Published in final edited form as:

N Engl J Med. 2020 July 09; 383(2): 129–140. doi:10.1056/NEJMoa2002183.

A Randomized Trial of a Multifactorial Strategy to Prevent Serious Fall Injuries

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

A data sharing statement provided by the authors is available with the full text of this article at NEJM.org.

Abstract

BACKGROUND—Injuries from falls are major contributors to complications and death in older adults. Despite evidence from efficacy trials that many falls can be prevented, rates of falls resulting in injury have not declined.

METHODS—We conducted a pragmatic, cluster-randomized trial to evaluate the effectiveness of a multifactorial intervention that included risk assessment and individualized plans, administered by specially trained nurses, to prevent fall injuries. A total of 86 primary care practices across 10 health care systems were randomly assigned to the intervention or to enhanced usual care (the control) (43 practices each). The participants were community-dwelling adults, 70 years of age or older, who were at increased risk for fall injuries. The primary outcome, assessed in a time-to-event analysis, was the first serious fall injury, adjudicated with the use of participant report, electronic health records, and claims data. We hypothesized that the event rate would be lower by 20% in the intervention group than in the control group.

RESULTS—The demographic and baseline characteristics of the participants were similar in the intervention group (2802 participants) and the control group (2649 participants); the mean age was 80 years, and 62.0% of the participants were women. The rate of a first adjudicated serious fall injury did not differ significantly between the groups, as assessed in a time-to-first-event analysis (events per 100 person-years of follow-up, 4.9 in the intervention group and 5.3 in the control group; hazard ratio, 0.92; 95% confidence interval [CI], 0.80 to 1.06; P= 0.25). The rate of a first participant-reported fall injury was 25.6 events per 100 person-years of follow-up in the intervention group and 28.6 events per 100 person-years of follow-up in the control group (hazard ratio, 0.90; 95% CI, 0.83 to 0.99; P= 0.004). The rates of hospitalization or death were similar in the two groups.

CONCLUSIONS—A multifactorial intervention, administered by nurses, did not result in a significantly lower rate of a first adjudicated serious fall injury than enhanced usual care. (Funded by the Patient-Centered Outcomes Research Institute and others; STRIDE ClinicalTrials.gov number, NCT02475850.)

AMONG OLDER AMERICANS, FALLS ARE the leading cause of injury-related deaths.[1] Approximately one in four older adults falls each year, and 20 to 30% of those who fall have moderate-to-severe injuries, resulting in approximately 30,000 deaths, 3 million emergency department visits, and 800,000 hospitalizations annually.[2–5]

Despite evidence from efficacy trials that many falls in older adults can be prevented,[6–12] the quality of care for the prevention of falls remains low,[13,14] and age-adjusted mortality attributable to falls has continued to rise.[2] Barriers at multiple levels — health care systems, payers, providers, and patients — have contributed to sub-optimal implementation of prevention strategies that have been shown in efficacy trials to reduce the risk of falls.[9–12]

In 2014, the Patient-Centered Outcomes Research Institute and the National Institute on Aging funded a pragmatic trial, Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE), to determine the clinical effectiveness of a patient-centered intervention that combined elements of practice redesign (reconfiguration of workflow to improve quality of care) and an evidence-based, multifactorial, individually tailored intervention

implemented by specially trained nurses in primary care settings. This cluster-randomized trial was conducted at 86 primary care practices across 10 health care systems in the United States.[15] Here, we report the main findings of the trial.

METHODS

TRIAL DESIGN

Details of the trial design, recruitment and retention strategies, intervention, and adjudication procedures have been reported previously,[15–19] and the full trial protocol and statistical analysis plan are available with the full text of this article at NEJM.org. A single institutional review board approved the protocol. Oral informed consent was obtained from each participant or from a proxy with the participant's assent.[15] Input from stakeholders, including older persons not participating in the trial, was integrated into the planning and implementation of the trial.

Investigators, biostatisticians, and committees of content experts designed the trial (see the list of contributors in the Supplementary Appendix, available at NEJM.org). Personnel at the Yale Recruitment and Assessment Center and specially trained nurses collected the data, and personnel at the Yale Data Coordinating Center analyzed the data. The first four authors and the last author vouch for the accuracy and completeness of the data and analyses and for the fidelity of the trial to the protocol. These authors wrote the manuscript and made the decision to submit the manuscript for publication.

