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

Shravya Budidi, DO
Fellow in Geriatrics

Case

- 92F w/ DM, HTN, severe kyphosis with recurrent falls who presented to clinic for annual visit.

Past Medical/ Surgical History	Medications	Social History
Type II DM Hypertension Hyperlipidemia Mild Cognitive Impairment Osteoporosis Osteoarthritis Appendectomy C-section x 3	Alendronate Vitamin D 2000U Voltaren gel Lasix 80mg Lisinopril 40mg Metoprolol 50mg ER Amlodipine 10mg Simvastatin 20mg Senna Miralax	Alcohol: None Smoking: Never Drugs: No ADL: Assistance in some ADLs IADL: Dependent Home: Bedroom on the second floor Lives with children

Case

- **Vitals:** BP 121/68, HR: 72, RR: 18 O2: 98%
- **Physical exam:**
  - Gen: Good hygiene, sitting in chair.
  - CV: RRR
  - Pulm: CTAB
  - MSK/Gait
    - Kyphosis
    - Difficulty rising from the chair
    - Get up and go 25 seconds
    - Uses walker

Case

For fall prevention, what strategies should we consider implementing?

Case

- **On 11/3, seen in office with following recommendations for fall prevention:**
  - Physical therapy
  - Deprescribing medication
  - Life alert bracelet

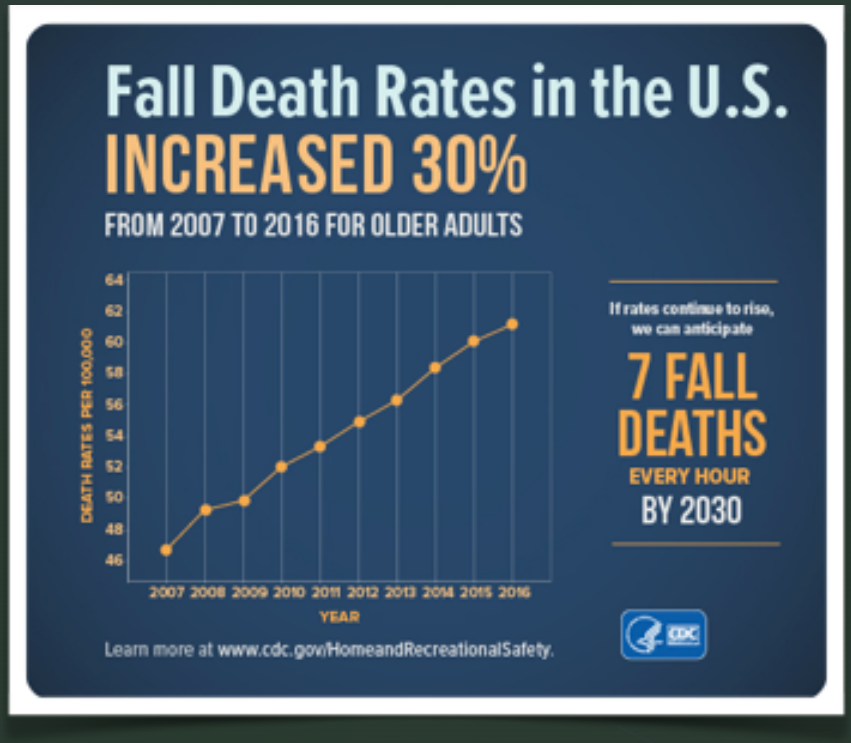
- **On 11/11, presented to the ER s/p fall**

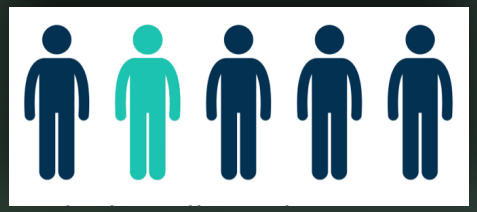
Clinical Question

- In community dwelling patients at risk for falls, does implementing a multifactorial fall prevention strategy reduce serious fall injuries compared to usual care?

