

# Multifactorial assessment and targeted intervention to reduce falls among the oldest-old: a randomized controlled trial

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**Background:** The purpose of this study was to assess the effectiveness of a multifactorial intervention to reduce falls among the oldest-old people, including individuals with cognitive impairment or comorbidities.

**Methods:** A randomized, single-blind, parallel-group clinical trial was conducted from January 2009 to December 2010 in seven primary health care centers in Baix Llobregat (Barcelona). Of 696 referred people who were born in 1924, 328 were randomized to an intervention group or a control group. The intervention model used an algorithm and was multifaceted for both patients and their primary care providers. Primary outcomes were risk of falling and time until falls. Data analyses were by intention-to-treat.

**Results:** Sixty-five (39.6%) subjects in the intervention group and 48 (29.3%) in the control group fell during follow-up. The difference in the risk of falls was not significant (relative risk 1.28, 95% confidence interval [CI] 0.94–1.75). Cox regression models with time from randomization to the first fall were not significant. Cox models for recurrent falls showed that intervention had a negative effect (hazard ratio [HR] 1.46, 95% CI 1.03–2.09) and that functional impairment (HR 1.42, 95% CI 0.97–2.12), previous falls (HR 1.09, 95% CI 0.74–1.60), and cognitive impairment (HR 1.08, 95% CI 0.72–1.60) had no effect on the assessment.

**Conclusion:** This multifactorial intervention among octogenarians, including individuals with cognitive impairment or comorbidities, did not result in a reduction in falls. A history of previous falls, disability, and cognitive impairment had no effect on the program among the community-dwelling subjects in this study.

**Keywords:** elderly, falls, intervention

## Introduction

In recent decades, the oldest-old segment of the population has been the most rapidly expanding, and is expected to reach 10% in developed countries by 2050.<sup>1</sup> Approximately one third of the population aged over 65 years and one half of nonagenarians experience at least one fall each year, and 15% fall at least twice. Therefore, falls are a major health problem, especially in the oldest-old group and the consequences of falling are severe.<sup>2,3</sup> Nearly 10% of falls result in a fracture and the mortality index with a fracture increases 33%.<sup>4,5</sup>

The evidence from randomized trials suggests that there are a number of fall prevention interventions with proven effectiveness.<sup>6–9</sup> However, most studies have specifically excluded the oldest-old age group, older people who are cognitively impaired, and those with comorbidities.<sup>6,7</sup> Therefore, the results of these studies may not be generalizable to this important group of elderly people at risk. However, two studies do

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exist on the oldest group of people in our community, ie, the Stepping On study that involved community-dwelling veteran subjects<sup>10</sup> and the home-based study on rural community-dwelling nonagenarians, which found that intervention was effective.<sup>11</sup> Another study of cognitively impaired older people included an intervention that was fully organized and coordinated by a hospital-based research team, which made adherence difficult. The results showed that this intervention was not effective.<sup>12</sup> A trial that did not exclude cognitively impaired participants and aimed to improve vision in individuals with a mean age of 81 years may even have increased the risk of falls.<sup>13</sup> These facts emphasize the need to know which group of oldest people are the most suitable for assessment. Moreover, various clinical practice guidelines<sup>14,15</sup> and recent prevention programs recommend multifactorial intervention as a primary treatment strategy.<sup>8,16,17</sup> However, none of these assessments contain high-level evidence on all community-dwelling older persons, including those with cognitive impairment.<sup>18</sup>

The aim of this study was to evaluate the effectiveness of a multifactorial assessment and targeted intervention to reduce falls among the oldest-old community-dwelling persons, including those with cognitive impairment and comorbidities.