The 10 clinical sites, representing 10 health care systems, at which the trial was conducted included rural and urban locations and involved 15 individual reimbursement plans. Among 162 practices within the participating health care systems that were evaluated, 86 were selected on the basis of prespecified criteria that included the size of the practice, the ability to implement the intervention, the geographic proximity of the practice to other practices, the accessibility of electronic health records, and access to community-based exercise programs. Practices underwent cluster randomization to the intervention (intervention group) or to an enhanced usual care approach (control group) with the use of covariate-constrained randomization,[20] with stratification according to health care system and balancing covariates (i.e., the size of the practice, the location of the practice [urban vs. rural], and the race and ethnic group of the majority of persons in the practice [nonwhite vs. white, and Hispanic vs. non-Hispanic]). The maximum duration of intervention was 40 months, and the maximum duration of follow-up was 44 months.

PARTICIPANTS

Participants were community-dwelling adults, 70 years of age or older, who were at increased risk for fall injuries. Risk was determined on the basis of whether the participant had had a fall-related injury in the previous year or had fallen two or more times in the previous year or whether the participant was afraid of falling because of problems with balance or walking.[15,17] Persons with clinically significant cognitive impairment, defined by four or more errors on the six-item Callahan screening instrument,[21] could be included in the trial if they had a proxy who was willing to provide consent and assist them during the

trial. Persons who were incapable of providing consent or assent (with proxy consent) or were unable to speak English or Spanish were excluded.

SCREENING AND RECRUITMENT

At 9 of the 10 sites, we used a centralized screening strategy through the Yale Recruitment and Assessment Center, whereby age-eligible persons were mailed a letter asking them to complete a screening questionnaire that assessed their risk of fall injuries.[17] At the remaining site, practice staff screened age-eligible persons during clinic visits. For both strategies, persons who were assessed as having an increased risk of fall injuries were mailed an informational package and were later contacted by telephone by a recruiter at the Yale Recruitment and Assessment Center. The recruiter explained the trial, obtained oral informed consent or assent, confirmed eligibility, and collected baseline information.[17]

INTERVENTION

The multifactorial intervention was delivered by nurses who had completed a 26-module online course supplemented with a face-to-face session, as well as training in motivational interviewing and continuing education.[16] The nurses implemented the fall intervention strategy in partnership with the participants and their primary care providers. The intervention included five components. The first component was a standardized assessment of seven modifiable risk factors for fall injuries (impairment of strength, gait, or balance; use of certain medications; postural hypotension; problems with feet or footwear; vision impairment; osteoporosis or vitamin D deficiency; and home safety hazards). The second was standardized protocol-driven recommendations[22] for management of risk factors that were explained to the participant, caregiver, or both with the use of motivational interviewing. The third was the development of an individualized care plan, initially focused on one to three risk factors, that was approved by primary care providers. The fourth was implementation of the care plan, including referrals to community-based programs, if needed. The fifth was follow-up care, which was conducted by telephone or in person.[16] The risk factors for fall injuries were reassessed annually, and the care plan was revised, as needed.

A webinar about preventing falls[23] was made available to primary care providers in both trial groups. Participants in the control group received an informational pamphlet about falls that was created by the Centers for Disease Control and Prevention and were encouraged to discuss fall prevention with their primary care provider, who had received the results of the participant's screening evaluation.

TRIAL OUTCOMES

The primary outcome, assessed in a time-to-event analysis, was the first adjudicated serious fall injury, which was defined as a fall resulting in a fracture (other than a thoracic or lumbar vertebral fracture), joint dislocation, or cut requiring closure or a fall resulting in hospitalization for a head injury, sprain or strain, bruising or swelling, or other serious injury. The secondary outcome, assessed in a time-to-event analysis, was the first participant-reported fall injury. Data on fall injuries were collected every 4 months by means of telephone interviews, which were conducted by personnel who were unaware of the

treatment assignments. During these interviews, participants were also asked about hospital admissions, emergency department visits, and other health care utilization. To facilitate participants' recall, the participants were provided with a monthly calendar in which to record their falls and injuries.[24]

Serious adverse events, which included adverse events that resulted in hospitalization or death, were ascertained from the interviews that occurred every 4 months, from electronic health records, and from encounter data obtained from trial sites or from claims data obtained from the Centers for Medicare and Medicaid Services. Serious adverse events were categorized with the use of the *Medical Dictionary for Regulatory Activities*, version 18.1.[25]

