Comparison of a fall risk assessment tool with nurses' judgement alone: a cluster-randomised controlled trial

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Abstract

Background: the impact of fall risk assessment tools on clinical endpoints is unknown.
Objective: we compared a standardised fall risk assessment tool alongside nurses' clinical judgement with nurses' judgement alone.
Design: a 12-month cluster-randomised controlled trial.
Setting: nursing homes in Hamburg (29 per study group).
Subjects: 1,125 residents ($n = 574$ intervention group, IG; $n = 551$ control group, CG).
Interventions: all homes received structured information on fall prevention before randomisation. The IG monthly administered the Downton Index, and the CG did not use a tool. Measurements were number of participants with at least one fall, falls, fall-related injuries and medical attention, fall preventive measures, physical restraints.
Results: the mean follow-up was 10.8 ± 2.9 months in both groups: 105 (IG) and 114 (CG) residents died or moved away. There was no difference between the groups concerning the number of residents with at least one fall (IG: 52%, CG: 53%, mean difference -0.7, 95% confidence interval -10.3 to 8.9, $P = 0.88$) and the number of falls ($n = 1,016$ and $n = 1,014$). All other outcomes were also comparable between the IG and CG.
Conclusions: application of a fall risk assessment tool in nursing homes does not result in the better clinical outcome than reliance on nurses' clinical judgement alone.

Keywords: *accidental falls/prevention and control, risk assessment, nursing assessment, residential facilities, randomised controlled trial, elderly*

Introduction

A remarkable number of fall risk assessment tools have been developed [1–4]. Nursing experts regularly recommend that nurses should not rely on their clinical judgement alone but to add on a standardised tool to increase their professional awareness [5, 6]. In Germany, fall risk assessment tools are increasingly used in nursing homes [7], although their effectiveness is unknown. Their impact on clinically relevant endpoints has never been investigated in randomised controlled trials. Such a trial is warranted according to evidence-based standards on the evaluation of diagnostic procedures [8, 9]. The use of these tools might even be harmful as they waste sparse nursing resources which could better be spent on usual nursing care. In contrast to nurses' clinical judgement, risk assessment tools are administered at fixed intervals and therefore lack flexibility.

We performed a cluster-randomised controlled trial to compare the clinical effectiveness and consequence of the use of a standard fall risk assessment tool alongside nurses' clinical judgement with nurses' clinical judgement alone.

Methods

Nursing homes and residents

A total of 180 nursing homes are located in Hamburg and catchment area. Nursing homes were randomly selected from published registers [10, 11]. An invitation letter was sent to 78 nursing homes. Inclusion criteria were at least 30 residents

and no use of a fall risk assessment tool or willingness to stop using the tool.

In each cluster, a study coordinator was nominated who prepared a serially numbered list of all residents. Participants were selected using a random number table until 20 fulfilled the predefined inclusion criteria: ≥70 years old, able to walk with or without assistance and living in the nursing home for >3 months. Recruitment took place from September 2005 to February 2006.

Nursing staff collected baseline data supported by the investigators. For description of the functional and cognitive status, 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) [12] were used. The instruments were pre-tested in a pilot study with two randomly allocated nursing homes.

Randomisation

Computer-generated randomisation lists were prepared by the biostatistician for concealed allocation of clusters by external central telephone. To obviate disparate sample sizes random permuted blocks of 4, 6 and 10 were used.

Interventions

Structured information

Structured information of nursing staff on best evidence strategies to prevent falls and fall-related injuries aimed to optimise usual care and to minimise centre effects. The information programme was piloted in six nursing homes, which did not participate in the study. The session lasted for 60–90 min, took place in small groups and was delivered by one investigator. It covered information about the frequency of falls and fall-related injuries in older people, proven fall risk factors, fall-related morbidity and best evidence strategies to prevent falls and fractures [13, 14]. The use of physical restraints as a fall preventive measure was discouraged [15]. The session comprised slide presentation, group work and plenary discussion. Using fictitious vignettes, nursing staff members were asked to identify fall risk factors and to develop an individual fall prevention action plan. Brochures summarising the information session were provided. The information programme and all material used within the session are available by request from the authors.