## Materials and methods

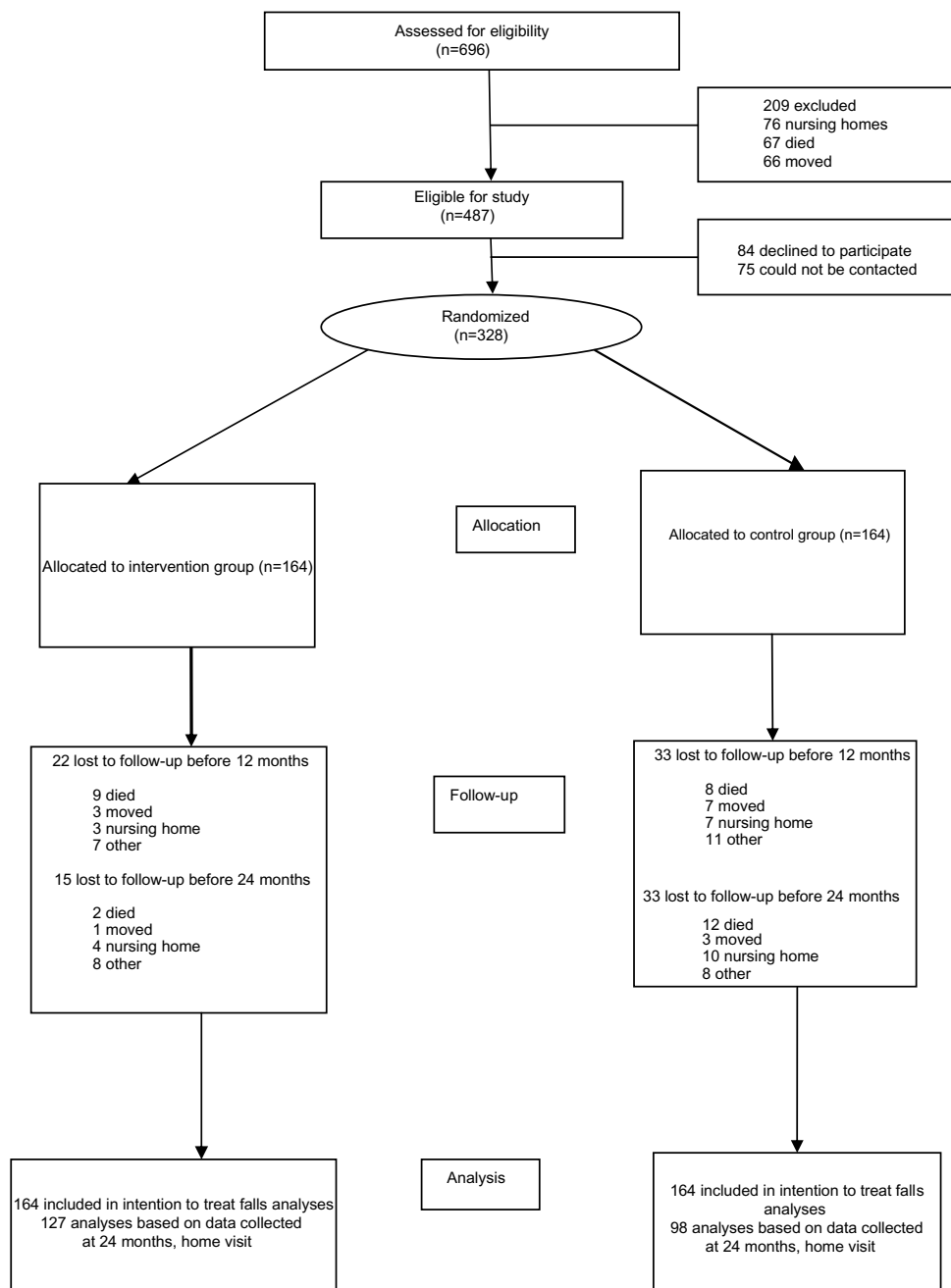
This was a randomized, parallel-group clinical trial (registration number NCT01141166)<sup>19</sup> conducted between January 2009 and December 2010. The design of the study has been published in detail elsewhere.<sup>20</sup> All community-dwelling individuals born in 1924 and registered at one of seven primary health care centers in Baix Llobregat, Barcelona, were contacted. The combined population served by these health care teams includes approximately 210,000 individuals from a total of 800,000 inhabitants of the Baix Llobregat area (where 17% of people are older than 65 years). The seven voluntary health care centers involved in other elderly assessments were from the same geographical area and have similar data with regard to proportion of immigrants (11%) and population served (70%). We did not use exclusion criteria for disease or cognitive impairment. The only exclusion criterion was being institutionalized. We selected an age of 85 years as that being very close to the maximum life span in developed countries and therefore representative of the oldest-old group (80 years or older). The institutional ethics committee of Jordi Gol Institute for Primary Care Research approved the study. Research assistants contacted potential participants, and individuals with

no exclusion criteria were asked to participate. All subjects who agreed to participate signed their informed consent before the study started. Persons who were unable to give informed consent were included if they had a relative or caregiver who could complete the assessment. There were no differences between respondents and nonresponders in terms of sex, health care center attended, or physician in charge. Data on the subjects were gathered by a health care professional (doctor, nurse, or member of health center), during the first year (baseline), and at 12 and 24 months of follow-up.