EVENT ADJUDICATION

Serious fall injuries that were reported during telephone interviews were reviewed by an adjudication team that was unaware of the treatment assignments. The events were then verified with the use of administrative claims data (provided by trial sites) or encounter data (provided by the Centers for Medicare and Medicaid Services) or both or by review of electronic health records.[19] Each case was reviewed independently by two physician adjudicators who were unaware of the treatment assignment. Events deemed as "definitely" or "highly likely" to be a serious fall injury on the basis of verification of participant report by at least one additional objective source were adjudicated as events that met the criteria for the primary outcome.

STATISTICAL ANALYSIS

The sample size for the primary outcome of this cluster-randomized trial was determined on the basis of a log-rank test that accounted for the competing risk of death with the use of PASS (Power Analysis and Sample Size) software, version 12. We estimated that a sample of 6000 participants would result in a total of 844 events of a first adjudicated serious fall injury, which would provide the trial with 90% power to detect a hazard ratio of 0.80 favoring the intervention over control, with the following assumptions: a trial duration of 36 months (including an 18-month enrollment period), a two-sided type I error rate of 0.05, an equal number of primary care practices assigned to each treatment group, follow-up of all participants until the end of the trial, an annual event rate of 14% in the control group, an annual death rate (i.e., competing risk) of 7%, an annual rate of loss to follow-up of 3%, and an intracluster correlation coefficient of 0.0076 (estimated from the Lifestyle Interventions and Independence for Elders study).[15] Because enrollment in the trial was slower than projected, the duration of the trial was extended from 36 months to 40 months and the sample size was reduced to 5322 participants, which provided power that was equivalent to that under the original sample-size assumptions. After recruitment had ended, the maximum duration of follow-up was further extended from 40 months to 44 months because of lower-than-projected event rates in the control group.

All analyses were performed according to the intention-to-treat principle. The primary outcome was evaluated with the use of a multistate survival model that incorporated the competing risks of death and clustering.[26–28] The model was adjusted for randomization of practices by health care system and included covariates (the size of the practice, the location

of the practice, and race and ethnic group of the majority of persons in the practice) used for the constrained randomization. Data from participants who were lost to follow-up and had not had a serious fall injury were censored at the time of the participant's last interview. In a sensitivity analysis of the primary outcome, we adjusted for prespecified baseline covariates of the participants, including age, sex, race or ethnic group, level of education, number of chronic coexisting conditions, and number of positive responses on the screening questionnaire. The effect of the intervention relative to the control was estimated in a time-to-first-event analysis as a hazard ratio with corresponding 95% confidence intervals. We analyzed the effect of the intervention on the primary outcome in five prespecified subgroups using tests of interaction: age (70 to 79 years vs. ≥80 years), sex, fear of falling only (yes vs. no; i.e., the participant had a negative response to all the fall-related screening questions except the question about whether he or she had a fear of falling), presence of at least two chronic coexisting conditions (yes vs. no), and previous hip fracture or other fracture after 50 years of age (yes vs. no). The Hochberg procedure was used to adjust for multiple comparisons to preserve the overall two-sided type I error rate at 0.05.[29] The cumulative incidence of serious fall injuries was calculated with the use of nonparametric maximum likelihood estimation.[26] In a supportive analysis, we evaluated all serious fall injuries (irrespective of when they occurred during the trial) using a practice-level Poisson regression model (i.e., the unit of analysis was the practice). The primary outcome was analyzed at a two-sided type 1 error rate of 0.05. The rate of participant-reported fall injuries was analyzed in a manner similar to that of the primary outcome, but a two-sided significance level of 0.01 and 99% confidence intervals were used.

The rate ratios of serious adverse events that resulted in hospitalization were analyzed with the use of a practice-level Poisson regression model. The hazard ratios of serious adverse events that resulted in death were analyzed with the use of the marginal Cox model.[27] In the safety analyses, two-sided P values of less than 0.05 were considered to indicate statistical significance; no adjustment was made for multiple comparisons. The efficacy and safety analyses were performed with the use of SAS software, version 9.4, and R software, version 3.6.1.