Immediately after the information session, nursing homes were randomly allocated either to the intervention group (IG) or control group (CG). Nursing homes of the CG were asked not to implement a fall risk assessment tool during the study period, and nursing homes of the IG were instructed to use only the Downton Index.

Fall risk assessment tool

The Downton Index [16] was chosen as it has been validated in a nursing home population [17] and described to be easily administered by nurses. Its predictive value is comparable to other instruments [1, 2].

One investigator translated the original English version into German. Validation of the translation included re-translation into English by a native speaker. The author of the original Downton Index authorised the translated version and its use within the study.

The Downton Index was accompanied by written instruction which was based on previous validation studies [17–19] and advice given by the author of the original version and the authors of validation studies.

The Downton Index requires information on history of falls during the preceding 12 months and medication data on tranquilisers or sedatives, diuretics, antihypertensive drugs, antiparkinsonian drugs and antidepressants. The information was gathered through residents' record review. The Downton Index also asks for sensory deficits. Residents' visual impairment was assessed by nurses using charts displaying short sentences in 10-mm block letters at reading distance. Hearing impairment was rated by nurses based on the definition as inability to perceive a conversation in a normal voice at a distance of 1 m. Limb impairment was assessed by nurses' judgement. The Downton Index also requires information on resident's mental state which was assessed by nurses using a validated proxy-rating tool [20]. The last item on gait was assessed by nurses' judgement. Participants were classified either as unable to walk, walk unsafe with or without aid, safe with aid or normal if no aid was necessary. Sensory deficits and mental state should be reassessed only if residents' condition had changed.

The cut-off was defined at ≥3 points according to previous validation studies [17–19].

Staff members of the IG were instructed to the use of the Downton Index. The nominated study coordinators were responsible for the monthly application of the tool.

Study outcomes

The primary outcome was the number of participants with at least one fall at 12 months. Nursing staff used a specially developed fall documentation sheet. Here, a fall was defined as an event, which results in a person unintentionally coming to rest on the ground, floor or other lower level. Fall data were checked at least every 2 months during personal visits.

Secondary outcome measures were the number of falls, and clinical consequences such as fall and injury prevention measures. In addition, the application of restraints was documented as possible unwanted side effects. Nurses were interviewed on the use of fall preventive measures using a structured assessment sheet. In the case of a fall event the external investigator filled in a sheet on medical resource use. Fractures and sutures related to falls, hospital admissions and consultations with a physician related to falls were recorded.

At the end of the study, the external investigator and the nominated study coordinator from each cluster reviewed all records to verify the completeness of data.

Economic evaluation was part of the study protocol [21]. It was planned to add up all costs and savings relevant from the viewpoint of health care insurers and party payers, i.e.

costs for optimisation of usual care in both study groups, costs for using the fall risk assessment tool in the IG as well as medical and nursing care costs following falls for both groups. At the end of the study, nursing staff of 11 nursing homes in the IG were asked how long it took on average to fill in the Downton Index. Nurses' gross salary in 2006 was estimated based on information given by a finance department of a nursing home in Hamburg.

Sample size

Based on previous published incidence rates [13], it was assumed that ∼45% of the participants in the control group would experience at least one fall in 12 months with an intra-class correlation coefficient of ICCC = 0.075. A cluster randomisation with about 20 participants in each nursing home was intended leading to a variation inflation factor of VIF = 2.425. Assuming an absolute difference of 15% at $\alpha = 5\%$ and 80% power, and considering that 20% of the participants would not complete the follow-up, a sample size of $n = 540$ participants residing in $n = 27$ nursing homes in each study group was calculated.