The baseline assessment included sociodemographic data (sex, marital status, studies, place of residence), functional status measured by the Barthel Index,<sup>21</sup> gait by the Tinetti test,<sup>22</sup> cognitive function measured by the Spanish version of the Mini-Mental State Examination,<sup>23</sup> nutritional status assessed using the Mini-Nutritional Assessment,<sup>24</sup> global comorbidity measured using the Charlson Comorbidity Index,<sup>25</sup> and chronic conditions (hypertension, diabetes mellitus, dyslipidemia, ischemic cardiomyopathy, heart failure, stroke, dementia, anemia, Parkinson's disease, and atrial fibrillation). The number of falls (defined as unexpected events in which an individual came to rest on the ground, floor, or a lower level),<sup>9</sup> fractures, and hospitalizations in the previous year were recorded, along with the number of long-term drug prescriptions. A health assistant undertook the baseline assessment for all subjects (an informant interview was conducted when the elder was unable to participate fully due to compromised health and/or cognitive ability), according to medical records and interviews in the primary care service or at home for subjects who were not ambulatory. The health care professional provided each subject with a monthly calendar similar to that used in other fall studies<sup>5</sup> for self-reporting of falls, fractures, and hospitalizations. A blood sample was collected from each participant after the baseline interview and 24 months later. After the baseline questionnaire had been administered, the subjects were randomized to an intervention or control group using a computer-generated randomization table. In total, 696 community-dwelling individuals registered at the seven primary health care centers were born in 1924. Of these, 142 did not meet the inclusion criteria and 67 died before they were contacted. Of the 487 eligible subjects, 328 (67.4%) were randomized (Figure 1).

## Intervention group

Subjects in the intervention group were assessed for their risk of falling and a treatment plan was devised based on their existing medical care and service networks in the community.



**Figure 1** Flow chart of participants throughout the trial.

The intervention used a specific algorithm that identified nine areas of potentially modifiable risk factors for falls, including psychotropic and cardiovascular drug use, auditory acuity, visual acuity, balance and gait disorders, risk of malnutrition, disability, cognitive impairment, social risk, and home safety (see Supplementary Table 1). A health care professional (doctor or nurse from the health center with specialized training in geriatrics) visited participants in the intervention group after their baseline interview to give recommendations according to the algorithm. For cognitively impaired participants,

caregivers were required to be an integral part of the program and ensure that the intervention was implemented. Participants were advised to contact their primary physician to review the results, recommendations, and referrals. Each participant's family physician was mailed after the examination to discuss referrals to medical specialists, changes in medication, and follow-up. Participants in the control group received usual health care.

The algorithm evaluated long-term prescriptions, with special emphasis on significant polypharmacy (five or more

prescriptions), progressive discontinuation of benzodiazepines, and nutritional or vitamin supplementation. Subjects were referred to an ophthalmologist if their worst corrected monocular near vision was less than 0.5/1 decimals on the Jaeger chart. If there was visual field impairment, the patient was advised to alter their lighting at home to improve visibility (high ambient light level, conventional wall-plug night light). Participants with gait disorders were referred to physical therapists for assessment and balance and strength training. There was a focus on progressive balance exercises over 3 months. Information given was reinforced with printed sheets of standard exercises adapted to this age group. The algorithm also generated recommendations for treatment of auditory impairment when the participant was unable to hear a whispered voice at approximately 0.6 m, for risk of malnutrition, and for functional or cognitive decline when deemed necessary. During the second year, two specific interventions were also offered as another set of recommendations, ie, rehabilitation and nutritional assessment. Rehabilitation assessment included subjects with one or more falls and no or minor cognitive impairment (Mini-Mental State Examination >19/35). These subjects received four 90-minute sessions with a physiotherapist over the course of 6 months coordinated by a specialist in rehabilitation at the referral hospital. Subjects at nutritional risk (Mini-Nutritional Assessment score  $\leq 23.5/30$ ) had three individual one-hour sessions with a dietician from the referral hospital, who developed plans for individualized nutrition. The nutritionist monitored nutritional intervention at the health care center at 3, 6, and 12 months. At the end of each session, the participants received printed information for use at home.

## Follow-up

The primary outcomes in the control and intervention groups were risk of falling (number of fallers) and time to first and second incident falls after entry into the study. Secondary outcomes were the number of adverse events (fractures, hospitalization) or the start of home care. Falls were ascertained during the annual assessment by self-report on the monthly calendar and from medical records. The health care professional telephoned participants at 3-monthly intervals to collect information from the calendar. To ensure blinding during data collection, measurements done by telephone were delegated to independent assessors at each center who were unaware of group allocation. Secondary outcomes were captured in a manner similar to that used for the primary outcome. Participants who were unavailable for follow-up or who had died were censored at the time of dropping out and were included

as censored information in the analysis. The health care professional conducted the 24-month follow-up assessment. In the event of loss to follow-up because of death, the date of death was documented. Adherence to recommendations was monitored by quarterly visits or telephone calls made by the therapist during the first and second years. A recommendation made by the health care professional was considered as adhered to if the participant completed at least 70% of the session's program at any time in the 24-month period.