RESULTS

PARTICIPANTS

On March 11, 2015, a total of 86 eligible primary care practices across 10 health care systems underwent cluster randomization; 43 were assigned to the intervention group and 43 to the control group (Fig. S1 in the Supplementary Appendix). The practices assigned to the two groups were similar with respect to the size of the practice, the number of practices that were in urban locations as compared with rural locations, the number of practices in which a majority of the participants was white as compared with nonwhite, and the practice-level baseline characteristics of the participants (Table S1).

A total of 18,571 persons were interviewed by telephone for assessment of eligibility; of these, 5451 were deemed eligible and provided oral consent or assent (Fig. S2). Among the 2802 participants in the intervention group, 155 (5.5%) died and 221 (7.9%) withdrew consent before having had a serious fall injury; in the control group, 141 of the 2649

participants (5.3%) died and 155 (5.9%) withdrew consent before having had a serious fall injury. Of the potentially observable person-years of follow-up for the primary outcome, 86.5% were observed in the intervention group and 88.5% in the control group.

The demographic and baseline characteristics of the participants in the two groups were similar at baseline. Across the groups, the mean age was 80 years, 62.0% were women, 38.9% had had a fall with an injury during the previous year, and 35.1% had had two or more falls during the previous year (Table 1).[18]

Among the 2404 participants who received the intervention (85.8% of the 2802 participants assigned to intervention), the most commonly identified risk factors included problems with strength, gait, or balance; osteoporosis or vitamin D deficiency; and vision impairment (Table 2). These three risk factors were also identified as the most common risk factors that participants prioritized and agreed to address (Table 2). The use of certain medications, postural hypotension, problems with feet or footwear, and home safety hazards were less commonly identified, and the use of certain medications was the least commonly prioritized. All the participants in the control group were mailed an informational pamphlet about falls.

OUTCOMES

The rate of a first adjudicated serious fall injury did not differ significantly between the intervention group and the control group (4.9 events per 100 person-years of follow-up in the intervention group and 5.3 events per 100 person-years of follow-up in the control group; hazard ratio, 0.92; 95% confidence interval [CI], 0.80 to 1.06; P= 0.25) (Fig. 1A). A practice-level analysis yielded similar results (hazard ratio, 0.92; 95% CI, 0.78 to 1.08), as did a sensitivity analysis with adjustment for participant-level covariates (hazard ratio, 0.88; 95% CI, 0.76 to 1.02). The effect of the intervention on the primary outcome was consistent across the prespecified subgroups (Fig. 2).

The rate of a first participant-reported fall injury was 25.6 events per 100 person-years of follow-up in the intervention group and 28.6 events per 100 person-years of follow-up in the control group (hazard ratio, 0.90; 95% CI, 0.83 to 0.99; P = 0.004) (Fig. 1B). The rates of all adjudicated serious fall injuries and all participant-reported fall injuries did not differ significantly between the groups (Table S2). The most common types of adjudicated serious fall injuries were bone fractures and injuries leading to hospitalization (Table S3).

SERIOUS ADVERSE EVENTS

The rates of serious adverse events that resulted in hospitalization or death were similar in the two groups (Table 3). The rate of death from serious adverse events was 3.3 deaths per 100 person-years of follow-up in both groups, and the rate of hospitalization for serious adverse events was 32.8 hospitalizations per 100 person-years of follow-up in the intervention group and 33.3 per 100 person-years of follow-up in the control group.

DISCUSSION

In this pragmatic, randomized trial conducted in primary care practices, an individually tailored intervention, administered by specially trained nurses, that addressed multiple risk

factors for falls did not result in a significantly lower rate of a first adjudicated serious fall injury than enhanced usual care among older adults who were at increased risk for fall injuries. The rate of all serious fall injuries, irrespective of when they occurred during the trial, also did not differ significantly between the two groups. Sensitivity and supportive analyses confirmed the findings of the primary outcome analysis. The intervention was associated with a lower rate of a first participant-reported fall injury than enhanced usual care. The point estimates of the intervention effect were consistent across prespecified analyses of the outcomes related to serious fall injury (with hazard ratios varying from 0.88 to 0.92), suggesting a modest treatment effect that was lower than the hypothesized 20% difference.

