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# Multifactorial Intervention to Reduce Falls in Older People at High Risk of Recurrent Falls

## A Randomized Controlled Trial

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**Background:** Falls occur frequently in older people and strongly affect quality of life. Guidelines recommend multifactorial, targeted fall prevention. We evaluated the effectiveness of a multifactorial intervention in older persons with a high risk of recurrent falls.

**Methods:** A randomized controlled trial was conducted from April 3, 2005, to July 21, 2008, at the geriatric outpatient clinic of a university hospital and regional general practices in the Netherlands. Of 2015 persons identified, 217 persons aged 65 years or older were selected to participate. They had a high risk of recurrent falls and no cognitive impairment and had visited the emergency department or their family physician after a fall. The geriatric assessment and intervention were aimed at reduction of fall risk factors. Primary outcome measures were time to first and second falls after randomization. Secondary outcome measures were fractures, activities of daily living, quality of life, and physical performance.

**Results:** Within 1 year, 55 (51.9%) of the 106 intervention participants and 62 (55.9%) of the 111 usual care (control) participants fell at least once. No significant treatment effect was demonstrated for the time to first fall (hazard ratio, 0.96; 95% confidence interval, 0.67-1.37) or the time to second fall (1.13; 0.71-1.80). Similar results were obtained for secondary outcome measures and for per-protocol analysis. One intervention participant died vs 7 in the control group (hazard ratio, 0.15; 95% confidence interval, 0.02-1.21).

**Conclusion:** This multifactorial fall-prevention program does not reduce falls in high-risk, cognitively intact older persons.

**Trial Registration:** [isrctn.org](http://isrctn.org) Identifier: ISRCTN11546541


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**F**ALLS OCCUR FREQUENTLY IN older persons. About 30% of persons older than 65 years fall at least once a year and 15% fall at least twice.<sup>1-3</sup> The consequences of falling are severe: 5% of falls lead to a fracture and 5% lead to other serious injuries.<sup>4,5</sup> About 1 in 4 fallers consults a hospital emergency department or primary care physician after the fall.<sup>5</sup> Other consequences are loss of function and mobility, fear of falling, and increased institutionalization.<sup>5</sup> These facts emphasize the necessity of measures to prevent falling in older persons.

### See Invited Commentary at end of article

The pathogenesis of falling is multifactorial.<sup>1,6</sup> The risk of falling is associated with impairments in balance, gait, muscle strength, visual acuity, and cognition and with chronic diseases, postural hypotension, and use of psychotropic medication.<sup>7-11</sup> Interventions to reduce the risk of falling have been successful to a varying de-

gree. Home visits by nurses were found to be ineffective,<sup>12</sup> whereas tai chi, exercise therapy, and multifactorial interventions seem to lower the incidence of falls.<sup>13-15</sup>

 CME available online at [www.jamaarchivescme.com](http://www.jamaarchivescme.com) and questions on page 1097

Several guidelines for the prevention of falls in older persons have been developed.<sup>16,17</sup> These guidelines recommend a systematic assessment and multifactorial treatment of fall risk factors in independently living older persons with a high risk of falling. Previous trials investigating the effect of multifactorial prevention strategies report conflicting results.<sup>18-23</sup> Even the meta-analyses are inconclusive.<sup>24-26</sup>

Many geriatric outpatient clinics have recently started multidisciplinary fall-prevention services. In older persons with a high risk of recurrent falls who were selected according to their history of falls or after identification of fall risk factors, the effectiveness of such a multifactorial inter-

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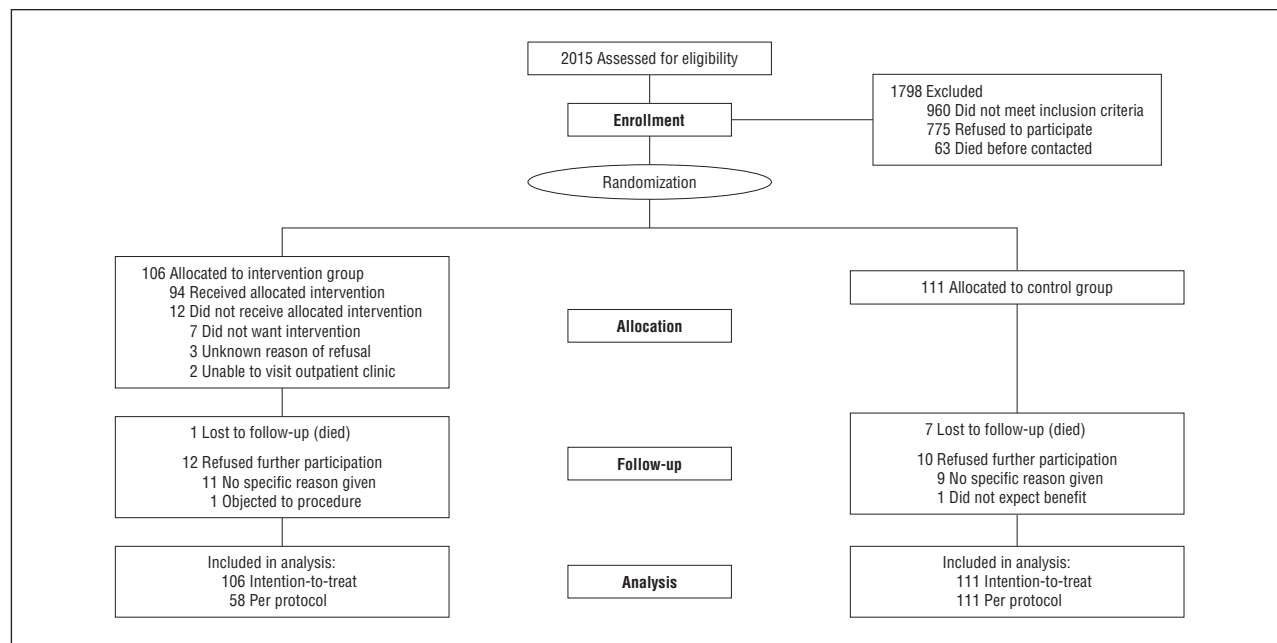