## Statistical analysis

The primary outcome of falls was analyzed as the risk of falling (number of fallers) and the time to first, second, and recurrent falls. The study sample is described in more detail elsewhere.<sup>20</sup> Three statistical methods were used for the primary analysis of falls: relative risk and 95% confidence interval to compare the number of intervention and control participants with one or more falls during the first and second years of follow-up; a Kaplan–Meier method and log-rank test to compare differences between the intervention and control groups for time to first and second fall; and Cox proportional models, with time from randomization to first fall and the same variables to assess recurrent falls (the first two falls). The hazard ratio of intervention was estimated in the crude model. Intervention, history of previous falls, disability, sex, impaired cognition, and Charlson Comorbidity Index were included in the adjusted model. Secondary outcomes were analyzed as continuous variables by assessing differences between the control group and intervention group at 24 months of follow-up. All analyses were carried out by intention-to-treat. Proportional hazards assumption were tested in all models using scaled Schoenfeld residuals and log(-log) transformation in Kaplan–Meier curves. Negative binomial models were adjusted with intervention and control group variables stratified by follow-up period in order to estimate incidence rates. Sample characteristics of participants who dropped out versus those who completed follow-up in the first and second year were tested for consistency. The statistical significance level was set at 0.05. All analyses were performed using R version 2.14.2 software (R Foundation for Statistical Computing, Vienna, Austria).

## Results

In total, 328 subjects (including 202 [61.6%] women) were randomized into this study. The baseline characteristics of the two study groups were similar (Table 1), although subjects in the control group reported more barriers ( $P=0.03$ )

**Table 1** Baseline characteristics of study subjects

Characteristics	Control (n=164)	Intervention (n=164)	P-value
Sex: female, n (%)	101 (61.6%)	101 (61.6%)	0.91
Widowed marital status, n (%)	85 (51.8%)	89 (54.3%)	0.38
Formal education >6 years, n (%)	31 (18.9%)	31 (18.9%)	0.83
Lives alone	50 (30.5%)	50 (30.5%)	0.91
Home hazards	94 (57.3%)	114 (69.5%)	0.03
Visual acuity, median (IQR)	5.00 (3.0–10.0)	5.00 (3.0–10.0)	0.33
Impaired auditory acuity, n (%)	58 (35.4%)	66 (40.2%)	0.42
Hypertension, n (%)	128 (78.0%)	121 (73.8%)	0.44
Diabetes mellitus, n (%)	26 (15.9%)	30 (18.3%)	0.66
Dyslipidemia, n (%)	84 (51.2%)	84 (51.2%)	0.91
Ischemic cardiomyopathy, n (%)	6 (3.7%)	14 (8.5%)	0.11
Heart failure, n (%)	21 (12.8%)	21 (12.8%)	0.87
Previous stroke, n (%)	19 (11.6%)	30 (18.3%)	0.12
Dementia, n (%)	17 (10.4%)	14 (8.5%)	0.71
Anemia, n (%)	36 (22.0%)	20 (12.2%)	0.03
Parkinson's disease, n (%)	8 (4.9%)	5 (3.1%)	0.57
Atrial fibrillation, n (%)	22 (13.4%)	19 (11.6%)	0.74
Charlson Comorbidity Index (0–37), median (IQR)	1.00 (0.0–2.0)	1.00 (0.0–2.0)	0.55
Number of drugs taken, median (IQR)	6.00 (4.0–8.0)	6.00 (4.0–8.0)	0.50
MNA, median (IQR)	25.0 (22.5–27.5)	25.5 (23.0–27.5)	0.33
Barthel Index <sup>†</sup> , median (IQR)	95.0 (80.0–100)	95.0 (85.0–100)	0.50
Tinetti test (0–9), median (IQR)*	8.00 (5.00–9.00)	8.00 (5.00–9.00)	0.56
MEC** median (IQR)	28.0 (22.0–31.0)	29.0 (23.8–32.0)	0.16
Falls in previous year, n (%)			0.47
0	120 (73.2%)	115 (70.1%)	
1	32 (19.5%)	36 (22.0%)	
2	9 (5.5%)	6 (3.7%)	
≥3	3 (1.8%)	7 (4.3%)	
HbA <sub>1c</sub> (%), median (IQR)	5.65 (4.9–6.7)	6.05 (5.2–7.0)	0.24
Total cholesterol (mmol/L), mean (SD)	5.02 (1.0)	5.04 (1.0)	0.88
HDL-c (mmol/L), mean (SD)	1.47 (0.4)	1.45 (0.4)	0.66
Albumin (g/L), mean (SD) <sup>‡‡‡</sup>	41.2 (3.9)	41.5 (3.8)	0.55
Calcium (mmol/L), mean (SD) <sup>‡‡‡‡</sup>	2.32 (0.1)	2.31 (0.1)	0.32
Home care, n (%)	21 (12.8%)	18 (11.1%)	0.76
Follow-up (days), median (IQR)	744 (649–771)	752 (706–774)	0.11

**Notes:** \*Impaired Jaeger score <5; \*\*MEC: Spanish version of the Mini-Mental State Examination (cognitive impairment .24/35); <sup>†</sup>Barthel Index, functional status (dependency <90); Tinetti test, 0–9; <sup>‡‡‡</sup>albumin (normal range 37.0–53.0 g/L); <sup>‡‡‡‡</sup>calcium (normal range 2.2–2.5 mmol/L).