Our finding that the multifactorial intervention was not significantly more effective than enhanced usual care in reducing serious fall injuries was unexpected, since previous efficacy trials have shown benefit with respect to individual components of the intervention.[30–32] In the real-world practice settings of this pragmatic trial, the intervention may have been less effective than expected for several reasons. First, adherence to the intervention plan may have been lower than in previous efficacy trials because of difficulties that participants faced in implementing recommendations that required transportation, copayments, or insurance coverage. Second, participants were referred to existing services provided by local health or community centers, but the trial provided no additional resources. Third, adherence to behavior modification interventions (e.g., exercise) was not routinely monitored; therefore, participation may have fallen below the thresholds needed to achieve an exercise benefit. Fourth, the participant-centered intervention used motivational interviewing that encouraged participants to choose recommendations they were willing to address; consequently, some potentially valuable recommendations were not implemented. For example, only 29% of the participants who were taking a medication identified as a risk factor agreed to address this risk factor, and only half the participants who had a home safety hazard agreed to mitigate this risk. Fifth, participants or their physicians may have chosen to implement less effective approaches to address risk factors (e.g., choosing calcium or vitamin D supplementation rather than medications for osteoporosis or choosing community exercise programs that were not evidence-based). Sixth, among the participants randomly assigned to intervention practices, 14.2% did not receive the intervention because of a change in health care provider, withdrawal from the trial, inability to complete the initial visit, or death. Finally, improving quality of care for falls may not be sufficient to reduce serious fall injuries.[33]

The observed intervention effect (approximately 8%) was similar to that achieved by a practice-change intervention (9%) in the Connecticut Collaboration for Fall Prevention trial[34] and that reported in a meta-analysis (6%) of multicomponent interventions.[35] These studies suggest that the effectiveness of programs to prevent fall injury in real-world practice may be considerably less than that in the controlled setting of an efficacy trial. Additional measures (e.g., interventions to increase adherence to exercise programs and more intensive strategies to encourage people to discontinue certain medications) may be needed to increase the effectiveness of strategies to prevent fall injury in the clinical practice setting.

The annual rates of adjudicated serious fall injuries (approximately 5%) in our trial were substantially lower than we had hypothesized (14%). The stringent adjudication criteria and

the inclusion in the definition of the primary outcome of falls resulting in hospitalization for injuries other than fractures, joint dislocation, or cut requiring closure, which was implemented to reduce ascertainment bias, may have contributed to the lower-than-expected observed rates of serious fall injury. It is also possible that conducting the trial within health care systems may have increased awareness of the risk of falls among participants and providers, thereby influencing fall prevention practice[36] and leading, in turn, to lower rates of serious fall injuries in both groups and to dilution of the intervention effect toward the null.

Our trial had several strengths. It integrated practice redesign, comanagement of care by a specially trained nurse, motivational interviewing, and individualized, risk factor–guided, multifactorial intervention into primary care practices. The fact that the trial had few exclusion criteria enabled enrollment of a population that was generally representative of older adults at increased risk for fall injuries, including those with cognitive impairment. We used a prespecified definition for a serious fall injury and required at least two independent sources in the adjudication process to increase accuracy in ascertainment of the primary outcome. The intervention was participant-centered, and the design and implementation of the trial were guided by substantial input from older persons not participating in the trial and other stakeholders.

Our findings should be interpreted in the context of their limitations. Participants were more educated than the general population, and the trial had modest representation of races and ethnic groups other than whites and of persons with substantial cognitive impairment.[17,18] Small independent group practices were not included. Because monthly ascertainment of falls was not feasible,[37] we combined the interviews that took place three times per year with verification of participant-reported serious fall injuries using encounter data, claims data, or medical records. Interpretation of the findings of the trial is also limited by the lack of process measures (e.g., adherence to behavioral interventions). Finally, the effects of the intervention on health care resource utilization have not been determined.

The nurse-administered multifactorial intervention in a primary care setting did not result in a significantly lower rate of a first adjudicated serious fall injury than enhanced usual care among older adults at increased risk for fall injuries.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

The content of this article is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Supported by the Patient-Centered Outcomes Research Institute and the National Institute on Aging of the National Institutes of Health (NIH) through a cooperative agreement (5U01AG048270) between the National Institute on Aging and Brigham and Women’s Hospital. The project is part of the Falls Injuries Prevention Partnership between the National Institute on Aging and Patient-Centered Outcomes Research Institute. This research is partially supported by the Boston Claude D. Pepper Older Americans Independence Center at Brigham and Women’s Hospital (P30AG013679) and Harvard Catalyst, the Harvard Clinical and Translational Science Center (National Center for Research Resources and the National Center for Advancing Translational Sciences, NIH Award

