·1). The proportion of residents with at least one physical restraint after the first observation week of 26·3% (21·3–31·3) cumulated to 39·5% (33·3–45·7) at the end of follow-up (10·4 SD 3·3 months). The relative frequency of observation days with at least one device ranged from 4·9–64·8% between centres. No characteristic was found to explain centre differences.

Conclusions. The frequency of physical restraints and psychoactive drugs in German nursing homes is substantial. Pronounced centre variation suggests that standard care is possible without restraints.

Relevance to clinical practice. Effective restraint minimisation approaches are urgently warranted. An evidence-based guideline may overcome centre differences towards a restraint-free nursing home care.

Key words: epidemiology, nurses, nursing, nursing homes, older people, restraint

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Introduction

Debate about neglect and abuse of nursing home residents continues. Physical and pharmacological restraints have been blamed as measures that go conversely with residents' autonomy, freedom and their right to take risks. Justification for controlling psychomotor agitation, delirium and increased risk of falling has been increasingly questioned. A

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restrained-free nursing care environment is demanded as standard of care while anything less is regarded as substandard (Flaherty 2004).

Reported prevalence of physical restraints ranges between 15–70% (Hamers & Huizing 2005). The wide variation can be explained by different underlying definitions of physical restraints, data collection techniques, different sample sizes, characteristics of care settings, legislation and nursing traditions. Various types of physical restraints have been reported. Bedrails, belts and chairs with a table are most frequently used (Hamers & Huizing 2005).

Prospective studies determining newly administered restraints and the frequency of application of the devices are rare (Tinetti *et al.* 1991, Hamers *et al.* 2004). Only few investigations included psychoactive drugs (Phillips *et al.* 2000) that could act as chemical restraint by controlling behaviour.

German media regularly report high numbers of physical restraints. A recent television feature claimed that 400,000 belts are used in nursing home residents per day (Report Mainz 2004). An earlier questionnaire survey reported a prevalence of 40% and raised concern about the legal justification of physical restraints (Hoffmann & Klie 2004). However, high quality epidemiological data on restraints in German nursing homes are lacking so far. Such information would be a necessary basis for future interventions to achieve a restraint-free nursing care.

Therefore, we performed a cross-sectional study on the prevalence of physical restraints and psychoactive medication prescriptions in nursing homes and a 12-month cohort study on newly administered physical restraints, the frequency of application of the devices and the frequency of psychoactive drugs on demand. We also investigated associations with restraint use. A survey on nurses' emotional distress due to decisions on physical restraints will be reported elsewhere.

Participants and methods

Nursing homes and residents

We consecutively invited nursing homes in Hamburg, Germany, until 30 of 150 agreed to participate. In total, 79 invitation letters were sent and 80 personal presentations were given for 45 nursing homes that were interested in participation (Fig. 1). Recruitment took place from November 2004 to April 2005. In each nursing home a study coordinator was nominated. Nursing staff collected baseline data supported by the investigators. Cognitive status was recorded using a validated eight-question proxy-rating tool