Falls

- Fall Prevalence





- Fall Prevention
  - Risk Assessment
  - Intervention

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ORIGINAL ARTICLE

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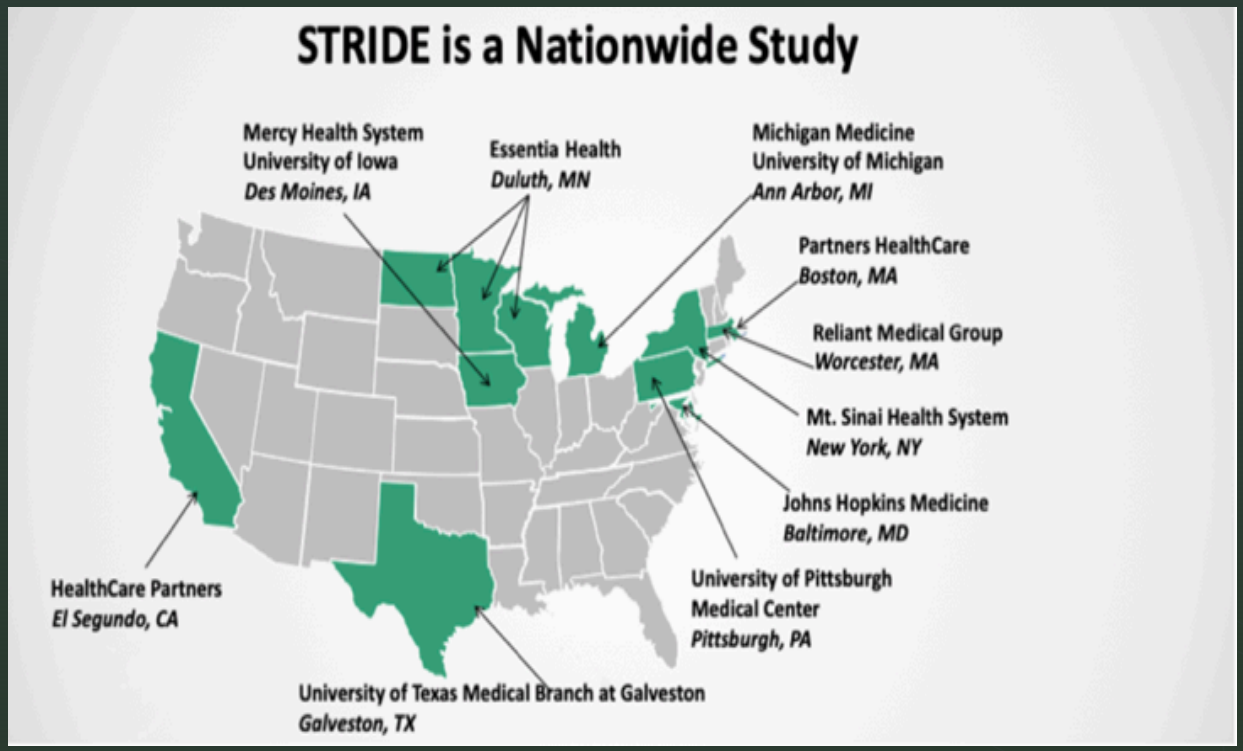
Study Aim

- To evaluate the effectiveness of a multifactorial intervention that included risk assessment and individualized plans, administered by specially trained nurses, to prevent fall injuries.