UL1TR001102) and financial contributions from Harvard University and its affiliated academic health care centers. Support was also provided by the Claude D. Pepper Older Americans Independence Centers at the University of California, Los Angeles (P30AG028748), Yale University (P30AG021342), Mount Sinai Medical Center (P30AG2874106), the University of Texas Medical Branch (P30AG024832), the University of Michigan (P30AG024824), the University of Pittsburgh (P30AG024827), Wake Forest University School of Medicine (P30AG021332), and the Older Americans Independence Center National Coordinating Center (U24AG059624). Mount Sinai Medical Center also received grant support from the New York Academy of Medicine. Additional support at Yale University was provided by the Clinical and Translational Science Awards program of the National Center for Advancing Translational Sciences of the NIH (UL1TR000142) and by the National Institute on Aging to Dr. Gill (Academic Leadership Award K07AG043587). Dr. McMahon was supported by grants (KL2TR000113 and UL1TR000114) from the University of Minnesota Clinical and Translational Science Institute, which is funded by the National Center for Advancing Translational Sciences of the NIH. The University of Michigan also received support from Michigan Medicine, its academic health care system. The University of Pittsburgh also received support from the University of Pittsburgh Medical Center, its academic health care system.

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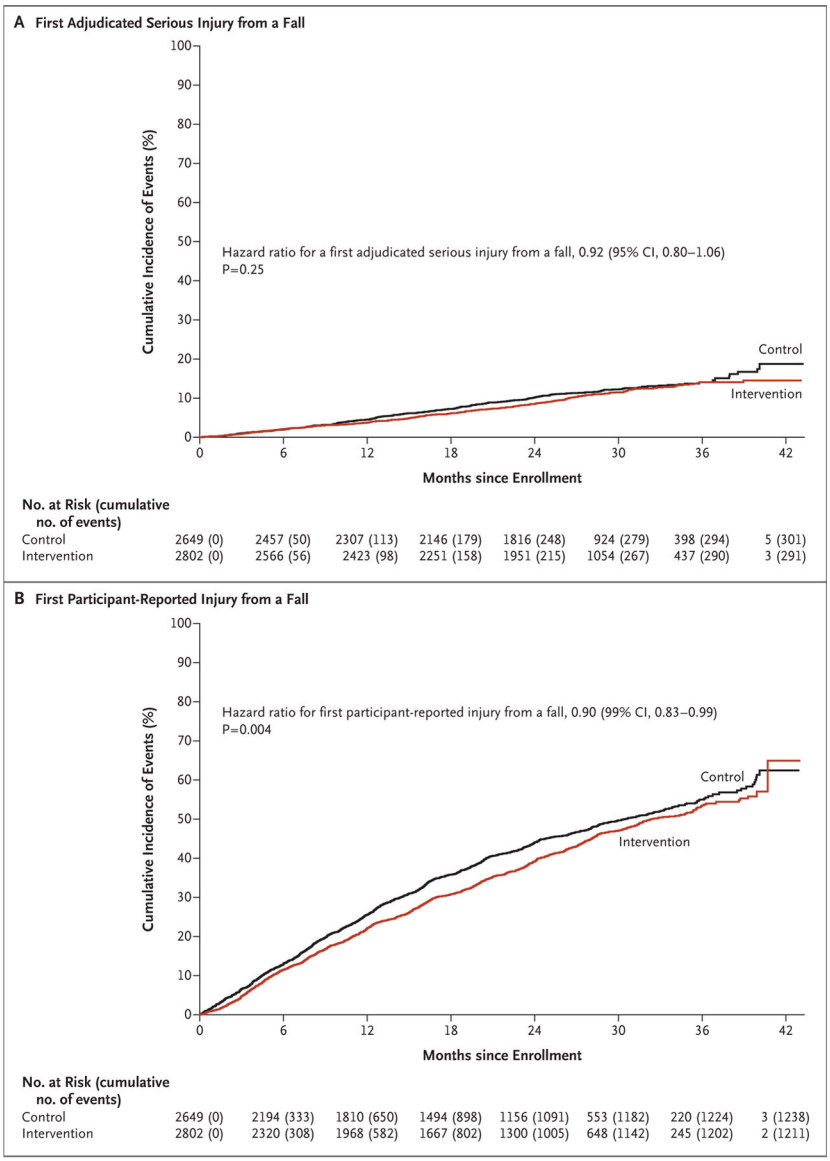

Figure 1. Cumulative Incidence of a First Adjudicated Serious Fall Injury and a First Participant-Reported Fall Injury.