Figure 1. Flow of participants through the trial.

vention program has not been conclusively demonstrated.<sup>12,15,18,22,23</sup> To identify older persons at high risk of falling, several risk profiles have been developed.<sup>3,27-30</sup>

In this randomized controlled trial, we studied the effects of a multidisciplinary intervention on fall risk in older persons at high risk of recurrent falls by using the fall-risk profile developed in the Longitudinal Aging Study Amsterdam (LASA).<sup>28</sup> The intervention consisted of a systematic assessment of the risk factors for falling and subsequent targeted individualized preventive measures.

## METHODS

### STUDY DESIGN AND POPULATION

The design of this study was published in detail elsewhere.<sup>31</sup> In short, this was a randomized controlled trial with 1-year follow-up (Figure 1). The study was conducted from April 3, 2005, to July 21, 2008. The medical ethics committee of the VU University Medical Center approved the study.

The study population consisted of persons 65 years or older who consulted the emergency department of the VU University Medical Center or their family physician between April 3, 2005, and June 17, 2007, after a fall. Inclusion criteria were living independently or in an assisted living facility, living in the vicinity of the hospital, and having experienced a fall. Exclusion criteria were the inability to sign informed consent, a Mini-Mental State Examination score of less than 24,<sup>32</sup> the inability to provide a fall history, experiencing a fall due to a traffic or occupational accident, living in a nursing home, experiencing a fall more than 3 months before randomization, and acute disease requiring long-term rehabilitation, such as a hip fracture or stroke. Sample size calculation indicated that 57 participants were needed in the intervention group and in the usual care (control) group for a significance level of .05, a power of 80%, and an expected difference in fall incidence of 50%.<sup>18</sup> We expected approximately 52% of control group participants to fall again in the following year.<sup>18</sup> Taking into account a dropout rate of 30%, a minimum of 82 participants were needed in each group.

Potential participants were contacted, and the participants who met all inclusion criteria were asked to participate. All participants signed informed consent. The validated LASA fall-risk profile was used to select participants at high risk of recurrent falls (score of  $\geq 8$ ).<sup>31</sup> This tool assesses fall risk on the basis of the following risk factors: level of education, fear of falling, number of previous falls, body weight, functional limitations, handgrip strength, alcohol use, and presence of pets. Participants with a low risk of recurrent falls were excluded from the trial. Participants residing in an assisted living facility were immediately assigned to the high-risk group, which is in accordance with the recommendations of the Dutch Institute for Health Care Improvement guideline.<sup>17</sup> Participants in the high-risk group were randomized into the intervention or control group. A block randomization with a block size of 4 was used. Participants were allocated with the use of numbered envelopes according to a computer-generated random sequence. Participants, intervention caregivers, and interviewers could not be blinded to group assignment.

### PROCEDURE

All participants were visited at their homes by a trained interviewer within 3 months after the presenting fall. During the first home visit, the fall-risk profile, fall history, cognitive functioning, medical history, medication use, independence in activities of daily living (ADL), quality of life (QOL), and physical performance were measured before randomization. All participants were asked to report falls for 1 year after randomization by recording them in a fall calendar. One year after randomization and the first home visit, participants were visited a second time to reassess ADL, QOL, and physical performance. Furthermore, questionnaires were administered 3, 6, and 12 months after the initial interview to evaluate therapy and recommendation adherence and medication use.

### INTERVENTION

The multidisciplinary intervention started with a visit to the geriatric outpatient clinic. A multifactorial fall-risk assessment was conducted that aimed to identify modifiable fall risk

factors. The assessment of fall risk factors and design of the treatment plan were based on the Dutch Institute for Health Care Improvement guideline.<sup>17</sup> The assessment consisted of a general medical and drug history, fall and mobility history, and physical examination results. According to the guideline, special emphasis was placed on signs and symptoms of potentially modifiable fall and fracture risk factors, such as postural hypotension, visual impairment, parkinsonism, osteoporosis, osteoarthritis, gait disorders, psychotropic and cardiovascular drug use, and environmental hazards. When indicated, additional diagnostic tests were performed (eg, laboratory tests or imaging). The multifactorial treatment could consist of several therapies and recommendations. In participants who used cardiovascular or psychotropic drugs, treatment withdrawal was recommended when no current medical or psychiatric condition warranted continuation of the drugs. Special emphasis was placed on the importance of discontinuation of benzodiazepines. When the 25-hydroxyvitamin D<sub>3</sub> level was below 20 ng/mL (to convert to nanomoles per liter, multiply by 2.496), treatment with a combination of calcium carbonate, 500 mg, and cholecalciferol, 400 IU, was initiated. Postural hypotension was treated primarily with compression stockings for the lower legs and discontinuation of vasodilating medication.

Every participant with a gait disorder was referred to one of the two designated physical therapists for home-based training for improvement of balance and strength. A home visit aimed at home hazard reduction by an occupational therapist was offered to every participant with a gait disorder. Referral to an ophthalmologist was initiated when the corrected visual acuity was less than 0.5 (20/40) OU on the Snellen chart. Referral to other medical specialists was initiated when deemed necessary (eg, referral to a cardiologist for participants with new or uncontrolled arrhythmias). The family physician of each participant was contacted by telephone immediately after the examination to discuss referrals to medical specialists, medication changes, and follow-up.

The control participants received usual care. In the Netherlands, usual care after a fall mainly consists of treatment of the consequences of the fall.