**Abbreviations:** IQR, interquartile range; SD, standard deviation; MNA, Mini Nutritional Assessment questionnaire (nutritional risk <23.5); HbA<sub>1c</sub>, glucose hemoglobin; HDL-c, high-density lipoprotein cholesterol.

and had more anemia ( $P=0.03$ ). The history of falls in the previous 12 months was similar between the groups, with 26.8% of subjects in the control group and 29.9% in the intervention group ( $P=0.47$ ) reporting at least one fall during the previous year. There was no difference between the intervention and control groups with regard to number of days of follow-up ( $P=0.11$ ). One hundred and three subjects were lost to follow-up. No statistically significant differences were found comparing the sample characteristics of participants who dropped out and those who completed follow-up in the first and second years.

“The completeness of the falls data showed that 275 subjects (including two subjects until they left the study

before 12 months) reported any fall during the first year and 238 subjects (fall data were collected for 13 subjects until they left the study from 12–24 months) during the second year.”

After one year of follow-up, there had been 62 falls in the control group and 57 falls in the intervention group; during the second year, the numbers of falls were 36 and 96, respectively. Forty-eight (29.3%) subjects in the control group and 65 (39.6%) in the intervention group reported one or more falls by the end of follow-up. The relative risk of having had any fall at 24 months of follow-up was increased (but not significantly so, relative risk 1.28, 95% confidence interval [CI] 0.94–1.75). Similarly, during

2 years of follow-up in this study, the Kaplan–Meier method revealed no significant differences between intervention and control participants in time to first ( $P=0.138$ ) and second fall ( $P=0.062$ ), as shown in Figure 2. In the Cox regression models for the first fall, the results were not significant for any of the variables in the final model (Table 2). In the analyses for recurrent falls, intervention had a significant negative effect (hazards ratio 1.46, 95% CI 1.03–2.09) in the third model. The intervention group showed no statistically significant difference in the crude first model (hazards ratio 1.42, 95% CI 1.00–2.02).

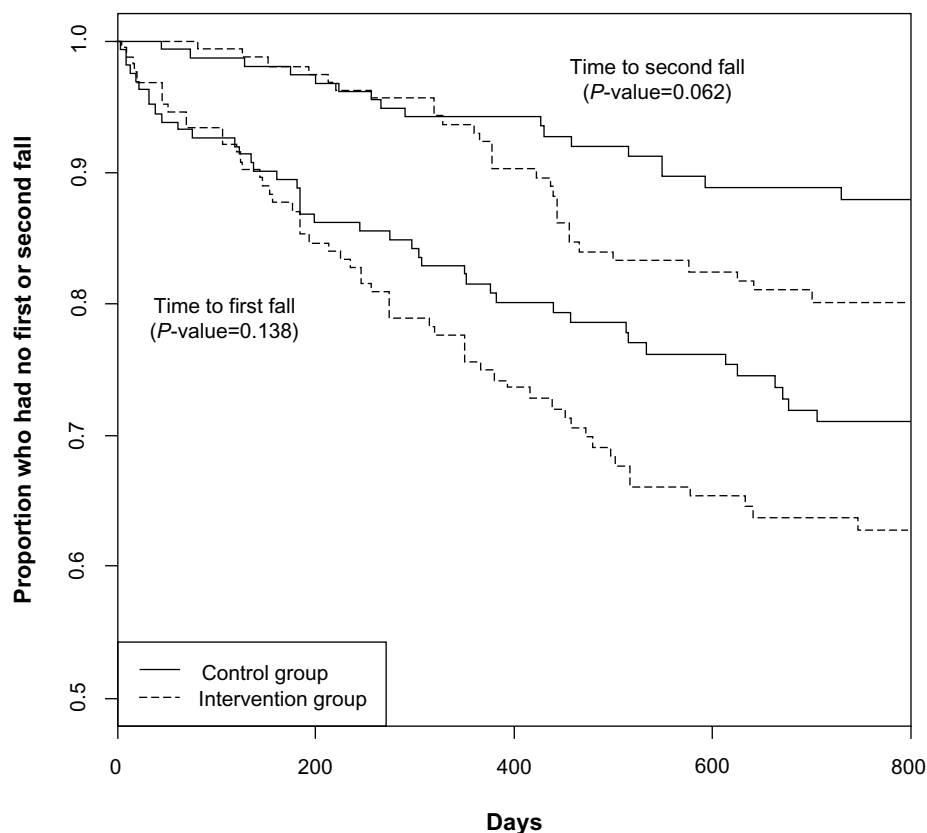
Analyses of secondary outcomes (Table 3) did not identify significant longitudinal changes in hospital emergencies or use of home care. However, a significant difference was found in number of fractures, and Table 4 shows the incidence rates (IR) for the intervention group. There was no statistically significant difference in fall rates between the two groups in the 12-month follow-up period, but there were differences during the 12–24-month period (IR 2.06, 95% CI 1.22–3.5). Adherence to recommendations in the first and second years is shown in Table 5. The 164 intervention participants received a total of 711 recommendations during the first year and 652 during the second year. Of these,

425 recommendations were adhered to in the first year and 522 in the second year.