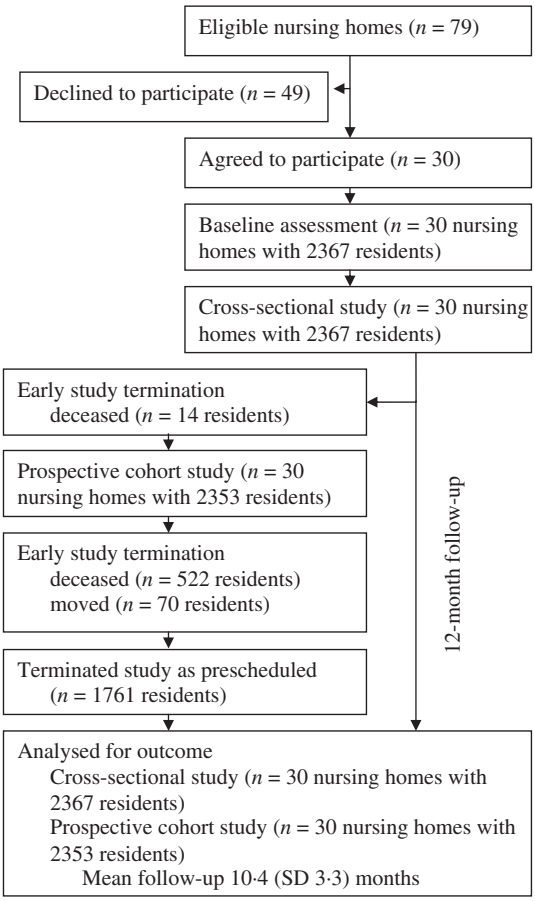

Figure 1 Flow of nursing homes and participants through trial.

with a maximum score of 16 points (highest impairment). All items except one are positively formulated statements related to personal, temporal and local orientation regarding the last four weeks. The cut off is defined as ≥4 points (Weyerer *et al.* 2005). Nurses were asked to rate residents' current risk taking behaviour using a six-point Likert scale (very high, high, fairly high, moderate, a little, not at all). Residents' dementia-related behaviour problems were determined using a modified Cohen Mansfield Agitation Inventory (Cohen-Mansfield 1986) on five symptom complexes: (1) general restlessness, defined as pacing, aimless wandering, trying to get to a different place; (2) verbal agitation, defined as making strange noises, screaming, repetitive sentences or questions; (3) handling things inappropriately, defined as inappropriate dressing or disrobing, (4) negative attitude, defined as complaining, negativism, constant request for attention; (5) aggression, defined as cursing or verbal aggression, hitting or hurting ones selves or others, throwing things, pushing, kicking, grabbing people. The items were rated on a four-point Likert scale (never, once or twice, repeatedly, permanently) regarding the last four weeks.

All other data were extracted from the residents' records. For description of the functional status of the residents we used degrees of disablement as assessed by expert raters of the medical service of the German statutory health insurance system (0, none; 1, considerable; 2, severe; 3, most severe) (Dalichau *et al.* 2002). All medication prescriptions were noted. Two trained investigators determined psychoactive medications according to the Anatomical Therapeutic Chemical Classification 2005 (ATC 2005). The study population consisted of all residents who were present in the nursing home at the day of data collection for the cross-sectional study. Residents newly admitted during the prospective cohort study were not included. All instruments were piloted for feasibility and acceptability in one nursing home which was not included in the main study.

Cross-sectional study

According to a widely accepted definition, physical restraints were 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' (Evans *et al.* 2002). Prevalence data were obtained by trained external investigators observing all physical restraints on three occasions (10 a.m., 3 p.m. and 8 p.m.) on one day. A case was defined as prevalent if at least one physical restraint was observed on at least one occasion. For ethical reasons and due to data protection regulations a member of the nursing staff accompanied the investigators. Residents' rooms were only entered after the nurse had asked the resident if he or she agreed to be visited.

The prevalence data collection sheet contained the options restrictive bedrails, belt in chair, belt in bed, chair with table and other measure. The latter included tipping chairs, blankets or sheets, vests, wrist or elbow restraints and manipulation of furniture. Restrictive bedrails were defined as bilateral bedrails or a bedrail at one side of the bed with the other positioned at the wall. If unsure whether a measure acted as physical restraint the investigators discussed the issue with the nurse in charge to verify their observations. The nurse in charge checked the residents' records on documented justification for restraint use. Nursing staff at the ward was not informed *a priori* about the prevalence data collection except the nurse in charge who was instructed to conceal date and time of the visits.

Prospective cohort study

The median time between prevalence data collection and the beginning of the prospective study was seven days (range 4–32). In advance, nursing staff were trained how to use the specially developed report form which covered four weeks and required shift-wise documentation of physical restraints administered at any time during a nursing shift. A sheet for each resident was provided and renewed monthly. Prospective data collection was restricted to bedrails, belts and chairs with tables, which fulfilled the definition of a physical restraint. We did not ask for other measures as the pilot study had shown that these are subject to personal interpretation, challenging data validity.