## MEASUREMENTS

### Primary Outcome Measures

At the first home visit, the participants received a fall calendar. For 1 year, the participants recorded each week whether they had fallen. A fall was defined as an unintentional change in position resulting in coming to rest at a lower level or on the ground.<sup>33</sup> The primary outcome measures were the time in days until the first and second falls. Participants who were unavailable for follow-up or who died were censored at the time of dropout.

### Secondary Outcome Measures

Level of independence in ADL was examined using the Barthel Index.<sup>34</sup> Instrumental ADL was examined using the scale developed by Lawton and Brody.<sup>35</sup> Quality of life was examined using the Dutch translations of the 12-Item Short-Form Health Survey<sup>36</sup> and the EQ-5D (EuroQol EQ-5D).<sup>37</sup> To assess physical performance, 3 tests (the chair stands, walk, and tandem stance tests) were conducted. The chair stands test is a standardized test in which the participant stands up and sits down 5 consecutive times as fast as possible with the arms folded in front of the chest.<sup>38</sup> During the walk test, the participant walks 3 m up and down a line.<sup>38</sup> The tandem stance test (one foot in front of the other) was used as a measure for standing balance.<sup>39</sup> The scores on the 3 tests (range for each, 0-4) were

summed for a total physical performance score (range, 0-12). In each secondary outcome, higher scores indicate better performance. By their response to a questionnaire sent 1½ years after the first home visit, participants were asked to indicate whether they had sustained a fracture since the first home visit.

## Other Measurements

Medication use was assessed by directly copying from the containers the prescription information of drugs used in the previous 2 weeks. Living situation was assessed and categorized as independent vs assisted living. The number of 7 major chronic diseases (ie, lung disease, cardiac disease, vascular disease, joint disease, malignant disease, diabetes mellitus, and stroke) was measured by means of a questionnaire. All consultations and acquired aids and adaptations were documented by participant responses to the questionnaires administered at 3, 6, and 12 months after the initial visit. Medication changes were assessed by comparing medication use at baseline with medication use at 12 months. In case of loss to follow-up because of death, the date of death was documented.

## ADHERENCE

During the second home visit in the intervention group, adherence to the treatment regimen was evaluated per the recommendation given. The questionnaires at 3 and 6 months also provided adherence data. Sufficient adherence was defined as completion of both an outpatient clinic visit and a second home visit plus adherence to at least 75% of the recommendations or, in case of referral to exercise therapy, full adherence to exercise therapy and to at least 60% of the remaining recommendations.

## STATISTICAL ANALYSIS

Data were analyzed according to the intention-to-treat principle; that is, we included all randomized participants whether or not they received the intervention. The results of the intention-to-treat analysis were compared with the results of the per-protocol analysis. Intervention participants included in the per-protocol analysis had fulfilled sufficient adherence criteria. To examine the effectiveness of the intervention, Cox proportional hazards analyses were performed, with time from randomization to the first fall and time to the second fall as outcome variables. Subsequently, univariate linear regression analyses were used to compare differences in secondary outcomes (ADL, QOL, and physical performance) at 12 months' follow-up between the intervention and control groups. For each outcome measure, interaction of randomization with sex was tested and, if an interaction was found ( $P < .10$ ), further analyses were stratified for sex. Effect sizes were also calculated (regression coefficients divided by the standard deviation of the total sample). Effect sizes greater than 0.30 suggest a medium effect; those greater than 0.80 suggest a large effect.<sup>40</sup> The effect of the intervention on fractures was tested using the Cox proportional hazards model, with time to first fracture during 1½ years as the outcome measure. Finally, the effect of the intervention on mortality was analyzed using the Cox proportional hazards model, with time to death during 1 year of follow-up as the outcome measure.

Missing values on the secondary outcomes were imputed using the MICE (multivariate imputation by chained equations) algorithm.<sup>41</sup> The imputation model was used to explain the pattern of missing data and to obtain imputed values for these missing data and included the following variables: group randomization, age, sex, education level, Mini-Mental State Examination score, number of chronic diseases, and fall-risk profile score. Imputed values were based on regression estimates.

**Table 1. Baseline Characteristics of Participants<sup>a</sup>**

| Characteristic                                | Intervention Group<br>(n=106) | Control Group<br>(n=111) | P Value |
|---|-------------------------------|--------------------------|---------|
| Age, mean (SD), y                             | 79.0 (7.7)                    | 80.6 (7.0)               | .10     |
| Female sex, No. (%)                           | 71 (67.0)                     | 82 (73.9)                | .27     |
| Residing in assisted living facility, No. (%) | 4 (3.8)                       | 5 (4.5)                  | .79     |
| Enrolled after visiting ED, No. (%)           | 90 (84.9)                     | 94 (84.7)                | .99     |
| Education $\geq$ 11 y, No. (%)                | 66 (62.3)                     | 61 (55.0)                | .32     |
| MMSE score, median (IQR)                      | 28.0 (26.0-29.0)              | 28.0 (27.0-29.0)         | .82     |
| LASA fall-risk profile score, median (IQR)    | 12.0 (10.0-15.0)              | 12.0 (9.0-14.0)          | .38     |
| No. of chronic diseases, median (IQR)         | 1.0 (0.0-2.0)                 | 1.0 (1.0-2.0)            | .35     |
| No. of medications, mean (SD)                 | 5.8 (3.2)                     | 5.8 (3.2)                | .96     |
| Barthel Index score, median (IQR)             | 19.0 (17.0-20.0)              | 19.0 (17.0-20.0)         | .30     |
| Lawton IADL score, median (IQR)               | 7.0 (5.0-8.0)                 | 7.0 (5.0-8.0)            | .36     |
| SF-12 component score, mean (SD)              |                               |                          |         |
| Physical                                      | 38.1 (8.4)                    | 37.7 (8.6)               | .71     |
| Mental  | 49.6 (11.0)                   | 50.9 (10.3)              | .37     |
| EuroQol score, median (IQR)                   | 0.78 (0.65-0.84)              | 0.78 (0.65-0.84)         | .89     |
| Physical performance score, mean (SD)         | 7.0 (2.6)                     | 6.4 (2.6)                | .12     |
| No. of falls in preceding year, median (IQR)  | 2 (2-4)                       | 2 (1-3)                  | .19     |

Abbreviations: ED, emergency department; EuroQol, EuroQol EQ-5D; IADL, instrumental activities of daily living; IQR, interquartile range; LASA, Longitudinal Aging Study Amsterdam; MMSE Mini-Mental State Examination; SF-12, 12-Item Short-Form Health Survey.