## Discussion

Strategies to reduce falls in the elderly have been found to be effective.<sup>7</sup> This was a randomized community care study on reducing falls in the oldest-old people with comorbidity, and included individuals with poor health status. Some studies have used inclusion criteria such as very old age<sup>13,26</sup> or poor health status (dementia, anemia, heart failure),<sup>13,14,27</sup> but none combined all of these criteria. Our study found no evidence of reduction in risk of falls in the intervention group. There may be several reasons for this, awareness of which could help in the implementation of alternative strategies in the future.

The first explanation is that this intervention may not have been sufficient to improve muscle weakness or balance in this age group, although adherence with physical therapy was high (74%) in the current study. These findings are in contrast with the effective intervention results described previously in younger elders<sup>28–30</sup> and are in accordance with other clinical trials that included subjects of a similar age.<sup>31–34</sup> Although it is difficult to identify the effect of a particular component in this type of multifactorial intervention, one



**Figure 2** Comparison of Kaplan–Meier survival curves for time to first and second fall between control and intervention group over 2 years of follow-up.



**Table 2** Cox models for time to first fall and for recurrent falls (control or intervention group)\*

	First fall			Recurrent falls		
	Model 1	Model 2 <sup>†</sup>	Model 3 <sup>†</sup>	Model 1	Model 2 <sup>†</sup>	Model 3 <sup>†</sup>
Intervention group	1.35 (0.91–2.02)	1.41 (0.94–2.10)	1.40 (0.93–2.10)	1.42 (1.00–2.02)	1.46 (1.03–2.08)	1.46 (1.03–2.09)
Previous falls	–	–	1.24 (0.81–1.90)	–	–	1.09 (0.74–1.60)
Disability <sup>‡</sup>	–	1.53 (1.01–2.33)	1.41 (0.90–2.19)	–	1.48 (1.02–2.13)	1.44 (0.97–2.12)
Female	–	–	1.27 (0.82–1.98)	–	–	1.18 (0.80–1.75)
Cognitive impairment <sup>§</sup>	–	–	1.16 (0.74–1.82)	–	–	1.08 (0.72–1.60)
Comorbidity <sup>  </sup>	–	–	0.96 (0.58–1.61)	–	–	0.86 (0.54–1.38)

**Notes:** \*Data are presented as the hazard ratio and corresponding 95% confidence interval; <sup>†</sup>adjusted by listed variable; <sup>‡</sup>disability, indicated by a Barthel Index <90; <sup>§</sup>cognitive impairment, indicated by Spanish version of the Mini-Mental State Examination <24/35; <sup>||</sup>comorbidity, measured by the Charlson Comorbidity Index (0–37).

explanation for the lack of effect could be a paradoxical rather than undesirable effect of increased physical activity. The higher physical therapy adherence during the second year (90%) versus the first year (74%) resulted in an increased time at risk and therefore a higher risk of falls and injuries (fractures). Another reason for this effect could be low adherence with the home safety assessment (54% adherence), ie, a systematic approach to identify home hazards as an important component of the intervention, including stairs in the home and lighting factors.<sup>35–37</sup> This might be supported by the proportion of home hazards at baseline, which was found to be higher in the intervention group than in the control group. Moreover, there was poor adherence with hospital-based physical therapy and nutritional interventions in the current study, despite Spain having a system of universal health insurance such that the population has free access to these facilities (without additional cost for transport or specialist consultation). This suggests that, at the age of 85 years, more targeted physical therapy is needed as well as better integration of the different health care professionals (specialists, transport services, caregivers), especially if hospital-service specialists are used.

The second explanation is a differential in the quality of falls reporting. There is more opportunity for recording a fall in people visited more frequently (ie, our intervention group), which minimizes loss of data due to minor memory deficits in

these oldest-old people.<sup>14</sup> Therefore, “nonclassical” methods (including house alarm systems and effective telephone systems that provide health care 24 hours a day all year round) should be used in this oldest group, in addition to monthly calendars and telephone calls to report falls and gain a clearer picture of what happened with our elders.