The cumulative incidence curves are plotted to the last event time in each treatment group. The cumulative incidence of a first adjudicated serious fall injury over the course of 3.5 years was 15% in the intervention group (95% bootstrap CI, 13 to 16) and 19% in the control group (95% CI, 14 to 24) (Panel A). The cumulative incidence of a first participant-reported fall injury over the course of 3.5 years was 65% in the intervention group (99% CI, 53 to 80) and 63% in the control group (99% CI, 56 to 71) (Panel B).

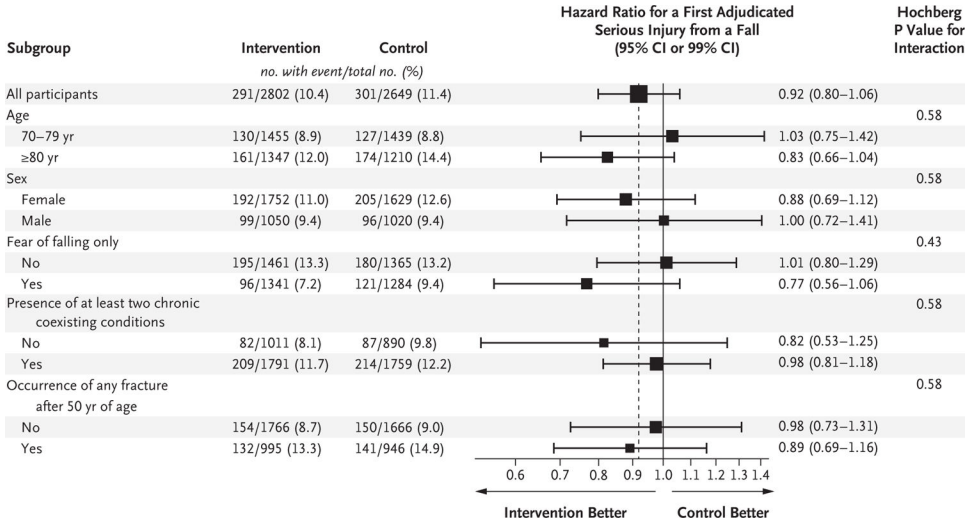

Figure 2. Prespecified Subgroup Analysis of the Primary Outcome.

The effect of the intervention on the first adjudicated serious fall injury was evaluated in five prespecified subgroups with the use of tests of interaction. Adjustment for multiple comparisons was made with the use of the Hochberg procedure to preserve an overall two-sided type 1 error rate at 0.05. The point estimates of the hazard ratio and the associated confidence intervals (95% for the overall analysis and 99% for each subgroup) are shown. Participants in the “Fear of falling only” subgroup had a negative response to all the fall-related screening questions except the question about whether they had a fear of falling. The dashed vertical line represents the hazard ratio for the overall intervention effect. The size of each black square is proportional to the total number of participants in the subgroup.

Table 1.

Demographic and Clinical Characteristics of the Participants at Baseline.*

Characteristic	Intervention (N = 2802)	Control (N = 2649)
Age — yr	79.9±5.7	79.5±5.8
Female sex — no. (%)	1752 (62.5)	1629 (61.5)
Race — no. (%)†		
White	2571 (91.8)	2394 (90.4)
Black	128 (4.6)	164 (6.2)
Other or unknown	103 (3.7)	91 (3.4)
Hispanic ethnic group — no. (%)†	196 (7.0)	211 (8.0)
Educational level — no. (%)		
High school graduate or less	602 (21.5)	643 (24.3)
Some college or equivalent	697 (24.9)	659 (24.9)
College graduate or higher	1502 (53.6)	1343 (50.7)
Unknown	1 (<0.1)	4 (0.2)
Chronic coexisting conditions‡		
No. per participant	2.1±1.3	2.1±1.3
Fracture other than of the hip after 50 yr of age — no. (%)	918 (32.8)	876 (33.1)
Hip fracture after 50 yr of age — no. (%)	132 (4.7)	119 (4.5)
Clinically significant cognitive impairment — no. (%)§	85 (3.0)	75 (2.8)
Use of a mobility aid or inability to ambulate — no. (%)	972 (34.7)	909 (34.3)
Response to screening questions regarding risk of fall injuries — no. (%)		
Fell two or more times in the past year	1015 (36.2)	896 (33.8)
Had a fall-related injury in the past year	1089 (38.9)	1031 (38.9)
Was afraid of falling because of problems with walking or balance	2405 (85.8)	2273 (85.8)
Had a fear of falling only, with a negative response to the other three questions	1341 (47.9)	1284 (48.5)
No. of positive responses to screening questions regarding fall injuries — no. (%)		
1	1634 (58.3)	1571 (59.3)
2	629 (22.4)	605 (22.8)
3	539 (19.2)	473 (17.9)

