A multifactorial intervention for the prevention of falls in psychogeriatric nursing home patients, a randomised controlled trial (RCT)

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Abstract

Objective: to evaluate the effectiveness of a multifactorial intervention on incidence of falls in psychogeriatric nursing home patients.
Design: cluster-randomised controlled 12-month trial.
Setting: psychogeriatric wards in 12 nursing homes in The Netherlands.
Participants: psychogeriatric nursing home patients (n = 518).
Intervention: a general medical assessment and an additional specific fall risk evaluation tool, applied by a multidisciplinary fall prevention team, resulting in general and individual fall prevention activities.
Measurements: falls.
Results: there were 355 falls in 169.5 patient-years (2.09 falls per patient per year) in the intervention group and 422 falls in 166.3 patient-years (2.54 falls per patient per year) in the control group. Intention-to-treat analysis with adjustment for ward-related and patient-related parameters, and intra-cluster correlation, showed that the intervention group had a significantly lower mean fall incidence rate than the control group (rate ratio = 0.64, 95% CI = 0.43–0.96, P = 0.029). Subgroup analyses showed that fall risk declined further as patients participated longer in the intervention programme.
Conclusion: the introduction of a structured multifactorial intervention to prevent falls in psychogeriatric nursing home patients significantly reduces the number of falls. This reduction is substantial and of high clinical relevance.

Keywords: accidental falls, prevention, older people, long-term care, dementia, elderly

Introduction

Falls are a major problem in community residing elderly persons and even more in frail elderly residing in institutions [1, 2]. Falls are a frequent occurrence in nursing homes, with approximately two falls per bed per year [3]. They may have considerable consequences for the health status, the autonomy and the quality of life of the patients involved. Falls in cognitively impaired elderly are of particular concern [4]. Psychogeriatric nursing home patients especially have a high risk of falling [3–9]. As the mobility of these patients gradually deteriorates, so does their ability to recognise, judge and avoid hazards. This emphasises the importance of adequate measures to prevent falls in this group of patients.

Research indicates that multifactorial interventions to prevent fall incidents can have positive effects, but most existing evidence concerns community-dwelling elderly [10–13]. Though falls in nursing homes occur most frequently among psychogeriatric patients, to our knowledge, there have not been any intervention studies that specifically target this population. Several nursing homes’ fall intervention studies even excluded patients with dementia. Of the studies that did not, only one study reported effects for psychogeriatric patients separately [14]. It is therefore important to investigate whether fall prevention interventions result in a reduction of falls among psychogeriatric patients.

We developed a multidisciplinary and multifactorial fall prevention intervention for psychogeriatric nursing home patients, based on a review of the literature and consultations.
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with experts on fall prevention and geriatric nursing [15,16]. The primary objective of the present study was to assess the effect of this intervention on the number of falls in this population.

**Methods**

**Design**

The design is a cluster randomised controlled trial (RCT), performed on one psychogeriatric ward in 12 nursing homes in The Netherlands. Six nursing homes were allocated to the intervention group and six to the control group. After approval by a certified ethics committee, the RCT started in November 2003. The inclusion period for each ward was 12 months.

In the intervention group, general staff and professionals on the intervention wards received written and oral information and instructions about the intervention programme and data collection.

In the control group, general staff and managers on the control wards received written and oral instructions about data collection. They had no insight in the fall prevention programme. All patients received usual care.

**Participants and setting**

Study participants were psychogeriatric patients residing on the selected psychogeriatric wards, regardless of whether their stay lasted the entire inclusion period or only part of this period. Of the included patients in the intervention group, only those whose relatives or legal guardians had given written informed consent actually participated in the intervention programme.

**Sample size**

For practical reasons, we were able to include a maximum of 12 nursing homes with one ward (~30 patients) per home. Based on earlier research among Dutch nursing home patients, the fall rate in our study population was estimated to be 3.3 per patient per year, with a standard deviation of 2.5. With a sample size of 180 patients per group, a reduction of the fall rate with 30% can be detected with a power of 0.80 at 5% significance. On the basis of this power analysis, the minimum sample size for the trial was set at 180 patients per group.

**Randomisation**

In 2002, we sent a questionnaire to all 371 nursing homes in The Netherlands, to determine how many fall incidents annually occur in these homes and general staff were asked whether they would agree to participate in our intervention study [3]. Out of 202 responding nursing homes, 119 provisionally agreed to inclusion and met the trial inclusion criteria. In 2003, these 119 nursing homes received more information about the study and were asked again whether they would participate. Forty homes did not respond, 45 declined participation and 34 agreed to participate. The latter were divided into three groups based on the mean fall incidence rate of psychogeriatric patients per psychogeriatric bed (low ≤ 1.86, medium 1.87–2.61, high ≥ 2.62) in the years 2000 and 2001, as reported in the questionnaire. At random, using computer techniques, two intervention homes and two control homes were selected from each group, resulting in a total of six intervention homes and six control homes.