Design

Pragmatic Randomized Control Trial



Design

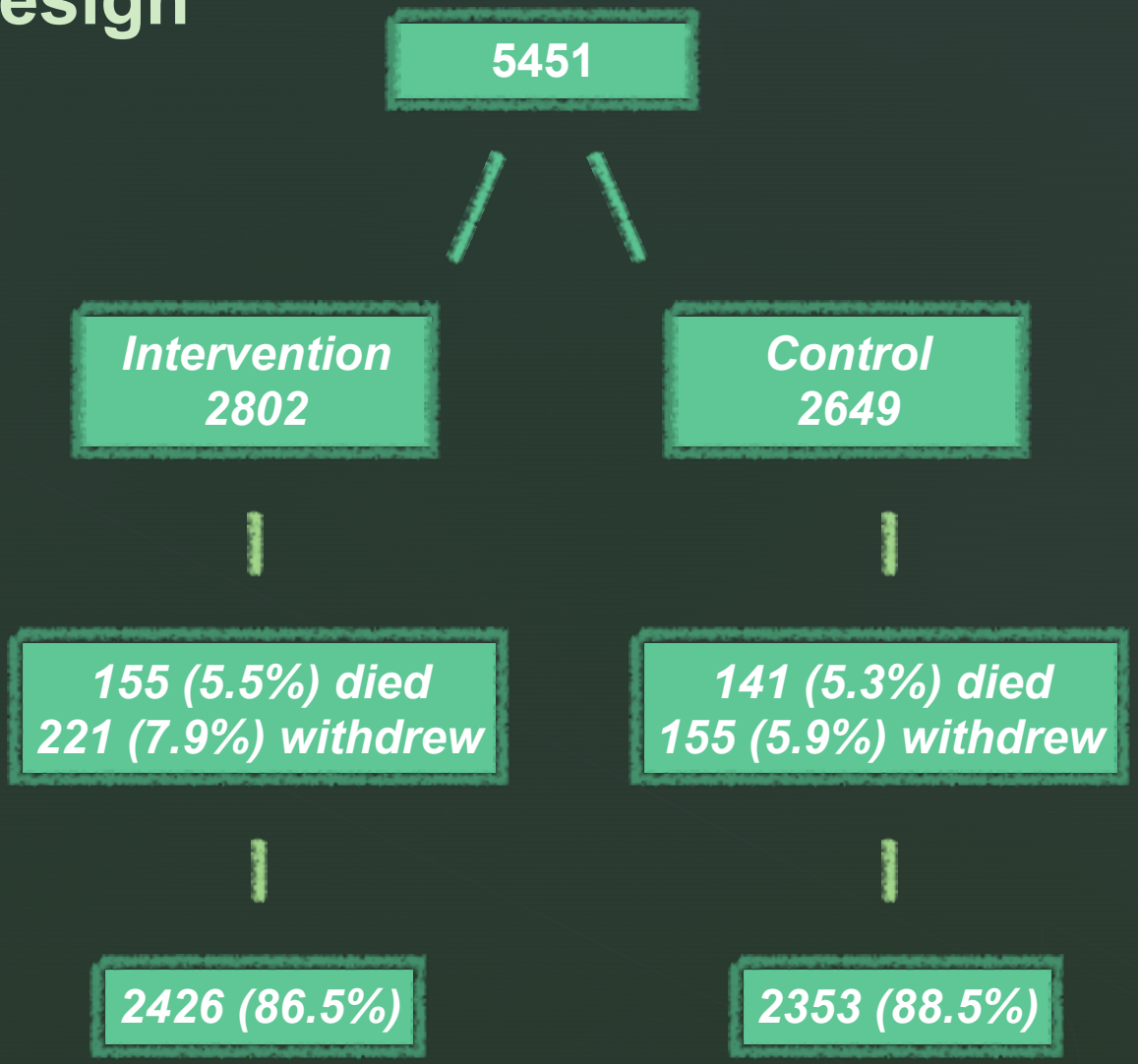
Participants:

- Community-living persons
- 70 years of age or older
- Increased risk for serious fall injuries
- Speak English or Spanish
- Excluded: cognitive impairment without proxy

Recruitment

- Recruitment packets mailed to screen positive patients (n=31,872)
- Telephone interviews (n=18,571)
- Enrolled (n=5,451)

Design


5451
Intervention
2802
Control
2649
155 (5.5%) died
221 (7.9%) withdrew
141 (5.3%) died
155 (5.9%) withdrew
2426 (86.5%)
2353 (88.5%)