<sup>a</sup>Data are presented as mean (SD) for normally distributed variables, median (IQR) for skewed variables, and percentages for categorical variables. Group differences were tested using the unpaired, 2-tailed *t* test; Mann-Whitney test; and  $\chi^2$  test, respectively.

Five imputed data sets were created. The quality of the imputations depends on the amount of missing data. When the amount of missing data does not exceed 50%, 5 imputations are enough to obtain valid estimates.<sup>42</sup> The analyses were performed in each data set, and the results were pooled using the Rubin rules.<sup>43</sup> R software (version 2.7.2; The R Foundation for Statistical Computing, Vienna, Austria) was used to perform imputation; all other analyses were performed using SPSS statistical software (version 15.0; SPSS Inc, Chicago, Illinois).

## RESULTS

During the inclusion period, 2015 persons aged 65 years or older experienced a presenting fall (Figure 1). Of these, 775 did not wish to participate. Nonresponse analyses showed more women (76.4% vs 70.5%) and emergency department presentations (96.2% vs 84.8%) in the nonresponders group. The inclusion criteria were not met by 960 persons, and 63 persons died before being contacted. The remaining 217 persons were included in the trial. Randomization resulted in 106 participants in the intervention group and 111 in the control group. The baseline characteristics of the 2 groups were similar (Table 1). None of the participants had intercurrent missing values on primary outcome measures before death or loss to follow-up otherwise. However, 20 intervention participants (18.9%) and 27 control participants (24.3%) did not have a second home visit, resulting in missing values on secondary outcome measures. Reasons for not having a second home visit were dropout before the visit (n=19), refusal (n=18), death (n=8), and other reasons (n=2).

The intervention participants visited the geriatric outpatient clinic after a median of 15 days (range, 0-57 days) after the initial presentation at the emergency department or to a family physician. These 106 participants received a total of 359 recommendations (median, 3 recommendations per participant; range, 0-8). The recommendations

included 176 referrals, 111 medication revisions, 52 instructions, and 19 other recommendations (Table 2). Self-reported consultations, medication changes, and acquired aids and adaptations in the intervention and control groups are reported in Table 3. Of the 651 questionnaires, 596 (91.6%) were completed.

For the per-protocol analysis, 48 persons in the intervention group were excluded because they did not come to the outpatient clinic (n=12), did not follow or only partially followed therapeutic advice (n=23), or did not receive a second home visit (n=13). In all, 58 intervention participants (54.7%) met our criteria for sufficient adherence and were compared with all control participants in the per-protocol analyses.

During 1 year of follow-up, 55 intervention participants (51.9%) and 62 control participants (55.9%) fell at least once, and 37 (34.9%) and 35 (31.5%), respectively, fell at least twice. The percentages of fallers and recurrent fallers did not differ significantly between the intervention and control groups ( $P > .55$ ). The median number of falls in the treatment group was 1 (interquartile range, 0-3), and the median number of falls in the control group was also 1 (0-2). Intention-to-treat analysis showed no significant treatment effect on the time to the first fall (hazard ratio [HR], 0.96; 95% confidence interval [CI], 0.67-1.37) or on the time to the second fall (1.13; 0.71-1.80) (Figure 2). Per-protocol analysis did not change the treatment effects (data not shown).

Analysis of secondary outcomes did not yield significant differences in longitudinal changes of ADL, instrumental ADL, QOL, and physical performance. The physical component score of the 12-Item Short-Form Health Survey showed a small, nonsignificant increase in both the intervention and control groups. The 2 groups did not differ significantly in changes on the Barthel Index during the 12-month follow-up period (Table 4).



**Table 2. Specification of Recommendations and Adherence in the Intervention Group**

| Type of Recommendation                                  | Total No.   | Adhered to Recommendation |                          |           |           |
|---|-------------|---------------------------|--------------------------|-----------|-----------|
|   |             | Yes                       | Alternative <sup>a</sup> | No        | Unknown   |
| Referrals   | 176         | 101                       | 25                       | 25        | 25        |
| Physical therapy  | 80          | 47                        | 11                       | 11        | 11        |
| Occupational therapy                                    | 30          | 17                        | 5                        | 5         | 3         |
| Ophthalmologist   | 20          | 10                        | 1                        | 3         | 6         |
| Cardiologist  | 11          | 8                         | 1                        | 0         | 2         |
| Other referrals   | 35          | 19                        | 7                        | 6         | 3         |
| Medication changes                                      | 111         | 49                        | 19                       | 22        | 21        |
| Initiate therapy with calcium carbonate/cholecalciferol | 19          | 11                        | 3                        | 4         | 1         |
| Discontinue benzodiazepine therapy                      | 17          | 6                         | 5                        | 4         | 2         |
| Other medication changes                                | 75          | 32                        | 11                       | 14        | 18        |
| Instructions  | 52          | 27                        | 13                       | 9         | 3         |
| Riskful behavior  | 8           | 4                         | 1                        | 3         | 0         |
| Reduce alcohol intake                                   | 10          | 4                         | 3                        | 2         | 1         |
| Other instructions                                      | 34          | 19                        | 9                        | 4         | 2         |
| Mixed recommendations                                   | 20          | 10                        | 2                        | 4         | 4         |
| Use compression stockings                               | 15          | 8                         | 1                        | 3         | 3         |
| Other recommendations                                   | 5           | 2                         | 1                        | 1         | 1         |
| Total No. (% of recommendations)                        | 359 (100.0) | 187 (52.2)                | 59 (16.5)                | 60 (16.8) | 53 (14.5) |

<sup>a</sup>Indicates that the participant took action in response to the recommendation but did not do exactly what was recommended or only partially did what was recommended.

