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# Falls prevention in residential care homes: a randomised controlled trial

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## Abstract

**Objective:** to determine the effect of risk factor modification and balance exercise on falls rates in residential care homes.
**Design:** cluster randomised controlled trial.
**Participants:** 196 residents (aged 60 years or over) in 20 residential care homes were enrolled (38% response rate). Homes were randomly allocated to intervention and control arms. A total of 102 residents were consigned to the intervention arm and 94 to the control arm.
**Intervention:** a multifactorial falls prevention programme including 3 months gait and balance training, medication review, podiatry and optometry.
**Main outcome measures:** number of falls/recurrent falls per person, number of medications per person, and change in Tinetti gait and balance measure.
**Results:** in the intervention group there was a mean of 2.2 falls per resident per year compared with 4.0 in the control group; this failed to reach statistical significance ($P=0.2$) once the intra-cluster correlation (ICC, 0.10) had been accounted for. Several risk factors were reduced in the intervention arm.
**Conclusions:** falls risk factor reduction is possible in residents of care homes. A modest reduction in falls rates was demonstrated but this failed to reach statistical significance.

Keywords: *falls, institutional care, randomised controlled trial*

## Introduction

Falls are an extremely common problem in older people, leading to injury, dependency and death in a significant proportion. Falls can be reduced in community-dwelling older adults by up to 40% as a result of exercise programmes [1] and multidisciplinary risk factor modification [2, 3]. In the UK, developing such programmes is a major national priority [4].

There is a growing evidence base for the effectiveness of falls prevention programmes in institutional settings. In the nursing home setting there have been randomised trials such as those by Ray [5] and Becker [6], which have shown a reduction in the rate of falls. These have focused mainly on staff education, balance training and medication reduction. In the residential care home setting specifically, a previous study in the UK has been carried out, which failed to reduce falls [7], and a larger study from Sweden was undertaken by Jensen, which did demonstrate a reduction in falls [8].

The aim of this study was to conduct a cluster randomised controlled trial to determine whether the number of falls/recurrent falls in older adults in residential homes could be reduced through a comprehensive programme of risk factor assessment and intervention, including progressive exercise. As the overall programme was delivered to care homes, rather than individuals, it was necessary to cluster the results by home.

## Methods

### Participants and setting

Study participants were people aged 60 years or more living in residential care homes in Western Wiltshire. We targeted all single registered residential homes for older people (minimum

five residents), which did not specialise in the elderly mentally ill, or provide nursing facilities. We only excluded temporary residents and those suffering from a clearly defined terminal illness. All residents were invited to take part, and they received written and oral information concerning the study.

### Design

This study was approved by the Bath Local Research Ethics Committee. We sought written informed consent from all participants, with additional written or verbal permission from the next of kin of any resident who was judged by the investigators to lack sufficient mental capacity to make an informed decision.

A physiotherapist, nurse and an occupational therapist conducted baseline assessments of all participating residents and homes prior to randomisation. This team was independent of the teams employed for the intervention, and masked to allocation. Personal details, Barthel ADL index [9] and Abbreviated Mental Test Score (AMTS) [10] were recorded. Specific falls risk factors were identified including orthostatic hypotension, number of oral medications taken (except osteoporosis treatment), Timed Get Up and Go Test [11], Tinetti gait and balance score [12], 180° turn (number of steps) [13], condition of feet and footwear (observational scale) and visual acuity. We also noted whether the resident was on treatment for osteoporosis. These assessments were repeated at 3 months by the same team, who did not participate in the intervention programme.

### Interventions

The control group received no intervention, but was visited every 3 weeks by the research assistant (M.R.) to ensure completion of falls records. The intervention group received a multifactorial risk factor modification programme for 12–14 weeks, consisting of an exercise programme, staff education, medical reviews, environmental modification and optician and podiatry assessments.

### Exercise programme

Each residential home in the intervention arm was visited thrice weekly by experienced exercise assistants supported by a qualified physiotherapist. All exercise sessions aimed to improve balance and gait, flexibility, strength and endurance. Wherever possible, exercises were linked to functional lifestyle tasks such as safe transfers, dressing and the use of walking aids. The group sessions consisted of a warm-up, a targeted circuit programme and a warm-down, lasting 40 minutes. The emphasis throughout was on fun and teamwork, the groups often carried out simple dancing to music and a variety of games encouraging a move from volitional to automatic action and movement. All exercises were progressed as appropriate, and weights and thera-bands were also used. Individual sessions were used for those residents who were unable to carry out group exercise, mainly those with physical frailty and marked cognitive impairment. All participants were also encouraged to carry out individual exercise outside of the visits.