Data were checked for completeness and plausibility at least every two months during personal visits. Uncertainties were discussed with the nurse in charge. Psychoactive medication on demand and falls were extracted from residents' records by the nurse in charge. Falls during follow-up were assessed for association analysis purpose only.

At the end of the study we aimed to verify the validity of nurses' documentation on physical restraints through direct observation. Six nursing homes were randomly selected and unscheduled visits were carried out to document the physical restraints applied. The two investigators were blind to the last results of nurses' documentation. Results of the observation were compared with nurses' documentation on the report form.

Sample size

Assuming a prevalence of 30% of restraint use and a corresponding intra-cluster correlation coefficient (ICCC) of 0·005 it was planned to recruit 1478 evaluable participants in 30 nursing homes to estimate a 95% confidence interval (CI) of the prevalence of restraint use in a precision of ±2·5% (i.e. 27·5–32·5%). However, in the study 2367 evaluable participants were recruited in 30 nursing homes and the corresponding ICCC was estimated as 0·08 resulting in a 95% CI of about double width compared to the planning.

Statistical methods

Baseline characteristics of nursing homes and residents were described as means ± standard deviations (SD) and numbers and percentages. Cluster-adjustment of these data was avoided to describe the raw baseline characteristics of the study population. All parameters describing the use of restraints, psychoactive medication and falls during follow-up were considered as outcomes. These outcome variables are

correlated within the clusters. Without adjustment for cluster-correlation the variances would be underestimated. Methods for cluster-adjusted estimation of prevalences, means and their variances are well known from cluster-randomised trials (Donner & Klar 2000, Kerry & Bland 2001) and are also recommended for non-randomised trials (Donner & Klar 2000). Residents' values are averaged within the clusters, the estimator is the weighted mean over all clusters and the cluster-adjusted variance is the variance of the weighted mean taking into account the variance of the cluster means (Kerry & Bland 2001). As weights cluster sizes are frequently used as described by Donner and Klar (2000). We used the minimum variance weights because in case of unequal cluster sizes these weights yield a smaller increase of the variance due to the design effect from clustering (Kerry & Bland 2001). The differences from the results using cluster size weights (results not shown) were small.

For each outcome variable the cluster-correlation was estimated by the corresponding ICCC. To allow statisticians of future trials precise sample size estimation ICCCs are reported in this paper. From the cluster-adjusted estimators cluster-adjusted approximate two-sided 95% CIs for prevalences and cluster-adjusted standard deviations (SDs) were calculated.

The primary outcome of the cross-sectional study was prevalence of restraints at the observation day. In the prospective study the application of restraints was documented daily for each resident. Observation time could have been temporarily interrupted due to hospitalisation or vacancy or terminated early due to death or moving.

First, the overall prevalence of restraints during the observation period was estimated. The time to the first restraint was evaluated as event time. Temporary absence was counted as period without restraints. Residents with application of restraints at the first observation day were included. If residents were not restrained during observation the last day of observation was evaluated as censoring time. Time dependent proportions of residents with at least one application of restraint since study entry were calculated using Kaplan–Meier curves. The corresponding proportion after 12 months (end of the trial) is the estimator of the cumulative prevalence after 12 months. The 95% CIs of the Kaplan–Meier estimators were calculated using corresponding variance estimators adjusted for cluster-correlation (Williams 1995). The frequency of application of restraints was estimated by the relative frequency of restrained days for each resident (absent days not counted).

Associations of characteristics of institutions or residents with restraint use were investigated by multiple logistic regression analysis. For the cross-sectional part of the study the outcome was defined as at least one physical restraint on at least one of the three observation occasions, for the prospective part as use of restraints in more than half of observation days per resident. Correlation within the clusters was considered by robust variance estimation (Huber-White-sandwich estimates of variance) (Rogers 1993, Williams 2000). Cluster-adjusted odds ratios (AORs) were estimated in these models.