Ward allocation occurred after randomisation. At each home, the management selected one ward to be included in the study, based on the following criteria: at least 25 beds, not using a fall prevention protocol, and with the largest number of mobile patients. In total, the six intervention wards had 177 beds and the six control wards had 171 beds.

**Study outcomes**

The outcome parameter in the study was the number of falls on the participating wards during the inclusion period.

**Intervention programme**

The intervention programme consisted of a general medical assessment focusing on fall risks, and an additional specific fall risk evaluation tool assessing fall history, medication intake, mobility and the use of assistive and protective aids [16]. The total fall risk assessment resulted in general fall prevention activities and/or individually tailored fall prevention interventions for each patient [16].

Each intervention ward installed a multidisciplinary fall prevention team, consisting of routine staff: a nursing home physician, two nurses, a physiotherapist and an occupational therapist. These teams coordinated the intervention programme during fortnightly fall prevention conferences. They discussed each patient at admission, after a fall, at request of professionals on the ward and in any case at least twice a year, even if there had been no fall incident or request.

General medical assessments were performed by medical staff when a patient was admitted or when there was a change in medical condition. The fall prevention teams carried out the fall risk evaluation tool of each patient, they discussed its outcome in conjunction with the findings of the general medical assessment and they decided which individual fall prevention activities were necessary. Then they, or colleagues, executed these specific fall prevention activities, which could include any or all of the following: anticipating the circumstances and causes of falls, critically reviewing and monitoring medication intake (type, number, dose and time of intake), individually designed exercise programmes, carefully (re)assessing the need for assistive and protective aids, and promoting the correct use of these aids.

Overall, the occupational therapist screened the main areas of each ward using a checklist for environmental hazards.

Besides specific fall prevention activities, the team could also implement general fall prevention activities, such as staff training and education. Figure 1 outlines the structure of the intervention programme.
Data collection

Data on falls were collected prospectively by asking all participating wards to keep records of any fall incident on a structured report form [17]. At baseline, nursing home staff assessed the following characteristics of study participants: age, gender, Barthel ADL Index score [18], MMSE score [19], standing pattern and gait pattern (independent, using assistive device and/or professional assistance, impossible), total number of drugs used by patients and the use of certain types of drugs (cardiovascular, psychotropic, antihistaminic, diabetes-related and others) [20, 21]. Data about the use of alarm devices and restraints were also collected during the inclusion period.

In addition, we recorded information about the study wards: nursing staff man-hours, and the number of falls on the study ward during the 12 months preceding the start of the trial. These data were collected retrospectively, using the register of falls that Dutch nursing homes are required to maintain [17].

For each patient, we registered the starting and ending date of inclusion in the study, as well as the date of inclusion in the intervention programme which was the date when the fall prevention team discussed the results of the first fall risk evaluation. All patients residing on the study wards at the start of the inclusion period were automatically included in the study. Patients admitted in the course of the inclusion period were included on the day of admission. Inclusion in the study ended either on the last day of the inclusion period or, in the event of earlier discharge or a patient passing away, on the date of discharge or death.

Statistical analysis

Data were analysed with multilevel Poisson regression analysis. Multilevel analysis was used because of the hierarchical structure of the data (patients were clustered within wards), and Poisson regression was used because the outcome variable was a ‘count’. All analyses were performed with MLwiN (version 1.1) [22].

Data were analysed according to the intention-to-treat principle, with adjustment for ward-related parameters (nursing staff man-hours per bed and number of falls per bed in the 12 months previous to the trial), length of stay on the ward during the inclusion period and other patient-related parameters (age, gender, Barthel ADL Index score, MMSE score, gait pattern, total number of drugs used, duration of use of alarm devices, and use of fixation, bedrails and other restraints during the inclusion period).

Complementary to the primary analyses according to the intention-to-treat principle, a subgroup analysis was performed that used only those patients in the intervention group who actually participated in the intervention programme and the entire control group. For the intervention group, the value of the parameter ‘length of stay on the ward during the inclusion period’ concerned the duration of inclusion in the intervention programme, and the value of the outcome variable concerned the number of falls during this period. Additional subgroup analyses were performed to estimate the effect of the intervention programme for different durations of participation in the intervention.

A significance level of 0.05 was maintained for all analyses.