### Staff education

All staff were encouraged to be involved in the interventions, and each care home manager received written information about the study aims to disseminate to their staff. At the end of the exercise programme, representatives from each of the intervention homes were invited to take part in an education day. Following this, all homes received an information pack detailing the home exercise programme, and a falls prevention strategy.

### Medical reviews

All baseline assessment records were screened by one of two consultant geriatricians (C.A.E.D. and D.R.R.). Residents with suspected medical risk factors were then seen and examined, and medical recommendations were reported by letter to the participants' general practitioners. Uptake of recommendations was at the discretion of the general practitioner. We targeted particularly culprit medication, notably sedative and diuretic medication, poly-pharmacy and advice on correction of orthostatic hypotension. We advised on the use of osteoporosis prevention where necessary.

### Environmental modification

An occupational therapy assistant visited each home to assess risk factors on an individual basis, and provided each intervention home with a written report detailing specific risk factors. In addition, environmental health teams also visited the homes to carry out their routine assessments of the environment. The homes were then alerted to any major risk factors.

### Optician and podiatry

A review from an optician was arranged by the study team for any resident identified as having a visual acuity of 6/12 or less, or if they had not seen an optician in the previous year. Podiatry was arranged for those residents whose foot condition was of concern at baseline assessment.

### Outcome measures

The primary outcome measures were the number of falls and recurrent falls (three or more) per resident in the year after the baseline assessment. Secondary outcomes were the number of oral medications per resident, including number of sedative medications, change in the Tinetti gait and balance score, and number of injurious falls (fractures).

We collected data on falls prospectively by asking all residential homes to keep records of any falls (in diaries) occurring in participating residents for a 3-month run-in period prior to baseline assessment, to allow practices to be standardised with the support of a researcher (M.R.). Each home was visited every 3 weeks to maintain the support of homes and to collect data from individual falls diaries and the accident book. The data were collected until 1 year after the first assessment date.

### Statistical analysis

Based on a conservative figure of 1.5 falls per person per year with a standard deviation of 1.5 we would require a total of 300 subjects to demonstrate a 33% reduction in falls with 80% power at the 5% significance level. However, this estimate was based on a non-clustered sample, as we were unsure of the inter-cluster correlation coefficient that would be derived. Pragmatically we had a maximum of 510 residents

in 23 homes potentially available to participate in our Western Wiltshire area.

Analysis was undertaken using SPSS release 11.1 (SPSS Inc., Chicago, IL, USA) and ACLUSTER 2.0 (World Health Organization). As the residential homes are the unit of randomisation, where possible, the analysis was also undertaken at this level. Baseline data were analysed within each home and overall without accounting for clustering. In all of the subsequent analysis clustering has been accounted for.

All outcome data were assessed for normality and appropriate parametric or non-parametric methods used. Initial testing of the allocations (at patient level) used two-sample independent *t* tests or Mann–Whitney tests. For categorical variables Chi-squared or, where relevant, Fisher's exact tests were applied. After the initial baseline comparison of groups, data were provided on the results for each of the individual homes. The outcomes were then tested using an independent two-sample *t* test adjusting the variance for the clustering effect using the technique outlined in Donner and Klar [14] and implemented in the ACLUSTER statistical software package.

Analysis, where possible, has been implemented on an intention-to-treat analysis basis.

### Randomisation

Randomisation was used to allocate individual homes to control or intervention arms of the study. The allocation sequence was generated from computer-generated random number tables, and the homes ordered alphabetically and allocated according to odd and even numbers, and according to the size of the home. The allocation sequence was performed and kept secure by a researcher independent of the study, and blinded to baseline assessment results. Interventions started within 1 month of randomisation.

## Results

### Baseline characteristics and falls risk factors identified

The homes' sizes varied from 9 to 50 residents (median 20). In most respects the homes were similar, all residents having private rooms with shared communal areas, meals provided, and with their needs met by care assistants, not nurses.