A set of 27 baseline variables on nursing homes and residents and additional three prospectively generated characteristics (length of observation time, fall during follow-up, psychoactive medication on demand) were evaluated in cluster-adjusted univariate models. All covariables significantly associated with the outcome were included in cluster-adjusted multiple logistic regression models. These were in the cross-sectional part of the study: length of residence, short term care, degree of disablement, legal guardian designated, fall during preceding four weeks, fracture during preceding 12 months, repeated or permanent restlessness, verbal agitation, aggression, cognitive impairment, church owned nursing home; and within the prospective part: length of residence, degree of disablement, legal guardian designated, fracture during preceding 12 months before the study, repeated or permanent restlessness, verbal agitation, aggression, cognitive impairment, church owned nursing home, length of observation time, fall during follow-up.

The final model was built in two steps: at first the significant covariables (i.e. cluster-adjusted odds ratio differing significantly from the univariate models) were included into a multiple model. From this multiple model all non-significant covariables were deleted in the second step. For classified covariables with more than two classes all classes were included or excluded simultaneously from the model depending whether one class was significant. The level of significance was 5%. Statistical analysis was performed using the statistical software packages SAS 9·1 TS1M3 and STATA 9·0 (robust variance estimation).

Ethical approval and funding

The protocol was approved by the ethics committee of the Hamburg chamber of physicians and the regional data protection office and published in a German language nursing journal (Meyer *et al.* 2005).

Results

Figure 1 shows the flow of nursing homes and residents through the trial. A total of 2367 residents were seen at least once at the day of data collection and therefore included into

the cross-sectional study. Fourteen residents died between the cross-sectional study and the beginning of the prospective cohort study, resulting in a follow-up cohort of 2353 residents. A total of 592 residents (25%) terminated the 12-month follow-up period early, mostly due to death (n = 522), resulting in an observation period of 10·4 (SD 3·3) months. All nursing homes completed the study. Baseline characteristics of nursing homes and residents are displayed in Tables 1 and 2.

Mechanical restraints

The cross-sectional study resulted in a cluster-adjusted prevalence of residents with at least one physical restraint of 26·2% (95% CI 21·3–31·1). Bed rails were the most frequently observed restraint (in 24·5% of residents, 95% CI 19·5–29·5). Residents observed with belts, chairs with a table and other measures were comparably rare (Table 3). Centre prevalence of residents with at least one physical restraint ranged from 4·4 to 58·9%.

Approximately half of the restraints were authorised by a judge (42·9%) or residents' written consent (10·9%) and therefore fulfilled current legal standards in Germany. In 10·1% nurses stated that the resident had given his or her verbal consent. Other devices were applied due to nurses' or legal guardians' decision (14·1% respectively 15·7%) or to relatives' (3·3%) or physicians' (3·1%) decision.

The cluster-adjusted proportion of residents with at least one mechanical device after the first observation week of 26·3% (95% CI 21·3–31·3) cumulated to 39·5% (33·3–45·7) at the end of follow-up (Fig. 2). Again, pronounced centre variation was documented as the relative frequency of observation days with at least one device ranged from 4·9 to 64·8%.

For verification of nurses' documentation a representative subgroup of 206 residents from six randomly selected nursing homes were directly observed during an unscheduled visit at the end of the study. Agreement between the two data collection methods was high. Except for one belt there was no underreporting.

Table 1 Baseline characteristics of nursing homes*

Characteristic	n = 30
Ownership of homes	
Private	12 (40)
State owned	1 (3)
Affiliated to church	6 (20)
Non-profit	11 (37)
Homes with at least one dementia care unit	10 (33)
Residents per home	80 ± 51 (19–210)
Residents per caregiver	2·4 ± 0·7 (1·1–4·0)
Proportion of trained nursing staff	58 ± 7 (43–69)
Residents per night nurse	36 ± 14 (16–62)
Homes with instruments to control restraint use	
In-house standard of care	18 (60)
Special nursing documentation sheet	24 (80)

Values are numbers (percentage) or mean ± standard deviation (range).
*Not cluster-adjusted.