**Table 3. Self-reported Number of Consultations, Medication Changes, and Acquired Aids and Adaptations in the Intervention and Control Groups<sup>a</sup>**

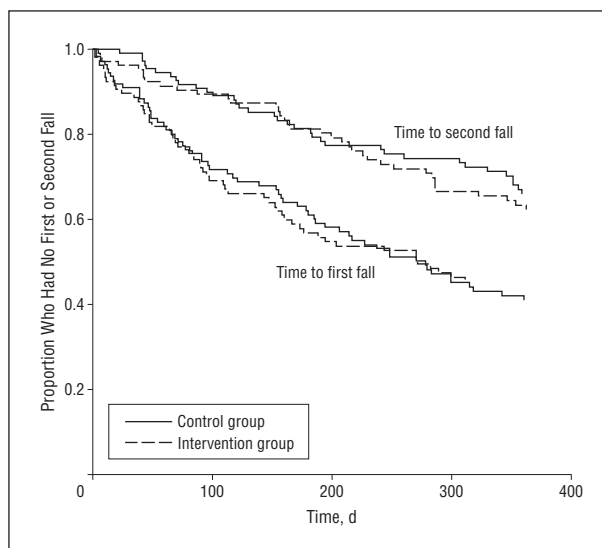
|   | Intervention Group (n=106) | Control Group (n=111) |
|---|----------------------------|-----------------------|
| Consultations   |                            |                       |
| Family physician  | 502                        | 377                   |
| Other physicians  | 284                        | 200                   |
| Physical therapy  | 678                        | 502                   |
| Occupational therapy                                    | 67                         | 17                    |
| Medication changes                                      |                            |                       |
| Initiate therapy with calcium carbonate/cholecalciferol | 17                         | 8                     |
| Discontinue benzodiazepine therapy                      | 9                          | 8                     |
| Acquired aids and adaptations                           |                            |                       |
| Walking aids  | 56                         | 57                    |
| Home modifications                                      | 140                        | 106                   |

<sup>a</sup>Participants in the control group received usual care.

Five participants in each group sustained a fracture (HR, 0.99; 95% CI, 0.73-1.34). One participant in the intervention group died compared with 7 in the control group. This difference was not statistically significant (HR, 0.15; 95% CI, 0.02-1.21).

**COMMENT**

In our multidisciplinary fall-prevention study, the selected high-risk patients did not benefit from the multifactorial intervention. The resulting risk of becoming a recurrent faller, the level of physical functioning, and QOL did not differ from results for the control group. Several explanations for the lack of difference in outcome between the 2 groups are possible.



**Figure 2.** Times to first and second falls for the intervention and control groups.

One explanation may be that, after publication of several hallmark studies and guidelines on fall prevention,<sup>16-18,24</sup> usual care has incorporated many beneficial strategies that are equally effective as a multifactorial intervention. This may have resulted in a lack of contrast between the groups. Care received in the control group (Table 3) illustrates the therapeutic response in usual care following a fall. Compared with the intervention group, the control group received 70.4% of the number of referrals to medical specialists and 74.0% of the number of sessions with physical therapists. This explanation is supported by the finding that patients from both the intervention and control groups reported a higher fall rate in the year before the study than was measured during study follow-up ( $P < .001$ ): both groups reported a median of 2 falls in the preceding year (Table 1). The mag-

**Table 4. Linear Regression Analyses of Secondary Outcome Measures<sup>a</sup>**

| Assessment Instrument<br>(Potential Score Range) | Mean Difference (SD) |               | Regression Coefficient<br>(95% CI) | Effect Size |
|--|----------------------|---------------|------------------------------------|-------------|
|  | Intervention         | Control       |                                    |             |
| Barthel Index (0-20)                             | -0.23 (2.24)         | 0.15 (1.90)   | -0.17 (-1.31 to 0.97)              | -0.08       |
| Lawton IADL (0-8)                                |                      |               |                                    |             |
| Women  | 0.10 (1.51)          | -0.08 (1.48)  | 0.20 (-0.89 to 1.29)               | 0.13        |
| Men  | -0.66 (2.03)         | 0.28 (1.93)   | -0.95 (-3.63 to 1.74)              | 0.47        |
| EuroQol (0-1)                                    | 0.01 (0.16)          | 0.07 (0.16)   | -0.01 (-0.30 to 0.29)              | -0.04       |
| SF-12 component                                  |                      |               |                                    |             |
| Mental (0-100)                                   |                      |               |                                    |             |
| Women  | -1.34 (11.44)        | -1.03 (10.48) | -0.56 (-3.72 to 2.60)              | -0.05       |
| Men  | 1.79 (11.12)         | -2.58 (9.55)  | 4.38 (-7.65 to 16.40)              | 0.41        |
| Physical (0-100)                                 | 2.60 (8.60)          | 1.86 (8.83)   | 0.69 (-2.15 to 3.53)               | 0.08        |
| Physical performance (0-12) <sup>b</sup>         | -1.12 (3.05)         | -0.72 (3.40)  | -0.36 (-1.98 to 1.27)              | -0.11       |