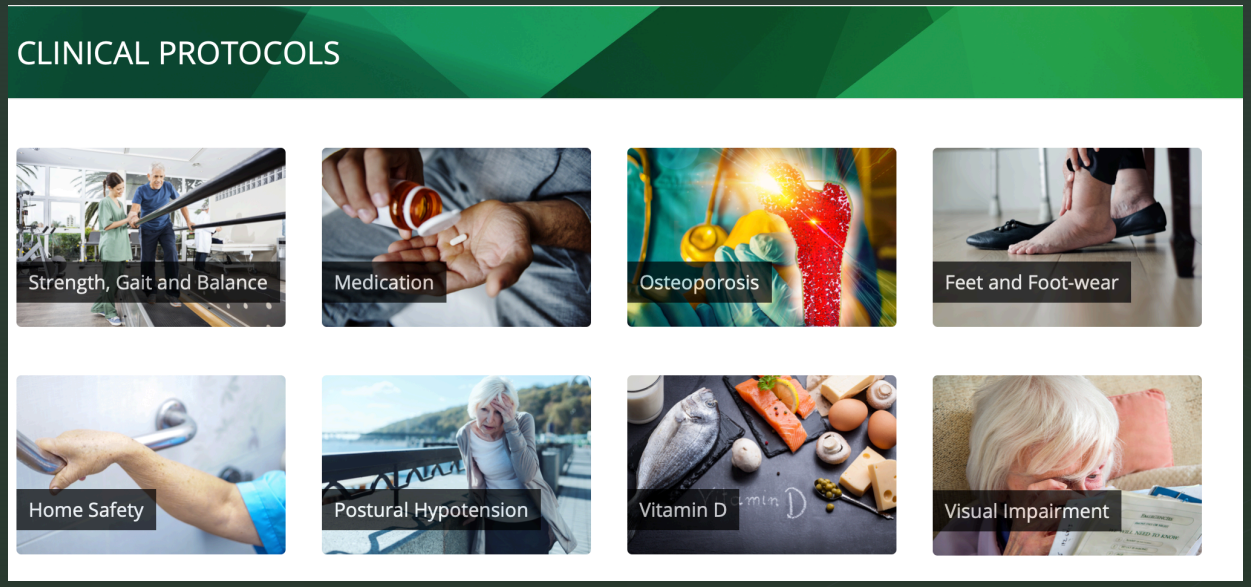
Baseline Characteristics

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)

Intervention Group

- ***5 Components***
  - Standardized assessment of seven modifiable risk factors for fall injuries
  - Standardized protocol-driven recommendations for management of risk factors
  - Development of an individualized care plan that focused on 1-3 risk factors
  - Implementation of care plan
  - Follow up care



Intervention group

Table 2. Risk Factor Assessment and Prioritization among Participants in the Intervention Group.*

Risk Factor	Participants Assessed for Risk Factors†	Participants Assessed and Determined to Have Risk Factor	Participants Who 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.

Control Group

- Webinar about fall prevention made available to primary care providers in both groups
- Received informational pamphlet about falls and were encouraged to discuss fall prevention with their PCP.

Endpoint

Primary Endpoint

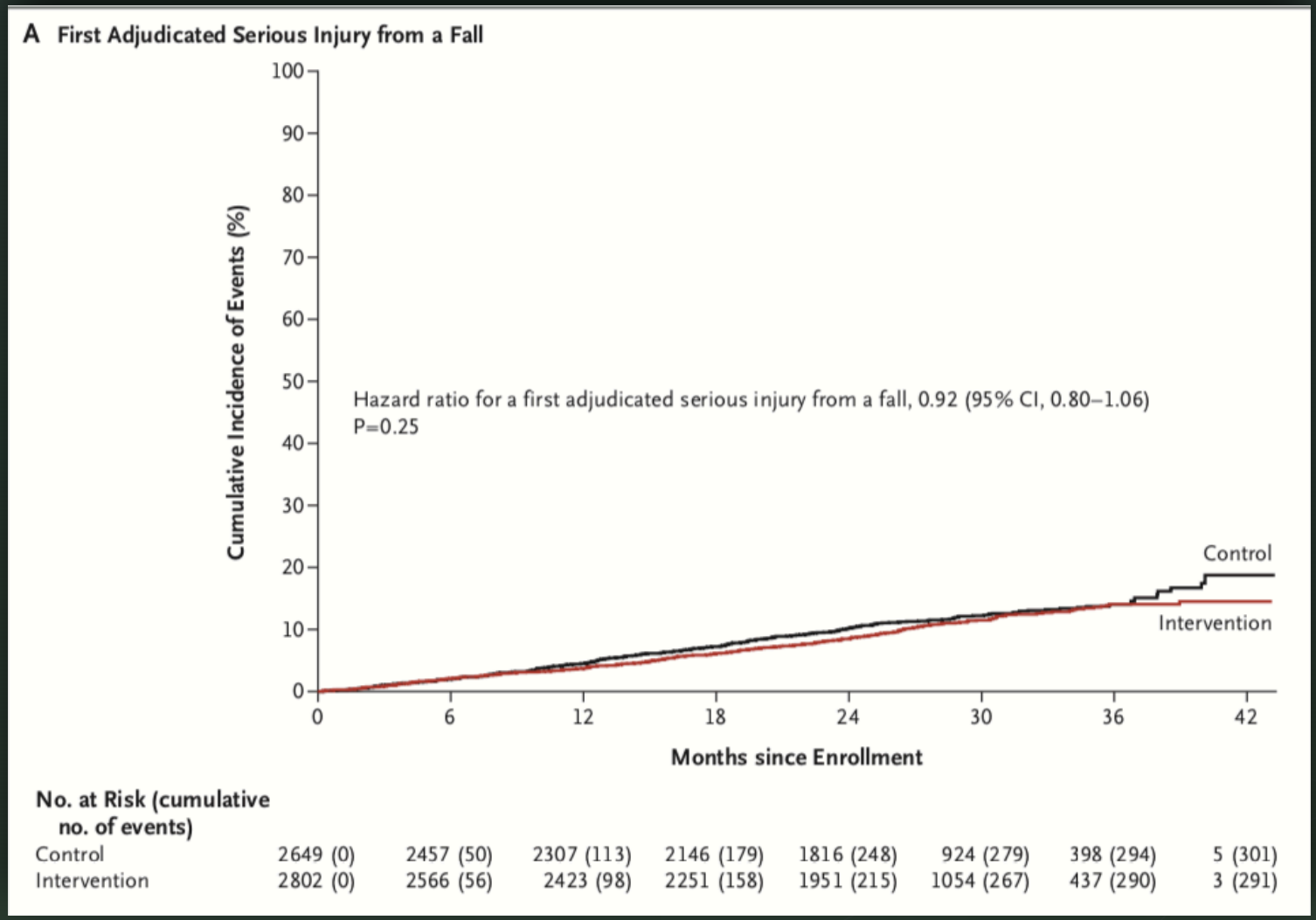
Time to first adjudicated serious fall injury