Table 2 Baseline characteristics of nursing home residents*

Characteristic	n = 2367
Women	1919 (81)
Mean ± SD (range) age, years	86 ± 8 (40–108)
Median (interquartile) length of residence, months	29 (12–54)
Residence at special dementia care unit	260 (11)
Legal guardian designated	958 (40)
Degree of disablement	
None	225 (10)
Considerable	777 (33)
Severe	942 (40)
Most severe	423 (18)
Indwelling urinary catheter	192 (8)
Feeding tube	115 (5)
Cognitive impairment	1335 (56)
Risk taking behaviour	
Not at all	1186 (50)
Low/moderate	758 (32)
High/very high	423 (18)
Agitated behaviour ≥1 during preceding four weeks	
Restlessness	847 (36)
Verbal agitation	556 (24)
Handling things inappropriately	588 (25)
Negative attitude	727 (31)
Aggression	536 (23)
Fall during preceding 12 months	893 (38)
Unknown	97 (4)
Fall during preceding four weeks	303 (13)
Unknown	25 (1)
Fracture during preceding 12 months	168 (7)
Unknown	81 (3)

Values are numbers (percentage) unless stated otherwise.
*Not cluster-adjusted.

Psychoactive medication and falls

The cluster-adjusted prevalence of residents with at least one prescription of psychoactive medication was 52·4% (95% CI 48·7–56·1), with antipsychotic medication most commonly prescribed in 28·4% (24·2–32·7) of residents (cross-sectional data, Table 4). Prevalence of residents with antidepressants was 20·1% (17·9–22·3), of these about one third were

Table 3 Frequency of mechanical restraints

	% (95% confidence interval)	ICCC
Cross-sectional study (***n*** **= 2367**)		
Residents with ≥1 restraint	26·2 (21·3–31·1)	0·0818
Residents with observed application of restrictive bedrails	24·5 (19·5–29·5)	0·0906
Waist belt used in a chair or bed	2·7 (1·6–3·9)	0·0230
Chair with a table	2·1 (1·3–2·9)	0·0115
Other device	2·3 (0·8–3·9)	0·0593
12-month follow-up study (*n* = 2353)		
Residents with ≥1 restraint	39·8 (33·6–45·9)	0·1074
Residents with documented application of restrictive bedrails	38·5 (32·2–44·8)	0·1170
Waist belt used in a chair or bed	8·9 (5·8–12)	0·0647
Chair with a table	9·9 (7–12·7)	0·0569
Observation days with documented application of restrictive bedrails	27·7 (22·5–33)	0·1065
Waist belt used in a chair or bed	3·1 (1·7–4·5)	0·0475
Chair with a table	2·2 (1·3–3·1)	0·0312
Observation days within the subgroup of restrained residents with documented application of restrictive bedrails (*n* = 870)	70·4 (65·9–74·8)	0·0593
Waist belt used in a chair or bed (*n* = 233)	33·8 (24·3–43·2)	0·2204
Chair with a table (*n* = 227)	22·9 (16·1–29·7)	0·1794

Values are cluster-adjusted percentages (95% confidence interval) and intra-cluster correlation coefficients (ICCC).

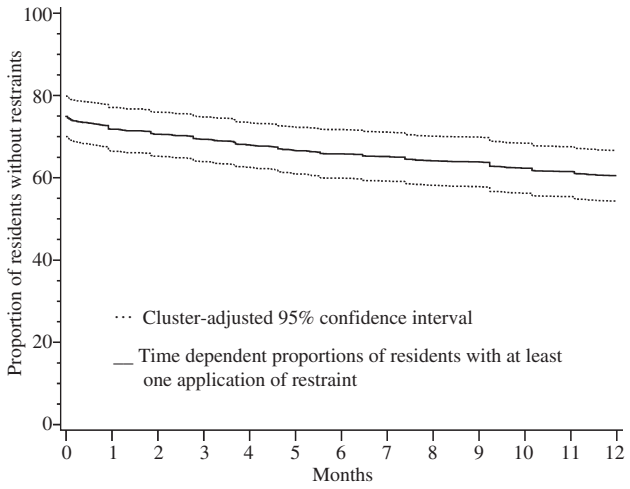

Figure 2 Kaplan-Meier curve and 95% confidence interval.

selective serotonin reuptake inhibitors with a prevalence of 6·3% (4·9–7·7).