Abbreviations: CI, confidence interval; EuroQol, EuroQol EQ-5D; IADL, instrumental activities of daily living; SF-12, 12-Item Short-Form Health Survey.  
<sup>a</sup>Participants in the control group received usual care. Mean differences (follow-up–baseline) and SDs for the intervention and control groups are presented. Negative mean differences indicate a decline in the outcome measure. The crude regression coefficients and corresponding 95% CIs present the differences between the intervention and control groups in difference scores. Effect sizes (regression coefficient/SD of total sample) greater than 0.30 and 0.80 suggest a medium and large effect, respectively.<sup>41</sup> All results were pooled across the 5 imputed data sets.  
<sup>b</sup>Computation of the physical performance score is described in the “Secondary Outcome Measures” subsection of the “Methods” section.

nitude of the difference between the number of falls in the year preceding the study and those experienced in the year of the study is probably even greater than measured because the impact of recall bias is expected to be greater when falls are recorded retrospectively (year before study) compared with prospective follow-up.<sup>44</sup>

Second, screening and telling patients about the aim of the study and their estimated fall risk may be an effective intervention. Increased awareness of their high fall risk and precautionary measures such as avoiding dangerous situations may lower the incidence of falls.

Third, the lack of effectiveness may be attributed to a small study sample (type II error). When the study was designed in 2004, no major negative fall-prevention studies had been published, resulting in the expectation that the persons at highest risk would benefit most from fall-prevention strategies. This led us to an expected relative risk reduction of 50% in the intervention group and subsequently a minimum of 82 participants per group. However, an inverse power calculation with the current sample size demonstrates sufficient power to detect a difference of 19% in the proportion of fallers and 17% in the proportion of recurrent fallers. These findings render a type II error improbable.

Furthermore, by using the LASA risk profile to select high-risk participants, we may have selected a population with shared characteristics that rendered a multifactorial intervention ineffective. However, more than 70% of the included participants (81 in each group) also would have been selected had we chosen as participants individuals who had reported 2 or more falls in the previous year. When the times to first and second falls were analyzed for these 162 participants, the results did not change (HR > 0.90; *P* > .60).

Finally, the intervention we offered may not have been adequate to lower the fall risk in the very high-risk group we selected. The dose of cholecalciferol supplements prescribed may have been too low. A recent meta-analysis<sup>45</sup> showed that a cholecalciferol supplement containing less than 700 IU probably does not reduce fall risk. Furthermore,

physical therapy aimed at improving balance and strength may have led to hazardous situations during and after therapy. Increased muscle strength may have preceded improvement of balance and endurance. This hypothesis is supported by the results of a recent systematic review and meta-analysis<sup>46</sup> that showed superiority of exercise programs aimed at challenging balance compared with walking programs. Because the number of physical therapy consultations in the control group also was high (502 and 678 self-reported consultations in the control and intervention groups, respectively), we performed a post-hoc evaluation in which we combined participants of both groups. Participants who attended at least 3 physical therapy sessions were compared with those who did not. To control for the effect of confounding by indication, we adjusted for sex and intervention. No significant difference was present in any of the other potentially confounding baseline characteristics. The fall risk was significantly elevated in the physical therapy group (time to first fall: HR, 1.73; 95% CI, 1.15-2.60; time to second fall: 1.69; 1.00-2.88). These findings are in accordance with a study<sup>47</sup> that found that frail older persons who received exercise therapy had an increased fall risk compared with control subjects. This gives some support to the hypothesis that performing exercises and regaining mobility results in an increase in the time at risk of falling. On the other hand, it is possible that our functional and other measurements did not reveal the apparent differences in vulnerability that made physicians decide which patient would benefit from a referral to physical therapy.

The principal outcomes of our study confirm previous findings and expert opinions,<sup>21,48</sup> feeding concerns about the effectiveness of fall-prevention programs in high-risk older persons. Another recently published Dutch study<sup>21</sup> attributed the lack of effectiveness of their fall-prevention program to insufficient adherence, partly because of the organization of the Dutch health care system. In our study, we achieved a much higher adherence rate, but this did not result in a positive outcome for the intervention group. Our study adds to the growing body of evidence that should urge guideline developers to reconsider the recommendations

in current fall-prevention guidelines concerning community-dwelling older persons at high risk of falls.

The strength of our study is the selection of older persons with a very high risk of recurrent falls who are also at high risk of fractures and loss of independence.<sup>28</sup> Being able to prevent falls in these patients is of the utmost importance. To achieve this, we have tried to optimize the use of the relevant hospital and primary health care services routinely available in the Dutch health care system.

Limitations of our study result from the limited resources in standard health care. To maximize the use of these resources and adherence, we were subject to the limited availability of primary care employees such as home care nurses. Second, practical limitations resulted in a study design that excluded 2 high-risk groups: persons with a recent hip fracture that required more than 3 months of rehabilitation and persons with cognitive impairment. Our results therefore cannot be generalized to these subgroups. Furthermore, we did not incorporate an intervention aimed at psychological components of fall risk such as fear of falling. Programs to address fear of falling are not routinely available in the Netherlands. We assumed that regaining confidence through balance and strength training would also have a positive effect on fear of falling. We have not recorded injuries resulting from a fall other than fractures. A difference in the number or severity of injuries between groups may therefore have gone unnoticed. The large initial dropout rate is probably an effect of selection of patients with a high risk of falling. These patients often have mobility impairments and other comorbid conditions that resulted in a refusal to visit our outpatient clinic to participate in the study. A general limitation of multifactorial intervention studies is the inability to study the effects of the separate components of such an intervention.<sup>49</sup> Finally, the nonsignificant difference in mortality between the intervention and control groups may be an indication of undetermined beneficial effects of our intervention. We were unable to ascertain the causes of death and therefore cannot comment on the possible relation with the intervention.