The managers of the 23 residential homes matching our criteria were approached and 20 homes agreed to take part (87%). The homes that declined were all privately run and varied in size: 10, 13 and 18 residents. Reasons stated for refusal were a recent change of management (one home), 'no problem with falls' (one home) and no reason given (one home).

The research profile is included in Figure 1. Although independently randomised, baseline comparison between intervention and control groups showed differences, with a lower AMTS, and a higher number of medications (Table 1) in the intervention group.

All subjects ($n=196$) participating in the study cooperated with baseline risk factor assessments. In the intervention group, 12 residents refused exercise and 7 were physically incapable of exercise, but 83 did participate and attended 1768 out of 2988 sessions (59%; median 22 sessions).

Medical assessments were conducted in 72 cases (70%) and a total of 155 recommendations were made to the residents' GPs by letter. No resident had experienced a syncopal episode. Opticians reviewed the 34 residents who had not seen an optician in the last year, and podiatrists reviewed 29 residents of the 30 who were referred (one refused to be seen).

Several falls risk factors were modified at the 3-month re-assessment in the intervention group (Table 2). Overall there were significant but modest reductions in medication use in the intervention group. There were also significant improvements in the rate of orthostatic hypotension, and in process markers such as the number of patients receiving an optician review and a podiatry assessment in the follow-up year. At 1 year, 80 residents in the intervention group had seen an optician compared with 48 controls ($P<0.001$, Chi-squared test), and 60 residents had seen a podiatrist compared with 33 controls ($P<0.001$). Unfortunately this did not translate into improved visual acuity, nor into improved condition of feet or footwear. However, there were significant improvements in Tinetti gait score and 180° turn in the intervention group. There were significantly more within-group differences in the intervention group than differences between the intervention and control groups (Table 2), probably reflecting baseline differences between the two groups as discussed earlier. In some cases, such as 180° turn and timed unsupported stand, risk factors for falls in the control groups worsened, whereas those in the intervention group were maintained or improved.

### Fall rates

There was no reduction in the number of residents falling in 1 year in the intervention group as a whole (Table 3): 56 of the 102 residents (54.3%) in the intervention group fell compared with 51 of the 94 (54.9%) residents in the control group [OR 1.03; 95% confidence intervals (CI) 0.59–1.80]. There were 194 falls in the intervention group and 266 in the control group. The rate of falls was reduced at 2.2 (1.3, 3.0) in the intervention group compared with 4.1 (2.3, 5.7) falls per person per year in the control group, but this difference failed to reach statistical significance (ICC 0.10; $P=0.27$).

## Discussion

Despite the high frequency of falls noted in residents of institutions [5, 8], notably in those with dementia [15], there are few trials of falls prevention programmes in this setting. There were 27% fewer falls in residents receiving exercise programmes and multifactorial intervention compared with controls, which did not reach statistical significance. This possibly relates to the study power, baseline differences between the groups and individual differences within the residential homes, which are difficult to evaluate. Residents in the intervention arm had significantly worse cognitive scores at baseline and were on significantly more medications, compared with the control group, which could have influenced our findings. Jensen *et al.* [8] did find a 44%