Centre prevalence of residents with at least one prescription ranged from 27·8 to 83·3%. Results for psychoactive medication on demand during the 12-month follow-up are displayed in Table 4. Fall documentation throughout the observation period yielded 804 residents (34·2% raw, 32·5% (95% CI 28·7–36·3) cluster-adjusted) experiencing a total of 2578 falls.

Associations of physical restraints use

Table 5 displays the results of the cluster-adjusted multiple logistic regression analysis within the cross-sectional study and the prospective cohort study. Degree of disablement, cognitive impairment and fracture during preceding 12 months before the study were positively significantly associated with the use of restraints in both studies.

The variable fall during four weeks before the observation period was inversely associated to the use of physical restraints within the cross-sectional study (AOR 0·69, 95% CI 0·49–0·95, $p = 0·025$), as well as the variable fall during follow-up to the use of restraints in more than half of follow-up days per resident (AOR 0·36, 95% CI 0·26–0·49, $p < 0·001$). Repeated verbal agitation was positively associated to the use of restraints within the prospective study (AOR 1·48, 95% CI 1·02–2·15, $p = 0·037$). None of the institutional characteristics assessed was associated with a higher likelihood of physical restraint use.

Discussion

This cross-sectional study is the first determining the prevalence of physical restraints in nearly 2400 residents from 30 nursing homes by direct observation, which is undoubtedly the most valid and reliable method (Laurin *et al.* 2004). The

Table 4 Psychoactive medication

	% (95% confidence interval)	ICCC
Cross-sectional data on prescribed medication (*n = 2367*)		
Residents with ≥1 psychoactive medication	52·4 (48·7–56·1)	0·0267
Residents with ≥1		
Antipsychotic medication	28·4 (24·2–32·7)	0·0554
Atypical antipsychotic medication	10·7 (8·5–13)	0·0250
Anxiolytic medication	12·9 (10·6–15·1)	0·0219
Hypnotic medication	10·7 (8·9–12·5)	0·0116
Antidepressant medication	20·1 (17·9–22·3)	0·0096
Residents with ≥2 medications	20·3 (17–23·6)	0·0388
Mean prescription per resident ± SD (range)	0·8 ± 2·1 (0–5)	0·0510
Mean prescription per resident with psychoactive medication ± SD (range)	1·5 ± 1·2 (1–5)	0·0372
12-month follow-up data of medication on demand (*n* = 2353)		
Residents with ≥1 medication	5 (2·7–7·2)	0·0816
Total number of administrations	704	
Mean administration per resident ± SD (range)	0·3 ± 5·7 (0–228)	0·0029

Values are cluster-adjusted percentages (95% confidence interval) and intra-cluster correlation coefficients (ICCC) unless stated otherwise.

Table 5 Characteristics associated with the use of physical restraints*

	Cross-sectional study† (*n* = 2281‡, R^2 = 0·237)		Prospective cohort-study§ (*n* = 2272¶, R^2 = 0·230)	
Characteristic	AOR (95% CI)	*p*-value	AOR (95% CI)	*p*-value
Length of residence (years, continuous variable)	1·04 (1·00–1·07)	0·041	–	–
Degree of disablement (reference: none)				
Considerable	5·69 (1·60–20·27)	0·007	5·36 (2·04–14·07)	< 0·001
Severe	37·75 (11·37–125·40)	< 0·001	30·69 (11·93–78·91)	< 0·001
Most severe	97·84 (26·25–364·64)	< 0·001	60·17 (19·66–184·17)	< 0·001
Fall during preceding four weeks before the study (reference: no)	0·69 (0·49–0·95)	0·025	–	–
Fracture during preceding 12 months before the study (reference: no)	2·87 (1·78–4·65)	< 0·001	2·30 (1·52–3·50)	< 0·001
Verbal agitation (reference: never)				
Once or twice	–	–	1·52 (0·90–2·56)	0·115
Repeatedly	–	–	1·48 (1·02–2·15)	0·037
Permanently	–	–	1·29 (0·89–1·88)	0·174
Cognitive impairment (reference: score ≤3)	2·19 (1·74–2·75)	< 0·001	1·77 (1·35–2·31)	< 0·001
Fall during follow-up (reference: no)	NA	NA	0·36 (0·26–0·49)	< 0·001