Secondary Endpoint

All fall injuries
All falls
Well-being

Results

Results - Primary Outcome



Results

Subgroup	Intervention	Control	Hazard Ratio for a First Adjudicated Serious Injury from a Fall (95% CI or 99% CI)	Hochberg P Value for Interaction
	no. with event/total no. (%)			
All participants	291/2802 (10.4)	301/2649 (11.4)	0.92 (0.80–1.06)	
Age				0.58
70–79 yr	130/1455 (8.9)	127/1439 (8.8)	1.03 (0.75–1.42)	
≥80 yr	161/1347 (12.0)	174/1210 (14.4)	0.83 (0.66–1.04)	
Sex				0.58
Female	192/1752 (11.0)	205/1629 (12.6)	0.88 (0.69–1.12)	
Male	99/1050 (9.4)	96/1020 (9.4)	1.00 (0.72–1.41)	
Fear of falling only				0.43
No	195/1461 (13.3)	180/1365 (13.2)	1.01 (0.80–1.29)	
Yes	96/1341 (7.2)	121/1284 (9.4)	0.77 (0.56–1.06)	
Presence of at least two chronic coexisting conditions				0.58
No	82/1011 (8.1)	87/890 (9.8)	0.82 (0.53–1.25)	
Yes	209/1791 (11.7)	214/1759 (12.2)	0.98 (0.81–1.18)	
Occurrence of any fracture after 50 yr of age				0.58
No	154/1766 (8.7)	150/1666 (9.0)	0.98 (0.73–1.31)	
Yes	132/995 (13.3)	141/946 (14.9)	0.89 (0.69–1.16)	