Further studies aimed at fall-risk reduction in older persons at high risk are urgently needed. We especially recommend studying the effects of the different kinds of physical therapy that are feasible in standard care. We postulate that balance and endurance training should precede muscle strength training. Furthermore, we believe that adherence to the intervention can be further improved with intensified primary care-based encouragement and supervision, for instance, by nurse-led home visit programs. Because of the addictive properties of benzodiazepines, adherence to schedules for tapering and discontinuing therapy with these drugs is especially low. Home visits to support patients while they are discontinuing treatment with these drugs may be beneficial. Most important, giving older persons at high risk of recurrent falls explicit information about their high fall risk should be an integral part of secondary fall prevention.

We conclude that this multifactorial fall-prevention program is not suited for reducing fall risk in cognitively intact older persons with the highest risk of falling. New intervention programs and strategies to fur-

ther increase adherence should be developed and tested in this target group. Until then, we recommend closely monitoring the effects of the current multifactorial intervention in high-risk patients to allow intervention when an individually increased fall risk becomes apparent.

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## REFERENCES

1. Nevitt MC, Cummings SR, Kidd S, Black D. Risk factors for recurrent nonsyncopal falls: a prospective study. *JAMA*. 1989;261(18):2663-2668.
2. Tinetti ME, Doucette J, Claus E, Marottoli R. Risk factors for serious injury during falls by older persons in the community. *J Am Geriatr Soc*. 1995;43(11):1214-1221.
3. Tromp AM, Pluijij SM, Smit JH, Deeg DJ, Bouter LM, Lips P. Fall-risk screening test: a prospective study on predictors for falls in community-dwelling elderly. *J Clin Epidemiol*. 2001;54(8):837-844.
4. CBO. *Osteoporose: Tweede herziene richtlijn*. Alphen aan den Rijn, the Netherlands: Van Zuiden Communications BV; 2002.
5. Stel VS, Smit JH, Pluijij SM, Lips P. Consequences of falling in older men and women and risk factors for health service use and functional decline. *Age Ageing*. 2004;33(1):58-65.
6. Tinetti ME, Speechley M. Prevention of falls among the elderly. *N Engl J Med*. 1989;320(16):1055-1059.
7. de Boer MR, Pluijij SM, Lips P, et al. Different aspects of visual impairment as risk factors for falls and fractures in older men and women. *J Bone Miner Res*. 2004;19(9):1539-1547.
8. Leipzig RM, Cumming RG, Tinetti ME. Drugs and falls in older people: a systematic review and meta-analysis. I: psychotropic drugs. *J Am Geriatr Soc*. 1999; 47(1):30-39.
9. Penninx BW, Pluijij SM, Lips P, et al. Late-life anemia is associated with increased risk of recurrent falls. *J Am Geriatr Soc*. 2005;53(12):2106-2111.
10. Stel VS, Smit JH, Pluijij SM, Lips P. Balance and mobility performance as treatable risk factors for recurrent falling in older persons. *J Clin Epidemiol*. 2003; 56(7):659-668.
11. van Schoor NM, Smit JH, Pluijij SM, Jonker C, Lips P. Different cognitive functions in relation to falls among older persons: immediate memory as an independent risk factor for falls. *J Clin Epidemiol*. 2002;55(9):855-862.
12. van Haastregt JC, Diederiks JP, van Rossum E, de Witte LP, Voorhoeve PM, Crebolder HF. Effects of a programme of multifactorial home visits on falls and mobility impairments in elderly people at risk: randomized controlled trial. *BMJ*. 2000; 321(7267):994-998.
13. Fiatarone MA, O'Neill EF, Ryan ND, et al. Exercise training and nutritional supplementation for physical frailty in very elderly people. *N Engl J Med*. 1994;330 (25):1769-1775.
14. Province MA, Hadley EC, Hornbrook MC, et al. The effects of exercise on falls in elderly patients: a preplanned meta-analysis of the FICSIT Trials. *JAMA*. 1995; 273(17):1341-1347.