Values are cluster-adjusted odds ratios (95% confidence interval). R^2, pseudo R^2 by McFadden (1974); AOR, adjusted odds ratio; NA, not applicable.

*This table only displays the covariables which turned out to be statistically significant within the final regression model.

†Outcome is defined as at least one physical restraint on at least one of the three observation occasions.

‡A total of 86 residents were excluded from the final model due to missing values.

§Outcome is defined as use of restraints in more than half of observation days per resident.

¶A total of 81 residents were excluded from the final model due to missing values.

large population was followed-up over 12 months to determine the number of newly administered physical restraints and the frequency of application of the devices. Compliance of nursing homes was excellent since all completed follow-up. We investigated a balanced mix of nursing homes in Hamburg, Germanys' second largest city. The results of our

study are likely to be transferable to other German regions. We found that physical restraints are still applied as routine care in nursing homes. The cross-sectional study suggests that approximately a quarter of residents received at least one device with bedrails predominately used. Prevalences of belts and chairs with a table were comparably low. However, during the 12-month follow-up period approximately one in ten residents was restrained at least once with a belt and/or a chair with a table.

Prevalence of psychoactive medication was high. More than 50% of residents had at least one prescription. These findings are in accordance with data reported by other German and international studies on nursing home residents (Alanen *et al.* 2006, Molter-Bock *et al.* 2006, French *et al.* 2007). Physicians obviously ignore the overwhelming external evidence on lack of effectiveness of psychoactive agents in geriatric populations. Adverse effects offset advantages in the efficacy of antipsychotic medication for patients with Alzheimer's disease (Schneider *et al.* 2006). In our population, 11% had at least one prescription of an atypical antipsychotic agent. These drugs are associated with an increased risk of cardiovascular events and mortality (Sink *et al.* 2005) and falls and hip fracture (Kolanowski *et al.* 2006).

We observed marked differences in the frequency of physical restraints and psychoactive medication between nursing homes. Although former studies also noted great differences within single studies investigating restraints across institutions (Evans *et al.* 2002) such a pronounced variance has not been reported.

We found that bedrails are more likely to be applied as daily routine measure compared to belts and fixed tables. The subgroup of residents with a bedrail received the device in 70% of observation days compared to the subgroup of residents with a belt or chair with a table who received the device in 34% and 23% of observation days, respectively. Tinetti *et al.* (1991) also investigated the use of physical restraints within a cohort of 397 residents during a 1-year follow-up study. The authors found that in the subset of 122 restrained residents the mean duration of restraint use was 86·5 SD 94·4 days (range 1–350); 32% were restrained routinely, defined as being restrained for at least 20 days every month.

We found associations between residents' characteristics and the likelihood of being physically restrained. An increase of degree of disablement which reflects a need for more assistance in activities of daily living was positively associated with the use of physical restraints. Earlier studies support this result (Tinetti *et al.* 1991, Karlsson *et al.* 1996). We also found a positive association between cognitive impairment and physical restraints – a result in accordance with a recently published analysis from the Netherlands (Huizing *et al.* 2007) and earlier studies (Tinetti *et al.* 1991, Karlsson *et al.* 1996, Sullivan-Marx *et al.* 1999).

Research findings on institutional characteristics as predictors of restraint use are inconsistent. Staff mix has been suggested to be associated with the use of restraints (Castle 2002, Bourbonniere *et al.* 2003). In contrast, our regression models did not indicate any institutional characteristic associated with the use of restraints. The analysis by Huizing *et al.* (2007) also suggests that staff mix and other institutional characteristics are less important compared to residents' characteristics.