Statistical analysis

The biostatistician was unaware of group allocation. Baseline characteristics of nursing homes and residents were described as absolute numbers, percentages, means ± standard deviations (SD), range, median or quartiles depending on the distribution of each variable. Cluster adjustment of these data was avoided in order to present the raw baseline characteristics of the study population.

The main outcome proportion of residents with ≥1 fall was estimated separately for the IG and CG. The proportions of both groups were compared using a two-sided χ^2 test adjusted for cluster randomisation [22, 23]. For the mean difference between groups, 95% confidence intervals were calculated using a method appropriate for cluster-randomised trials [24]. The overall cluster correlation was estimated by the corresponding ICCC [22] of the total sample.

Numbers of residents with secondary outcomes are shown separately for the groups. A more detailed analysis of secondary outcomes was performed using the cluster as a unit of analysis—that is, residents' values within clusters were averaged and means, SDs and 95% confidence intervals of the cluster values were calculated within the groups. For statistical comparisons between the study groups, the two-sided Wilcoxon rank-sum test was performed.

Incidences of all falls and of residents' first fall, respectively, were estimated separately for the IG and CG by an additional secondary analysis. Person months under risk were counted as cumulative follow-up time for each resident and cumulative follow-up time until the first fall of the resident, respectively. To adjust for cluster design [22], incidences were estimated in each cluster and mean incidences for the IG and the CG were calculated. Both study groups were compared using the Wilcoxon rank-sum test.
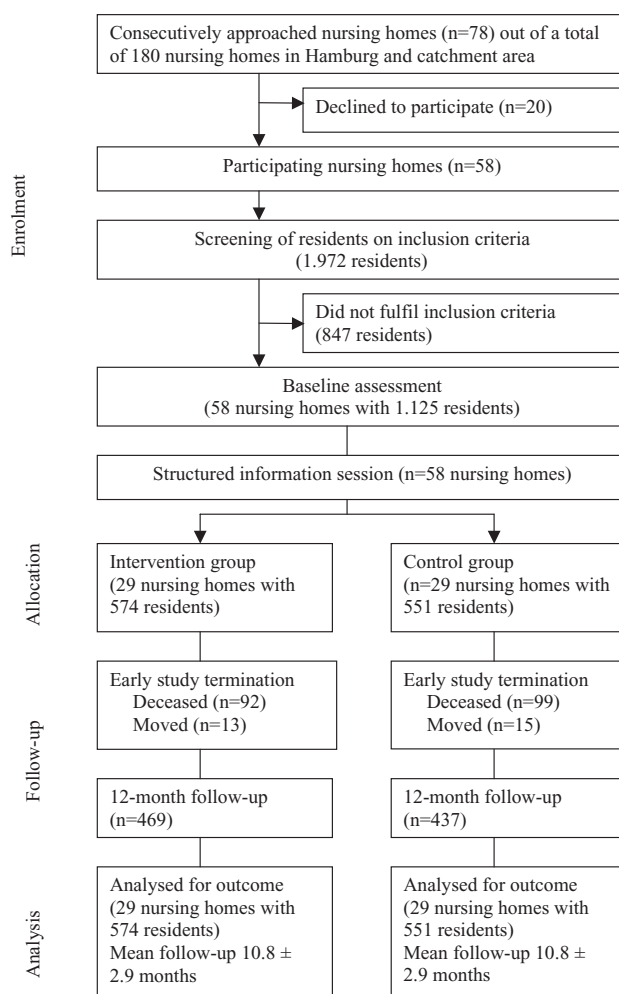

Figure 1. Flow of nursing home clusters and participants through the trial.

A two-sided 5% level of significance was chosen. Statistical analysis was performed using the statistical software packages SAS 9.1 TS1M3 and SAS 9.2 TS1M0.

Ethical approval, study registration and funding

The protocol was approved by the ethics committee of the Hamburg chamber of physicians and the regional data protection office. The study protocol was published in advance [21]. The trial was registered in the Current Controlled Trials register (ISRCTN37794278).