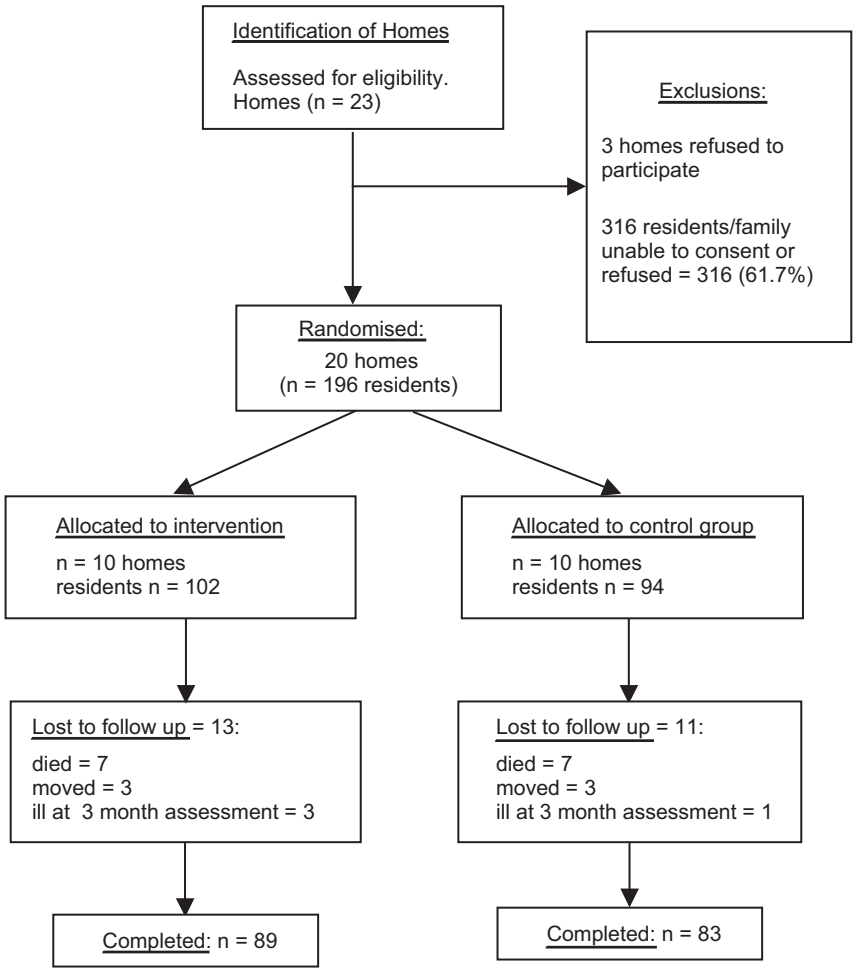


**Figure 1.** Flow of residential home clusters and participants.

**Table 1.** Baseline characteristics of study population, variables are mean (SD) unless stated otherwise

| | Control group ($n = 94$) | Intervention group ($n = 102$) | *P* value |
|---|---|---|---|
| Age | 87.4 (6.9) | 87.2 (6.9) | 0.86 (*t* test) |
| Male | 22 | 21 | |
| AMTS | 7.4 (2.6) | 6.20 (3.1) | 0.003 (*t* test) |
| Median Barthel (1Q, 3Q) | 16 (14, 17) | 16 (13.7, 17) | 0.83 (Mann–Whitney) |
| Use of any walking aid (*n*) | 84 (89.4%) | 84 (82.4%) | 0.22 (Fisher's exact test) |
| No. of medications | 4.1 (1.89) | 4.7 (2.13) | 0.04 (*t* test) |
| Tinetti gait and balance score | 16.0 (6.9) | 15.43 (6.8) | 0.56 (*t* test) |
| Tinetti gait score | 6.5 (3.2) | 6.12 (3.3) | 0.86 (*t* test) |
| Tinetti balance score | 9.4 (4.1) | 9.3 (4.1) | 0.41 (*t* test) |
| Orthostatic hypotension[a] *n* (%) | 21 (23.6) | 31 (32.0) | 0.25 (Fisher's exact test) |

AMTS = Abbreviated Mental Test Score.

[a]Systolic blood pressure drop of 20 mmHg or more 2 minutes after standing from lying position, or a diastolic drop of 10 mmHg or more.

statistically significant reduction in falls in residents of care homes in Sweden through a comprehensive prevention programme lasting for 34 weeks as opposed to 1 year in our study. Similarly in a nursing home population, Becker *et al.* [6] recently demonstrated a 45% reduction in falls in this frail population, which also reached statistical significance.

There are significant difficulties inherent in conducting research in this setting, and relating to use of a cluster design. Clustering was necessary because individual residents would not have been independent of their care home setting, although results may be conservative as a result of this type of analysis. The intra-cluster correlation coefficient looks at how similarly people within a cluster are behaving and therefore how much of the behaviour is due to the cluster (home) rather than any particular individual intervention. If each patient were acting truly independently (in their

**Table 2.** Risk factors for falls at baseline and at 3 months reassessment in both groups, values are median (Q1, Q3) unless otherwise stated[a]