Specialised dementia care might influence the proportion of residents with restraints. Studies investigating this issue revealed contradictory results (Phillips *et al.* 2000, Weyerer *et al.* 2005). We did not find a statistically significant difference in restraint use between the subgroup of residents living in special dementia care units (n = 260) and the rest of the study population.

Beside the large sample size and high quality prevalence data collection, our study has other strengths. We undertook strong efforts to ensure the quality of nurses' prospective documentation. We personally visited study centres at least every two months to check for data completeness and plausibility. At the end of the study we verified nurses' documentation through direct observation within unscheduled visits. Agreement was excellent suggesting high validity of data. Laurin *et al.* (2004) have shown that nursing staff interviews can also be used as collection method on data of restraint use. Our study suggests that future restraint frequency collection can also rely on documentation of trained nurses. On the other hand, this conclusion must be interpreted with caution. Under practice conditions documentation of high numbers of restraints might be associated with negative sanctions, in consequence leading to underreporting.

The present study has also limitations. We aimed to keep nurses' burden of documentation as low as possible to encourage compliance with the study. Thus, we asked nurses only to document psychoactive medication on demand rather than daily psychoactive medication. For data protection reasons, we were not able to assess residents' diagnoses. Therefore, indications for prescription of psychoactive medication could not be evaluated. Several studies have demonstrated discrepancies between mental health diagnoses and the use of psychoactive medications in nursing home residents (French *et al.* 2007, Welz-Barth & Füsgen 2007). Other studies reported that up to 30% of nursing home residents with psychoactive medication did not have a psychiatric diagnosis (Molter-Bock *et al.* 2006).

There have been efforts to explore reasons for the use of restraints (Hamers & Huizing 2005). We had decided not to ask nurses about reasons because nurses are likely to answer what is socially desired. One of the most commonly identified reasons for restraining people is the prevention of falls or fall related injuries (Hamers & Huizing 2005). However, evidence from observational studies and randomised controlled trials suggests that a reduction of physical restraints does not result in an increase in fall incidence and fall-related injuries (Capezuti *et al.* 1998, 2007, Evans *et al.* 2002). We found an inverse association between the variables fall during four weeks before the observation period and fall during the observation period and the use of restraints. However, this finding does not allow causal interpretation and its clinical relevance remains unknown since fall-related injuries have not been collected.

In conclusion, this study shows that the frequency of physical restraints and psychoactive medication in German nursing homes continues to be substantial. Bedrails are used as routine measure. Empirical evidence does not support the use of bedrails and other physical restraints to prevent falls (Evans *et al.* 2002). National reports and case series on fatal and non-fatal injuries due to bedrails highlight that the measures are not benign and not necessarily safe (O'Keeffe 2004). Therefore, an effective approach to safely reduce restraints and minimise centre variability is urgently warranted. Disappointingly, recent intervention studies providing an intensive education approach and nurse specialist consultation did not result in clinically meaningful reductions of physical restraints (Huizing *et al.* 2006, Capezuti *et al.* 2007, Lai *et al.* 2007). Thus, it might not be sufficient to educate nurses not to use restraints or to suggest alternatives. A paradigm shift is necessary. The observed pronounced centre variations suggest that standard care does not imply the use of restraints. In our association analysis the easily measurable institutional characteristics like case mix and staffing did not explain centre differences in restraint use. Therefore, philosophy of care determining attitude and beliefs of nursing staff is most likely to be a powerful determinant of restraint use as routine measure. Our questionnaire survey, which will be published soon, may contribute to clarifying the black box 'staff philosophy'.

Relevance to clinical practice

A carefully prepared evidence-based guideline may help to overcome centre differences towards a restraint-free care in nursing homes. Currently, we are developing a multidisciplinary evidence-based practice guideline, which will be evaluated within a randomised controlled trial before practice implementation.

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Contributions

Study design: GM, IM; data collection: GM, SK, data analysis and interpretation: BH, GM, SK; manuscript preparation: GM; comments on manuscript drafts: SK, IM, BH.

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