15. Tinetti ME, Baker DI, McAvay G, et al. A multifactorial intervention to reduce the risk of falling among elderly people living in the community. *N Engl J Med*. 1994; 331(13):821-827.
16. American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons Panel on Falls Prevention. Guideline for the prevention of falls in older persons. *J Am Geriatr Soc*. 2001;49(5):664-672.
17. CBO. *Richtlijn Preventie van valincidenten bij ouderen*. Alphen aan den Rijn, the Netherlands: Van Zuiden Communications BV; 2004.
18. Close J, Ellis M, Hooper R, Gluckman E, Jackson S, Swift C. Prevention of Falls in the Elderly Trial (PROFET): a randomized controlled trial. *Lancet*. 1999;353(9147):93-97.
19. Coleman EA, Grothaus LC, Sandhu N, Wagner EH. Chronic care clinics: a randomized controlled trial of a new model of primary care for frail older adults. *J Am Geriatr Soc*. 1999;47(7):775-783.
20. Davison J, Bond J, Dawson P, Steen IN, Kenny RA. Patients with recurrent falls attending Accident & Emergency benefit from multifactorial intervention—a randomized controlled trial. *Age Ageing*. 2005;34(2):162-168.
21. Hendriks MR, Bleijlevens MH, van Haastregt JC, et al. Lack of effectiveness of a multidisciplinary fall-prevention program in elderly people at risk: a randomized, controlled trial. *J Am Geriatr Soc*. 2008;56(8):1390-1397.
22. Hogan DB, MacDonald FA, Betts J, et al. A randomized controlled trial of a community-based consultation service to prevent falls. *CMAJ*. 2001;165(5):537-543.
23. Lightbody E, Watkins C, Leathley M, Sharma A, Lye M. Evaluation of a nurse-led falls prevention programme versus usual care: a randomized controlled trial. *Age Ageing*. 2002;31(3):203-210.
24. Chang JT, Morton SC, Rubenstein LZ, et al. Interventions for the prevention of falls in older adults: systematic review and meta-analysis of randomized clinical trials. *BMJ*. 2004;328(7441):680. doi:10.1136/bmj.328.7441.680.
25. Gates S, Fisher JD, Cooke MW, Carter YH, Lamb SE. Multifactorial assessment and targeted intervention for preventing falls and injuries among older people in community and emergency care settings: systematic review and meta-analysis. *BMJ*. 2008;336(7636):130-133.
26. Gillespie LD, Robertson MC, Gillespie WJ, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev*. 2009; (2):CD007146.
27. Graafmans WC, Ooms ME, Hofstee HM, Bezemer PD, Bouter LM, Lips P. Falls in the elderly: a prospective study of risk factors and risk profiles. *Am J Epidemiol*. 1996;143(11):1129-1136.
28. Pluijm SM, Smit JH, Tromp EA, et al. A risk profile for identifying community-dwelling elderly with a high risk of recurrent falling: results of a 3-year prospective study. *Osteoporos Int*. 2006;17(3):417-425.
29. Stalenhoef PA, Diederiks JP, Knottnerus JA, Kester AD, Crebolder HF. A risk model for the prediction of recurrent falls in community-dwelling elderly: a prospective cohort study. *J Clin Epidemiol*. 2002;55(11):1088-1094.
30. Stel VS, Pluijm SM, Deeg DJ, Smit JH, Bouter LM, Lips P. A classification tree for predicting recurrent falling in community-dwelling older persons. *J Am Geriatr Soc*. 2003;51(10):1356-1364.
31. Peeters GM, de Vries OJ, Elders PJ, Pluijm SM, Bouter LM, Lips P. Prevention of fall incidents in patients with a high risk of falling: design of a randomized controlled trial with an economic evaluation of the effect of multidisciplinary trans-mural care. *BMC Geriatr*. 2007;7:15. doi:10.1186/1471-2318-7-15.
32. Folstein MF, Folstein SE, McHugh PR. "Mini-Mental State": a practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res*. 1975; 12(3):189-198.
33. Kellogg International Work Group on the Prevention of Falls by the Elderly. The prevention of falls in later life. *Dan Med Bull*. 1987;34(suppl 4):1-24.
34. Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Md State Med J*. 1965;14:61-65.
35. Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist*. 1969;9(3):179-186.
36. Gandeck B, Ware JE, Aaronson NK, et al. Cross-validation of item selection and scoring for the SF-12 Health Survey in nine countries: results from the IQOLA Project. *J Clin Epidemiol*. 1998;51(11):1171-1178.
37. Brooks R. EuroQol: the current state of play. *Health Policy*. 1996;37(1):53-72.
38. Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol*. 1994; 49(2):M85-M94. doi:10.1093/geronj/49.2.M85.
39. Rossiter-Fornoff JE, Wolf SL, Wolfson LI, Buchner DM. A cross-sectional validation study of the FICSIT common data base static balance measures. *J Gerontol A Biol Sci Med Sci*. 1995;50(6):M291-M297.
40. Cohen J. *Statistical Power Analysis for the Behavioral Sciences*. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates; 1988.
41. Van Buuren S, Oudshoorn K. *Flexible Multivariate Imputation by MICE*. Leiden, the Netherlands: TNO Quality of Life; 1999.
42. Schafer JL. Multiple imputation: a primer. *Stat Methods Med Res*. 1999;8(1): 3-15.
43. Rubin DB. *Multiple Imputation for Nonresponse in Surveys*. New York, NY: John Wiley & Sons; 1987.
44. Ganz DA, Higashi T, Rubenstein LZ. Monitoring falls in cohort studies of community-dwelling older people: effect of the recall interval. *J Am Geriatr Soc*. 2005;53(12):2190-2194.
45. Bischoff-Ferrari HA, Dawson-Hughes B, Staehelin HB, et al. Fall prevention with supplemental and active forms of vitamin D: a meta-analysis of randomised controlled trials. *BMJ*. 2009;339:b3692. doi:10.1136/bmj.b3692.
46. Sherrington C, Whitney JC, Lord SR, Herbert RD, Cumming RG, Close JCT. Effective exercise for the prevention of falls: a systematic review and meta-analysis. *J Am Geriatr Soc*. 2008;56(12):2234-2243.
47. Faber MJ, Bosscher RJ, Chin A Paw MJ, van Wieringen PC. Effects of exercise programs on falls and mobility in frail and pre-frail older adults: a multicenter randomized controlled trial. *Arch Phys Med Rehabil*. 2006;87(7):885-896.
48. Tinetti ME. Multifactorial fall-prevention strategies: time to retreat or advance. *J Am Geriatr Soc*. 2008;56(8):1563-1565.
49. Kannus P, Sievänen H, Palvanen M, Järvinen T, Parkkari J. Prevention of falls and consequent injuries in elderly people. *Lancet*. 2005;366(9500):1885-1893.

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**INVITED COMMENTARY**

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## Why Multifactorial Fall-Prevention Interventions May Not Work

This well-done study by de Vries et al reports no significant decrease in falls with a multifactorial fall-prevention intervention. This is not the first negative study; there have been plenty. However, before we toll the death knell for multifactorial interventions as a prevention strategy, we need to figure out why multifactorial interventions appear to work in some studies but not others. What makes a multifactorial intervention succeed in reducing falls? Success may depend on 3 constructs: content, process, and choice of target group.

By *content*, I mean all the components that are considered part of a multifactorial intervention and are integral to its success.<sup>1</sup> The multifactorial intervention in the study by de Vries et al appears to contain the important elements. However, content related to physical therapy is not clearly described. Physical therapy is often the “black box” of a multifactorial fall intervention. Yet evidence suggests that, to be successful, therapy should last several months, focus on balance exercises, and become progressively more rigorous as balance im-