| | Control group ($n = 94$) | | | Intervention group ($n = 102$) | | | Cluster differences | |
|---|---|---|---|---|---|---|---|---|
| | Baseline ($n = 94$) | 3 months | *P* value | Baseline ($n = 102$) | 3 months | *P* value | Intra-cluster correlation coefficient | *P* value |
| **Medical factors** | | | | | | | | |
| Orthostatic hypotension present, *n* | 21 (23.6) | 14 (16.9) | 0.629 | 31 (32.0) | 17 (18.5) | 0.052 | 0.027 | 0.329 |
| No. of regular medications[a] | 4 (2, 5) | 4 (3, 5) | 0.238 | 5 (3, 6) | 4 (3, 6) | 0.014 | 0.025 | 0.052 |
| Use of more than three medications, *n* | 69 (73.4) | 64 (77.1) | 0.754 | 85 (83.3) | 69 (75.0) | 0.267 | 0.037 | 0.270 |
| Use of sedatives (including at night), *n* | 43 (45.7) | 37 (44.6) | 0.998 | 57 (55.9) | 50 (55.6) | 0.617 | 0.054 | 0.101 |
| Use of diuretics, *n* | 38 (40.4) | 37 (44.6) | 0.453 | 58 (56.9) | 41 (45.6) | 0.007 | 0.105 | 0.364 |
| Condition of feet adequate, *n* | 53 (56.4) | 72 (86.7) | 0.001 | 63 (63.6) | 62 (72.1) | 0.123 | 0.011 | 0.081 |
| Condition of footwear adequate, *n* | 67 (71.3) | 52 (62.7) | 0.108 | 71 (70.3) | 57 (65.5) | 0.855 | 0.069 | 0.351 |
| Osteoporosis treatment, *n* | 12 (12.8) | 9 (10.7) | *0.625* | 9 (8.8) | 27 (30.0) | 0.001 | 0.026 | 0.007 |
| Visual acuity 6/12 or less, *n* | 83 (88.3) | 77 (92.8) | 1.000 | 81 (81.0) | 82 (92.1) | 0.118 | −0.049 | 0.448 |
| **Gait and balance results** | | | | | | | | |
| 180° turn (no. of steps) mean (SD) | 7.72 (4.0) | 8.2 (4.4) | *.205* | 8.1 (3.9) | 7.2 (3.2) | 0.006 | 0.398 | 0.39 |
| TGUG[b] score, seconds[a] | 28.7 (20.2–48.1) | 29.9 (18.3– 3.1) | 0.088 | 31.0 (20.7–54.9) | 28.9 (17.5–53.1) | 0.187 | 0.035 | 0.365 |
| TUSS[c], seconds[a] | 60 (60, 60) | 60 (53, 60) | 0.002 | 60 (60, 60) | 60 (60, 60) | 0.475 | 0.013 | 0.008 |
| Right leg stand, seconds[a] | 0 (0, 0) | 0 (0, 0) | 0.445 | 0 (0, 0) | 0 (0, 1.41) | 0.025 | 0.007 | 0.277 |
| Left leg stand, seconds[a] | 0 (0, 0) | 0 (0, 0) | 0.136 | 0 (0, 0) | 0 (0, 0.76) | 0.011 | 0.116 | 0.662 |
| Tinetti gait score[a] | 6 (4, 9) | 10 (7, 13) | 0.034 | 6 (4, 8) | 12 (8, 14.5) | 0.044 | 0.098 | 0.019 |
| Tinetti balance score[a] | 9 (7, 13) | 6 (4 , 9) | 0.824 | 9 (7, 12.5) | 6 (5, 9) | 0.003 | 0.230 | 0.913 |
| Tinetti total score | 15 (11.25, 21.75) | 15 (12, 21) | 0.317 | 16 (11, 20) | 18 (13, 23) | 0.001 | 0.214 | 0.083 |

[a]Interquartile range (Q1, Q3). Otherwise percentages are included in parenthesis.

[b]TGUG = Timed Get Up and Go Test.

[c]TUSS = Timed Unsupported Stand (maximum 60 seconds).

Tinetti total score is the combined result of the gait and balance scores.

Table 3. Falls recorded during the 1-year study period on an intention-to-treat basis, values are means (SD) unless stated otherwise

| | Control group ($n = 94$) | Intervention group ($n = 102$) | Inter-cluster correlation coefficient | Odds ratio (95% CI) | Significance |
|---|---|---|---|---|---|
| **Falls** | | | | | |
| 1-year drop out rate | 11 (10.5%) | 13 (11.3%) | Not calculated | 1.09 (0.47, 2.55) | 0.844 |
| Residents falling (*n*) | 51 (54.3%) | 56 (54.9%) | 0.071 | 1.03 (0.59, 1.80) | 0.942 |
| Falls per person per year (calculated rate[a]) | 4.02 (CI: 2.33, 5.71) | 2.17 (1.32, 3.01) | 0.100 | | 0.272 |
| Cumulative number of falls | 266 | 194 | 0.100 | | 0.272 |
| Three or more falls per year (*n*) | 25 (26.6%) | 26 (25.5%) | 0.029 | 0.94 (0.50, 1.79) | 0.279 |
| Residents sustaining a fracture | 3 (3.2%) | 4 (3.9%) | 0.026 | 1.23 (0.27, 5.63) | 0.626 |