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Results

Seventy-eight nursing homes were consecutively invited to participate. Recruitment was closed after 58 homes had agreed to participate and fulfilled the inclusion criteria. Figure 1 shows the flow of study clusters and participants

Table 1. Fall incidence data

Measure	Intervention group (n = 574)	Control group (n = 551)	Mean difference between groups[a] (95% CI)[b]	P-value[b]
Residents with ≥ 1 fall (%)	299 (52)	291 (53)	−0.7 (−10.3 to 8.9)	0.88[c]
Number of falls	1,016	1,014	—	—
Falls per resident[d], mean ± standard deviation	1.8 (1.2)	1.8 (1.0)	−0.06 (−0.64 to 0.52)	0.6[e]

[a]Intervention minus control; [b]confidence intervals and *P*-values are cluster adjusted; [c]chi square test; [d]mean of averaged value per home; [e]Wilcoxon rank-sum test.

Table 2. Fall-related injuries and medical attention, and newly administered fall preventive measures and restrictive bedrails during the study period

	Intervention group (n = 574 residents with 1,016 falls)	Control group (n = 551 residents with 1,014 falls)	Mean difference between groups (95% CI)	P-value[a]
Fall-related injuries				
Residents with ≥ 1 fracture	39	38	—	—
Fractures	42	40	—	—
Hip fractures	21	22	—	—
Fractures per resident	0.07 ± 0.07	0.07 ± 0.05	0.003 (−0.03 to 0.03)	0.97
Fractures per faller	0.15 ± 0.16	0.15 ± 0.10	0.01 (−0.06 to 0.08)	0.70
Residents with ≥ 1 suture	42	49	—	—
Sutures	45	56	—	—
Sutures per resident	0.08 ± 0.07	0.10 ± 0.09	−0.02 (−0.06 to 0.02)	0.39
Sutures per faller	0.16 ± 0.16	0.20 ± 0.20	−0.05 (−0.14 to 0.05)	0.41
Fall-related medical attention				
Residents with ≥ 1 hospital admission	94	104	—	—
Admissions	121	135	—	—
Admissions per resident	0.21 ± 0.15	0.25 ± 0.14	−0.04 (−0.11 to 0.04)	0.33
Admissions per faller	0.39 ± 0.24	0.47 ± 0.23	−0.08 (−0.20 to 0.04)	0.18
Residents with ≥ 1 consultation with physician	73	78	—	—
Consultations	94	96	—	—
Consultations per resident	0.16 ± 0.15	0.18 ± 0.13	−0.01 (−0.08 to 0.06)	0.68
Consultations per faller	0.33 ± 0.28	0.32 ± 0.20	0.01 (−0.12 to 0.14)	0.82
Residents with newly administered fall preventive measures[b]				
Residents with ≥ 1 use of hip protector	28	30	—	—
Hip protectors per resident	0.06 ± 0.12	0.07 ± 0.10	−0.01 (−0.07 to 0.05)	0.63
Residents with ≥ 1 use of walking aid	43	46	—	—
Walking aids per resident	0.36 ± 0.32	0.37 ± 0.33	−0.01 (−0.19 to 0.17)	0.89
Residents with newly administered bedrails[b]				
Residents with ≥ 1 application of bedrail	45	55	—	—
Bedrails per resident	0.09 ± 0.09	0.12 ± 0.13	−0.03 (−0.09 to 0.03)	0.29

[a]Wilcoxon-rank sum test; [b]based on the subgroups of participants without documented use of the particular device at baseline (hip protector: n = 524, IG, n = 481, CG; walking aid: n = 134, IG, n = 118, CG; bedrail: n = 526, IG, n = 505, CG). All residents were counted who received a preventive measure or physical restraint at least once.
Values are numbers or cluster adjusted means (mean of averaged values of nursing homes) ± standard deviation.

through the trial. A total of 1,972 residents were screened for participation: 847 did not fulfil the inclusion criteria, mostly due to inability to walk with or without assistance (n = 699).