The third reason could be the contamination effect of the control group. Some of the health professionals at the centers involved in the trial had patients from both the intervention and control groups in their practices.<sup>38</sup> Due to the study design, they did not know the group allocation of their patients. Therefore, an increase in the design of 20% of participants<sup>20</sup> could compensate for contamination between groups to had a negligible effect in this study.

The fourth reason is that the remaining total cohort that remanded to follow-up was a healthy group of individuals (with a Barthel Index score of 95, a Charlson Comorbidity Index score of 1, and on a mean of six medications), and most (73.2%) had not fallen in the year prior to the start of the study. Therefore, given that this group may not have had a very high falls risk, the effects of the intervention may have been diluted by this subgroup of robust patients. However, fear of falling was not reported in this trial,<sup>39</sup> and those people who had reported multiple previous falls at recruitment (1.8% in control group, 4.3% in the intervention group) were more likely to have experienced this problem,

**Table 3** Analyses of secondary outcomes, with mean and 95% confidence interval for groups at 24 months' follow-up and mean difference between groups. Sample is shown for the complete follow-up period

	Mean (95% CI)		Mean difference <sup>a</sup> (95% CI)
	Control (n=98)	Intervention (n=127)	
Fractures	0.02 (–0.18; 0.22)	0.06 (–0.13; 0.25)	–0.03 (–0.09; –0.02)
Hospital emergencies	0.46 (0.21; 0.71)	0.47 (0.25; 0.69)	–0.01 (–0.24; 0.21)
Hospital admissions	0.16 (–0.07; 0.39)	0.19 (0.01; 0.37)	–0.03 (–0.15; 0.10)
Home care*	0.19 (0.12; 0.29)	0.20 (0.14; 0.29)	–0.01 (–0.13; 0.10)

**Notes:** \*Proportion results; <sup>a</sup>mean difference between the control and intervention group is estimated; negative mean differences indicate a decline in the outcome measure. **Abbreviation:** CI, confidence interval.

**Table 4** Incidence rate (95% confidence interval) of falls and follow-up durations

Follow-up	Control	Intervention	P-value*	Incidence rate**
12 months				
Subjects, n	131	142	0.56	0.85 (0.51–1.40)
0 falls, n (%)	98 (74.8%)	102 (71.8%)		
1 fall, n (%)	20 (15.3%)	29 (20.4%)		
2 falls, n (%)	5 (3.82%)	6 (4.23%)		
≥3 falls, n (%)	8 (6.11%)	5 (3.52%)		
12–24 months				
Subjects, n	98	127	0.08	2.06 (1.22–3.5)
0 falls, n (%)	71 (72.4%)	81 (63.8%)		
1 fall, n (%)	21 (21.4%)	23 (18.1%)		
2 falls, n (%)	3 (3.06%)	13 (10.2%)		
≥3 falls, n (%)	3 (3.06%)	10 (7.87%)		

**Notes:** \*Chi-square test between control and intervention group for number of falls; \*\*negative binomial model adjusted by control and intervention group variable; reference category is control group.

so this excess of 2.4% (four participants) in the intervention population with the highest number of previous falls might thus have had a small increasing effect on the mean fall risk and number of falls.

The fifth explanation is that the capacity of the national health care system may have influenced the results, as happens in other health care systems.<sup>17,40</sup> The relatively long time interval between the initial recommendations and completion of the program may have been due to the fact that referrals to medical specialists have to be made via general practitioners. Shortening this period would be difficult without deviating from routine procedures. Further, continuous endorsement by the therapist of the need for active management of risk factors for falls was essential to actively engage participants and their families, as was shown by the increased adherence in the second year. In the second year, adherence increased for all types of recommendations (from 41% to 80% for those made by the

ophthalmologist, and from 32% to 42% for those made by the audiologist) probably because of difficulties in accessing the recommended measures (such as hearing aids which are expensive and not covered by national health insurance). These findings support the notion that greater integration of health care services may be required to assess, treat, and support the elderly.<sup>41</sup>

The sixth issue is that when we analyzed for the presence of disability<sup>35</sup> and cognitive impairment<sup>42,43</sup> in this study, there was no difference in time to falling between the intervention or control groups. Therefore, minor baseline functional impairment (Barthel Index <90) did not impair effective self-management of risk in everyday life situations in either the control group or the intervention group. This pattern is in accordance with previous studies that have reported a non-linear U-shaped relationship between activity levels and risk of falls, whereby people with the lowest and highest activity levels are at greater risk.<sup>39</sup>