Results

During 12 months of follow-up, 518 patients were included in the trial (269 in the control group and 249 in the intervention group). In the intervention group, the relatives/legal guardians of 229 patients agreed to the patient’s participation in the intervention programme (92%). Of this group, 200 patients were actually included in the programme. The mean duration of inclusion was 0.50 years (SD 0.28). Thirty-seven per cent of the patients that stayed on the study wards at the start of the trial period or were admitted during the trial period dropped out before the end of the trial period. In the intervention group this is 36%, and in the control group this is 38%. Figure 2 shows the flow of study wards and participants.

Table 1 shows the characteristics of the control group and the intervention group. With regard to ward characteristics at baseline, the intervention wards had fewer nursing staff man-hours per bed and a higher number of falls per bed.
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Figure 2. Flow of nursing homes and patients.

Table 2 shows the main results of the intervention study. Data showed 355 falls in 169.5 patient-years in the intervention group (= 2.09 falls per patient per year), and 422 falls in 166.3 patient-years in the control group (= 2.54 per patient per year). The intention-to-treat analysis with adjustment for length of stay on the ward during the trial period showed that the mean fall incidence rate in the intervention group was lower than that in the control group (rate ratio = 0.79). This effect was not significant. The intention-to-treat analysis with adjustment for ward parameters (full time equivalents of nursing staff per bed and number of falls in the 12 months previous to the trial), length of stay on the ward during the trial period and the other patient-related parameters (age, gender, MMSE score, Barthel ADL Index score, gait pattern, total number of drugs used, use of alarm devices and use of restraints) showed that the intervention group had a lower mean fall incidence rate than the control group (rate ratio = 0.64). This effect was statistically significant.

The subgroup analysis, a comparison of the control group with those patients who participated in the intervention programme during their inclusion in it, reinforced this outcome (rate ratio = 0.54). Further subgroup analysis, which took account of the duration of inclusion in the intervention programme, showed that the longer patients participated in the intervention, the lower the fall risk. These effects were all statistically significant.

Discussion

This study shows that the number of falls in psychogeriatric nursing home residents can be significantly reduced by a targeted multifactorial fall prevention intervention. The reduction in number of falls is substantial and of high clinical relevance.

The results of this trial are consistent with several comparable studies evaluating multidisciplinary, multifactorial fall prevention interventions in nursing homes [10, 23–25]. This trial provides new evidence of the effectiveness of such interventions in psychogeriatric nursing home patients.

The present study has some limitations. First, the power calculation was based on detecting a 30% difference in falls. As a consequence, it is not possible to make a (reliable) estimation of the effect of the intervention on injurious falls, which have a much lower incidence. Secondly, it is possible that we unintentionally selected the more highly motivated nursing homes, because only 34 out of 119 nursing homes (28.6%) agreed to participate in the study. It is possible that especially nursing homes that were highly motivated to prevent falls agreed to participate. If this is true, it remains unclear whether the programme would also be effective in homes where staff might be less motivated to tackle this problem. We must therefore regard the external validity of this study with reservation. However, based on the reasons reported by the 45 homes that declined participation, we know that the majority of these homes declined due to merging procedures, and/or internal reorganisation of the care process. Thirdly, the reasons for dropout were not registered. According to the information from the nursing homes themselves, the dropouts were related to decease or admission to another ward and not to the fall prevention intervention programme. Fourthly, ward allocation occurred after randomisation in an unblended manner, and a selection bias might have been possible. However, looking for fall prevention activities, the nursing home staffs selected wards with a high number of fall incidents.

A detailed process evaluation performed alongside the trial revealed that in general the programme was feasible for the healthcare professionals. The majority of the costs were related to man-hours of routine staff. However, several recommendations were made to facilitate implementation in regular daily nursing home care (Neyens et al. Feasibility of a
Table 1. Characteristics of study wards and study patients