Baseline characteristics of clusters and participants were similar between the study groups (please see the tables in Appendices 1 and 2 in the supplementary data available at *Age and Ageing* online).

Fall incidence data are displayed in Table 1. There was no significant difference between the study groups concerning the number of residents with at least one fall (52% in the IG and 53% the CG, respectively) and the total number of falls.

The overall cluster correlation was estimated by ICCC = 0.0923.

Mean incidences of the homes concerning the first fall were 0.084 ± 0.046 per month in the IG and 0.082 ± 0.042 in the CG (P = 0.85). Mean incidences including all falls were 0.162 ± 0.108 per month in the IG and 0.167 ± 0.084 in the CG (P = 0.57).

Data on fall-related injuries and medical attention, newly administered fall preventive measures and bedrails administered during the study period are summarised in Table 2. Newly administered other physical restraints were rare (waist belt used in bed: n = 7, IG, n = 3, CG; waist belt used in chair:

$n = 3$, IG, $n = 4$, CG; chair with a table: $n = 3$, IG, none, CG). Again, there were no significant differences between the study groups. Therefore, we decided not to perform a full economic analysis and focused on costs which emerged from the Downton Index only. It was estimated that the introduction of staff members to the use of the Downton Index accounted for a total of 45 min staff time per nursing home, resulting in a total amount of 21.75 h nursing time. Based on nurses' response, an average of 3 min nursing staff time per Downton Index per resident ($n = 574$ over an average follow-up of 10.8 months) was computed, resulting in a total of 310 h nursing time. Fifteen minutes nursing staff time per resident for the initial application of the Downton Index including full assessment of medication data, sensory deficits and mental state were added, which means a further 143.5 h nursing time. Overall, we estimated that the Downton Index required 475.25 h of nursing time. The calculation was based on the nurses' gross salary of 22 euro per hour in 2006 as indicated by a finance department of a nursing home in Hamburg. Thus, the use of the Downton Index in this study incurred approximately a total of €10,500 ($16,170, £8,160) which was spent without measurable clinical benefit.

Discussion

The comparison of a standardised fall risk assessment tool alongside nurses' clinical judgement with nurses' clinical judgement alone did not reveal a difference in clinical outcomes in this carefully conducted study. Neither the number of fallers, falls, fall-related injuries and medical attention nor newly administered fall preventive measures differed between the study groups. Unwanted side effects defined as application of physical restraints were also comparable.

This is the first study aimed to evaluate the clinical consequences of a nursing fall risk assessment tool according to international methodological standards of diagnostic evaluation research [8, 9].

Only three tools had been repeatedly evaluated in geriatric populations at the beginning of the study: the Tinetti Test, the Mobility Interaction Fall (MIF) Chart and the Downton Index [17–19, 25, 26]. The Tinetti Test and the MIF are not suitable for routine assessment in nursing homes as they are time consuming and require special training, whereas the Downton Index has been described to be easily administered by nurses [17]. Nonetheless, generalisability of the results to other fall risk assessment tools is likely since the Downton Index reflects the same risk factors as other instruments [1,2].

The study may also be relevant to other areas of nursing assessment such as pressure sore risk. Several validation studies demonstrate the limited accuracy of nursing assessment tools [1, 2, 4, 5, 27]. Nevertheless, many authors conclude that despite the evidence nurses should not rely on clinical judgement alone. Instead nurses should continue to add on a standardised tool to increase their professional awareness [5, 6]. Obviously, nursing experts lack courage to refrain from recommending assessment tools.

Risk assessment tools which classify residents as high or low risk such as the Downton Index are different from those containing a list of common reversible fall risk factors which should subsequently prompt action. The latter have been investigated in randomised controlled trials in nursing home populations as part of multifactorial interventions administered by trained nurses [28, 29]. The results are unsatisfactory, suggesting that low intensity approaches without intensive external support and provision of additional resources are ineffective or even lead to more harm than good [28, 29]. We investigated the effectiveness of the Downton Index, since we had observed that the use of dichotomous tools is increasing in German nursing homes. The Downton Index reflects well-known fall risk factors and could guide initiation of interventions.