**Table 5** Adherence to recommendations in the intervention group in the first and second year

Type of recommendation	One year (n=150)		Two years (n=136)	
	Recommended n (%)	Adhered n (%)	Recommended n (%)	Adhered n (%)
Discuss medication with primary care physician	97 (65)	63 (65)	102 (75)	92 (90)
See ophthalmologist	88 (59)	36 (41)	94 (69)	75 (80)
See audiologist	59 (39)	19 (32)	45 (33)	19 (42)
See community dietician	135 (90)	104 (77)	109 (80)	97 (89)
See community physical therapist	128 (85)	95 (74)	88 (65)	79 (90)
See community occupational therapist	25 (17)	13 (52)	39 (29)	33 (85)
See neurologist	34 (23)	19 (56)	35 (26)	29 (83)
Environmental modifications	79 (53)	43 (54)	85 (63)	65 (77)
See social services	66 (44)	33 (50)	55 (40)	33 (60)
Referred to hospital dietician service			47 (35)	19 (40)
Referred to hospital rehabilitation service			59 (43)	30 (51)



Similarly, cognitive impairment did not have any effect on the number of falls recorded in this study, as reported elsewhere.<sup>39,44</sup> However, other intervention programs have described lower rates of falls in older people with various degrees of cognitive impairment<sup>45,46</sup> and efficacious programs in people with a caregiver and minor cognitive impairment (Mini-Mental State Examination <28).<sup>23</sup>

The major strengths of this study are the external generalizability and applicability of the results due to inclusion of all oldest-old residents of similar age registered in the national health care system in one area, regardless of their somatic and cognitive comorbidities. However, this strength might also represent a weakness in that it limits the generalizability of the findings of this study to other populations. Another major strength is the length of follow-up, given that many studies of fall prevention are limited to short periods of follow-up. The main limitation concerns the recording of falls. In an attempt to reduce memory bias, falls were confirmed by a caregiver when available or by medical records. As in other similar studies, a further limitation was the high number of study participants who were lost to follow-up; however, this resulted in a study sample size that was similar to the median population size in other fall prevention trials.<sup>2</sup>

We conclude that this multifactorial intervention to reduce falls among octogenarians, including those with cognitive impairment or comorbidities, did not lead to a decrease in the risk of falling. Further studies including new physical therapy training protocols, programs to implement new strategies for reporting falls, and increased assessment of falls risk in the oldest-old age group are needed.

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## Author contributions

AF and FF conceived and designed the study and helped with preparation of the manuscript, HS provided statistical support and drafted the manuscript, TB helped with data

collection and reviewed the manuscript, and OJdV and RP made critical revisions to the manuscript. All the authors made substantial contributions toward the interpretation of data and drafting of the article and agree to be accountable for all aspects of the work.

## Disclosure

The authors report no financial or any other type of personal conflict of interest in this work.

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## Supplementary Material

Supplementary Table 1 Algorithm for targeted risk factors and interventions

Risk factor	Recommendations	Baseline assessment	3 months by telephone	9 months by telephone	12-month assessment
<b>Medications</b>					
Use of $\geq 5$ medications (over more than 6 months) If drugs	Discussion with patient about secondary effects, adherence (Morinsky test)				
Anti-inflammatory					
Cardiovascular	Recommendations to discuss medication with physician; reduce usage of as-needed medication				
Antibiotics					
Benzodiazepines					
Antidepressants					
Neuroleptics					
Others (diuretics, vitamins)	Advice for nonpharmacological options for sleep, pain, and constipation				
<b>Nutrition</b>					
If MNA test $<23.5/30$	Provide nutrition and exercise booklet				
Problems chewing, swallowing, teething	Exercise 30 minutes before meals				
If defective mouthpiece, bad oral hygiene or not adjusted	Recommendations to physician to consider etiology				
<b>Vision</b>					
Visual acuity: jaeger tables $<5$	Nursing accident prevention advice				
Diabetes mellitus: mydriatic camera review	Attention to turning movements ocular–cephalic Optometrist or ophthalmologist				
<b>Sense of hearing</b>					
Whispered voice test abnormal	Annual review of headphones Recommendations to physician to consider etiology and review ORL				
<b>Locomotor system: balance and mobility</b>					
Joint deformity, callus	Revision of lumbar spine, and upper and lower extremities				
Tinetti gait test ( $<9$ )	Recommendations for safe performance of mobility tasks				
Hand grip dynamometry	Consider referral to physical therapy				
<b>Functional status</b>					
Barthel I $\leq 60/100$	Patient and caregiver education regarding safe performance task, increased supervision, or other social assistance Recommendations to environmental hazards				
<b>Cognition</b>					
MEC $<24/35$	Patient and caregiver education avoiding multitasking, review of diary repercussions, consider depression Recommendations occupational therapy Recommendations to physician for further testing or consider neurology advice				
<b>Home hazards</b>					
Carpets, baths, stairs	Removal of throw rugs Recommendations for bathroom safety Social assistance if necessary to completed assessment				
<b>Home help</b>					
Lives alone, social risk revision	Attention to cleaning, meals, personal care, dependency				

Abbreviations: MNA, Mini-Nutritional Assessment; MEC, Spanish version of Mini-Mental State Examination; ORL, otorhinolaryngologist.

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