[*] Plus–minus values are means ±SD. Percentages may not total 100 because of rounding.

[†] Race and ethnic group were reported by the participant.

[‡] Other chronic conditions reported included hypertension, cancer, arthritis, diabetes, chronic lung disease, myocardial infarction, stroke, congestive heart failure, and Parkinson's disease.

[§] Participants were assessed as having clinically significant cognitive impairment if they had four or more errors on the six-item Callahan cognitive screening instrument or if the initial telephone interview was completed entirely by proxy.

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Table 2.

Risk Factor Assessment and Prioritization among Participants in the Intervention Group.*

Risk Factor	Participants Assessed for Risk Factors†	Participants Assessed Determined to Have Risk Factor	Participants Who and Had Risk Factor and Prioritized Risk Factor	Participants Who Prioritized Risk Factor and Agreed to Address Risk Factor
		no./total no. (%)		
Use of certain medications	2402/2404 (99.9)	819/2402 (34.1)	429/819 (52.4)	234/429 (54.5)
Impairment of strength, gait, or balance	2354/2404 (97.9)	2354/2354 (100)	2252/2354 (95.7)	2148/2252 (95.4)
Postural hypotension	2331/2404 (97.0)	470/2331 (20.2)	437/470 (93.0)	281/437 (64.3)
Problems with feet or footwear	2375/2404 (98.8)	1478/2375 (62.2)	1226/1478 (82.9)	749/1226 (61.1)
Osteoporosis or vitamin D deficiency	2402/2404 (99.9)	2320/2402 (96.6)	2001/2320 (86.2)	1482/2001 (74.1)
Vision impairment	2399/2404 (99.8)	2086/2399 (87.0)	1831/2086 (87.8)	1403/1831 (76.6)
Home safety hazards	2400/2404 (99.8)	680/2400 (28.3)	548/680 (80.6)	341/548 (62.2)
Any risk factor	2404/2404 (100)	2402/2404 (99.9)	2379/2402 (99.0)	2265/2379 (95.2)

*The data presented in this table were collected by specially trained nurses with the use of structured questions during clinical encounters conducted in person or by telephone.

†A total of 2404 (85.8%) of the 2802 participants who were randomly assigned to the intervention group had an initial visit with a specially trained nurse and received the intervention.

Table 3.

Deaths or Hospitalizations Resulting from Serious Adverse Events.

Outcome of Serious Adverse Event	Intervention (N = 2802)*			Control (N = 2649)*			Adjusted Ratio (95% CI)†	P Value
	Participants	Events	Rate‡	Participants	Events	Rate‡		
	no. (%)	no.		no. (%)	no.			
Death	235 (8.4)	235	3.3	220 (8.3)	220	3.3	1.01 (0.84–1.23)	0.88
Hospitalization	1139 (40.6)	2344	32.8	1108 (41.8)	2246	33.3	0.98 (0.92–1.04)	0.47

*In the intervention group, the duration of follow-up for the 2802 participants was equivalent to 7141.0 person-years of follow-up; in the control group, the duration of follow-up for the 2649 participants was equivalent to 6746.1 person-years of follow-up.

†Each ratio was adjusted for clustering, health care system, and practice-level characteristics (size, geographic location, and race and ethnic group of the majority of persons in the practice). The hazard ratio for death was based on the marginal Cox model. The rate ratio for hospitalization was analyzed with the use of a practice-level Poisson regression model.

‡Rates are expressed as events per 100 person-years of follow-up.

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