The study has important strengths. A large sample size of nursing home residents was investigated over a clinically relevant observation period. Structured information on best evidence of fall prevention strategies was provided for all homes before randomisation in order to diminish centre differences. Cluster randomisation was essential, because the use of the Downton Index relied on changes to nursing techniques. Statistical analyses took cluster randomisation into account.

The present study has also limitations. Nursing staff and external investigators were not blinded. Therefore, a bias concerning follow-up data collection could not be ruled out. However, due to professional requirements nurses are obliged to document each fall event. Sample size calculation is based on an absolute fall risk reduction of 15% [13]. The actual centre variation was slightly higher than anticipated. However, based on the final results the study still had the power to detect a real change in the percentage of fallers from 53% to 39%.

In conclusion, the use of a fall risk assessment tool by nurses should be avoided since it has no clinical consequences other than the waste of scarce nursing resources. Advocates of fall risk assessment tools should stop proclaiming potential benefits of these instruments unless they have demonstrated clinical superiority compared to nurses' clinical judgement.

Key points

- A remarkable number of fall risk assessment tools have been developed and widely implemented into nursing home practice.
- The clinical effectiveness and the consequences of the use of a standard fall risk assessment tool alongside nurses' clinical judgement compared to nurses' clinical judgement alone have never been investigated.
- This study demonstrated that the monthly administration of a fall risk assessment tool in nursing homes did not result in a reduction of fallers and fall-related consequences.
- The use of a risk assessment tool should be avoided since it has no clinical benefit but wastes scarce nursing resources.

Conflicts of interest

Funding

Supplementary data

Supplementary data are available at *Age and Ageing* online.

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Falls and fear of falling: burden, beliefs and behaviours

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Abstract

Objectives: this study estimated the frequency of recent falls and prevalence of fear of falling among adults aged 65 and older.
Design: a cross-sectional, list-assisted random digit dialling telephone survey of US adults from 2001 to 2003.
Subjects: 1,709 adults aged 65 or older who spoke either English or Spanish.
Methods: prevalence estimates were calculated for recent falls, fall injuries, fear of falling and fall prevention beliefs and behaviours.
Results: an estimated 3.5 million, or 9.6%, of older adults reported falling at least once in the past 3 months. About 36.2% of all older adults said that they were moderately or very afraid of falling. Few older adults who fell in the past 3 months reported making any changes to prevent future falls.
Conclusions: the high prevalence of falls and fear of falling among US older adults is of concern. Both can result in adverse health outcomes including decreased quality of life, functional limitations, restricted activity and depression. Older adults' fear of falling and their reluctance to adopt behaviours that could prevent future falls should be considered when designing fall prevention programmes.

Keywords: *falls, fear of falling, injury, elderly*

Introduction

Falls are the leading cause of unintentional injuries and deaths among adults aged 65 and older [1]. In 2005, among older adults, there were nearly 16,000 fall-related deaths in the United States, and more than 1.8 million non-fatal fall injuries were treated in emergency departments [1]. The number of fall injuries treated in outpatient settings or that do not receive medical treatment is undetermined. Because falls are a risk factor for future falls and are associated with other adverse health outcomes such as fear of falling, it is important to know the extent of falls among older adults [2–5].

Falls and fear of falling are interrelated problems; each is a risk factor for the other [2–4]. Many older adults who fall, whether or not they sustain an injury, develop a fear of falling that may lead to restricted activity, a decline in social interactions, depression and an increased risk of falling [2–6]. The purpose of this study was to estimate both the frequency of recent falls and the prevalence of fear of falling among a nationally representative sample of non-institutionalised US adults aged 65 and older.

Methods

Data were obtained from the second Injury Control and Risk Survey (ICARIS-2), a cross-sectional, list-assisted, random-digit dialled telephone survey. It was conducted by the