[a]The calculated rate allows inclusion of the 24 patients who dropped out during the study.

response to the intervention) then the intra-cluster correlation coefficient would be zero. Higher coefficients therefore give lower power. The relatively high coefficients in this study suggest that the environment (the home) has a significant effect on falls rates.

Furthermore, the wide variability of falls rates in each cluster suggests that there may be other factors which may be involved in the failure or success of a falls intervention programme in addition to residents' baseline characteristics, even though the programme was delivered in a uniform way to all care homes. Residential care homes might differ in several respects: for example, in their client group (state-funded or private individuals), their philosophy (to provide care or promote autonomy) and their religious beliefs. The care home managers may also influence the style and running of each institution. The uptake of certain recommendations such as medication withdrawal (Table 2) made to the residents/care homes was not optimal. For example, night sedation reduction was particularly disappointing, perhaps reflecting the practical difficulties of establishing withdrawal regimes. However, uptake of simpler recommendations such as additional osteoporosis treatment was significantly more common in the intervention arm. Whether this is influenced by the frequency of GP visits to homes is uncertain, but warrants further investigation. Compliance with exercise, by contrast, was excellent, possibly because this service was directly provided through the research programme.

The relatively low response rate of residents may also limit the applicability of the results and reflects the practical difficulties of conducting studies in care institutions. Another possible confounding issue is the recording of falls, as we relied on the central record of falls held by homes. Bias in reporting of falls might have occurred, although we visited all participating homes regularly to minimise this possibility.

The recruitment rate for homes was extremely high, suggesting that most homes would welcome falls prevention programmes. The strategy to be employed within care homes is an important consideration. Global risk assessments in all care home residents may not work as only half of all residents fall each year, and cost-effectiveness needs to be considered. Further work targeting only those who have fallen might be more effective.

This study demonstrates that risk factors for falls can be reduced in residents of care homes, but we failed to demonstrate a reduction in falls rates. Further intervention studies targeting only those at high risk should also be considered.

## Key points

- Several falls risk factors were modified by the falls prevention programme in the residential home.
- Although there were fewer falls in the intervention arm, this failed to reach statistical significance.
- Other methods of delivering falls prevention programmes in this setting should be assessed, such as targeting those at highest risk of falls.

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## Conflicts of interest

None declared.

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# Postural stability in the elderly: a comparison between fallers and non-fallers

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## Abstract

**Background:** the identification of specific risk factors for falls in community-dwelling elderly persons is required to identify older people at risk of falling.
**Objective:** the aim of the study was to determine the ability of various biomechanical measures of postural stability to identify fallers in the elderly population.
**Method:** 19 subjects (78.4 ± 1.3 years old) who reported having fallen unexpectedly at least twice in the last 6 months, and 124 non-fallers (77.8 ± 0.53 years old) participated in the study. Balance measurements were made in the upright position in six different conditions using a force platform, and the Limits of Stability Test was carried out. Static two-point discrimination (TPD) testing to the underside of the first toe was made to evaluate the innervation density of the slowly adapting receptors. Finally, maximal isometric lower limb strength was measured in major muscle groups. Repeated measures analysis of variance tests were performed to assess the mean differences between the two groups (fallers and non-fallers). The level of significance was set to 0.05.
**Results and discussion:** results suggest that control of balance in narrow base stance may be an important tool in identifying elderly fallers. The findings show an increase in mediolateral sway in narrow base stance in older people who experienced recurrent falls. Also, TPD appears to be impaired in elderly fallers (14.93 ± 1.1 mm versus 12.98 ± 0.3 mm).
**Conclusions:** simple and safe laboratory quantitative tests were able to differentiate between elderly fallers and elderly individuals who did not fall, suggesting a possible clinical application as a preliminary screening tool for predicting future risk of falling.

Keywords: *postural stability, force platform, centre of pressure, sway, limits of stability, falls, elderly*