<table>
<thead>
<tr>
<th></th>
<th>Control group (n = 262–269)</th>
<th>Intervention group (n = 225–249)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ward characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of beds (sum)</td>
<td>171</td>
<td>177</td>
</tr>
<tr>
<td>Nursing staff man-hours per bed</td>
<td>0.67 (0.05)</td>
<td>0.62 (0.04)</td>
</tr>
<tr>
<td>Number of fall incidents per bed during the 12 months previous to the inclusion period</td>
<td>2.67 (0.87)</td>
<td>2.91 (1.43)</td>
</tr>
<tr>
<td><strong>Patient characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>83.3 (7.7)</td>
<td>82.1 (7.7)</td>
</tr>
<tr>
<td>Gender (% male)</td>
<td>29%</td>
<td>35%</td>
</tr>
<tr>
<td>Barthel ADL Index score (0–20)</td>
<td>8.6 (6.5)</td>
<td>8.1 (6.5)</td>
</tr>
<tr>
<td>MMSE score (0–29)</td>
<td>7.0 (6.6)</td>
<td>9.3 (7.8)</td>
</tr>
<tr>
<td>Standing pattern</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% independent</td>
<td>50%</td>
<td>42%</td>
</tr>
<tr>
<td>% assistive device and/or physical assistance</td>
<td>28%</td>
<td>39%</td>
</tr>
<tr>
<td>% impossible</td>
<td>22%</td>
<td>19%</td>
</tr>
<tr>
<td>Gait pattern</td>
<td></td>
<td></td>
</tr>
<tr>
<td>% independent</td>
<td>40%</td>
<td>32%</td>
</tr>
<tr>
<td>% assistive device and/or physical assistance</td>
<td>29%</td>
<td>32%</td>
</tr>
<tr>
<td>% impossible</td>
<td>51%</td>
<td>36%</td>
</tr>
<tr>
<td>Total number of drugs used</td>
<td>4.97 (3.06)</td>
<td>4.75 (3.39)</td>
</tr>
<tr>
<td>Use of drugs per type</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cardiovascular (% use)</td>
<td>57%</td>
<td>47%</td>
</tr>
<tr>
<td>Psychotropic (% use)</td>
<td>65%</td>
<td>66%</td>
</tr>
<tr>
<td>Antihistaminic (% use)</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>Diabetes related (% use)</td>
<td>17%</td>
<td>12%</td>
</tr>
<tr>
<td>Others (% use)</td>
<td>76%</td>
<td>81%</td>
</tr>
<tr>
<td>Length of stay on the ward during inclusion period in years</td>
<td>0.62 (0.39)</td>
<td>0.68 (0.34)</td>
</tr>
<tr>
<td>Duration of use of alarm device during inclusion period in years</td>
<td>0.14 (0.33)</td>
<td>0.11 (0.25)</td>
</tr>
<tr>
<td><strong>Duration of use of restraints during inclusion period in years</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixation</td>
<td>0.09 (0.23)</td>
<td>0.11 (0.25)</td>
</tr>
<tr>
<td>Bedrails</td>
<td>0.30 (0.39)</td>
<td>0.39 (0.41)</td>
</tr>
<tr>
<td>Others</td>
<td>0.07 (0.23)</td>
<td>0.08 (0.25)</td>
</tr>
</tbody>
</table>

aData are given as mean (SD) unless stated otherwise.

bValues not available for all residents.

Table 2. Incidence of falls during the trial period in the intervention and control groups

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Intervention group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>Falls per patient per year</td>
<td>Rate ratio (95% CI)</td>
</tr>
<tr>
<td>Intention-to-treat analysis</td>
<td>269</td>
<td>2.54</td>
</tr>
<tr>
<td>Subgroup analyses for diverse periods of inclusion in the intervention programme</td>
<td>249</td>
<td>2.09</td>
</tr>
<tr>
<td>&gt;0.0 years</td>
<td>200</td>
<td>2.05</td>
</tr>
<tr>
<td>≥0.3 years</td>
<td>141</td>
<td>1.91</td>
</tr>
<tr>
<td>≥0.5 years</td>
<td>100</td>
<td>1.69</td>
</tr>
<tr>
<td>≥0.7 years</td>
<td>57</td>
<td>1.52</td>
</tr>
</tbody>
</table>

aData rate ratio adjusted for length of stay on the ward during the trial and for intra-cluster correlation, calculated with multilevel analyses (see the Statistical analysis section).

bRate ratio adjusted for ward-related and patient-related parameters (including length of stay) and for intra-cluster correlation, calculated with multilevel analyses (see the Statistical analysis section).

In conclusion, this study proves that fall prevention targeted at psychogeriatric patients in a nursing home setting is both possible and effective in reducing falls among those at the highest risk, but certainly not easy because it requires a lot of effort. Implementation of the programme in daily nursing home care can be recommended. The intervention is also likely to be suitable for use in other settings like low-care residential homes for older people and geriatric wards in hospitals, but may need to be adapted to specific circumstances.

Finally, we think that it can be expected that the intervention also has favourable effects on the incidence of

multifactorial fall prevention programme for psychogeriatric nursing home patients. Submitted.
injurious falls, but this has to be established in a future study. There might also be scope for analysis to generate hypotheses for further research, e.g. were first falls prevented or only recurrent ones, and what are the costs and savings per fall prevented?

Key points

- The introduction of a structured multifactorial intervention to prevent falls in psychogeriatric nursing home patients significantly reduces the number of falls.
- This reduction is substantial and of high clinical relevance.

Conflicts of interest

No conflicts of interest

References


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