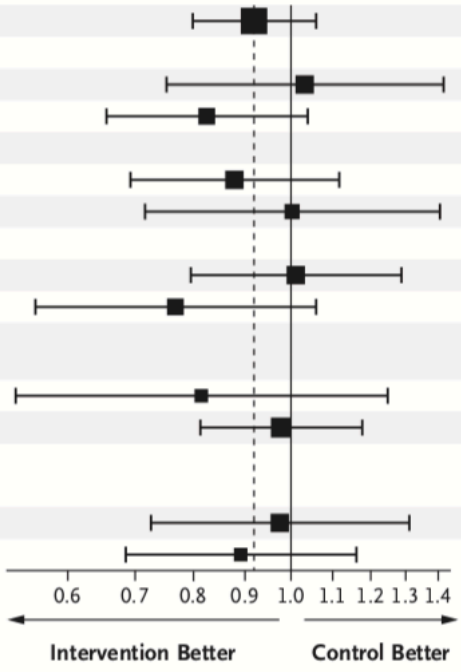
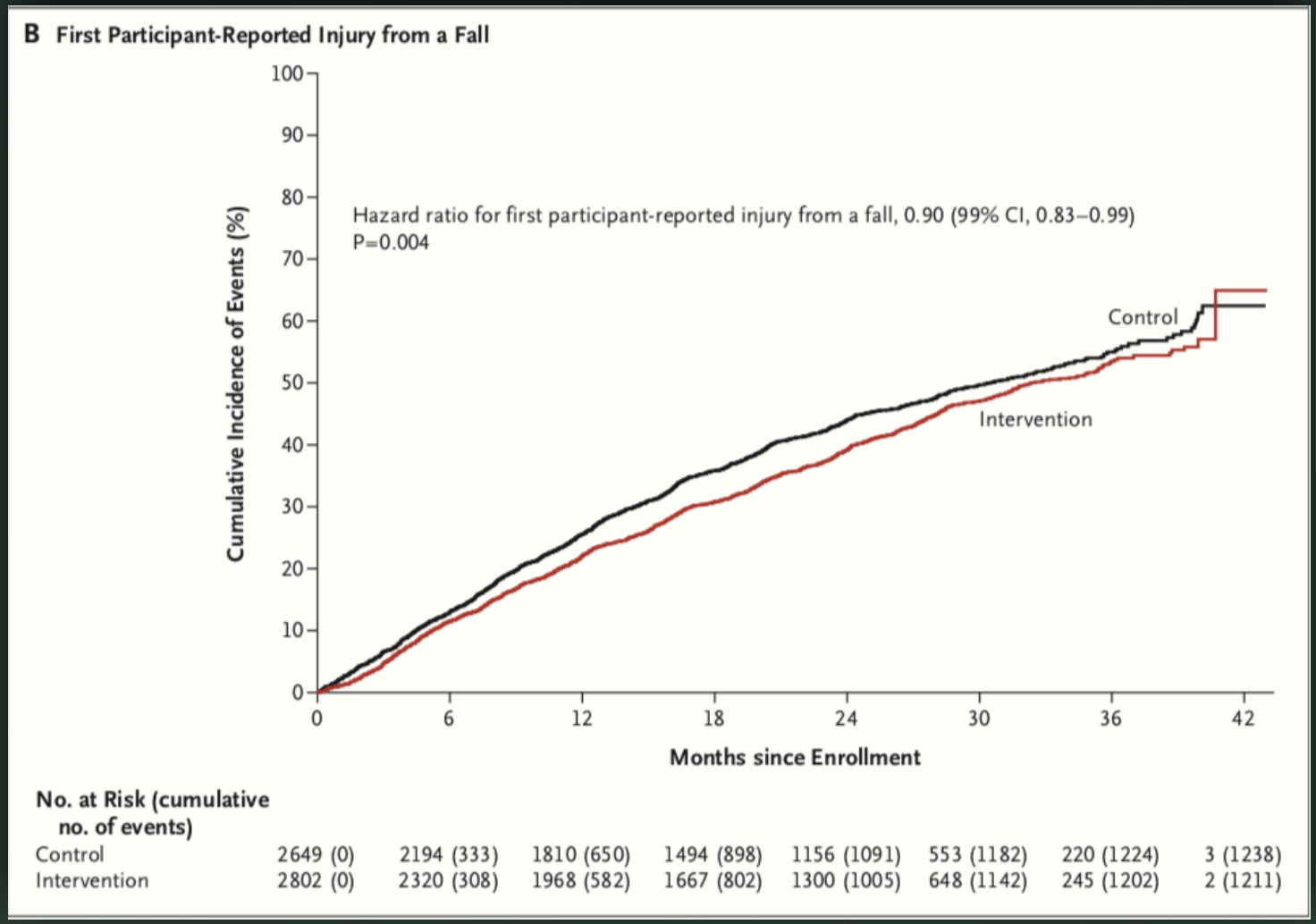


Figure 2. Prespecified Subgroup Analysis of the Primary Outcome.

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.

Results - Secondary Outcome



Conclusions

- 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).

Limitations

- Patient adherence
- Risk factors addressed
- Generalizability
- Recruitment

Critical Appraisal

1). Was assignment of people to the treatment group randomized?

2). Was randomization concealed by the personnel who entered patients into the trial and by personnel monitoring them?

3). Were clinicians, patients, and personnel monitoring blinded?

4). Were all patients analyzed in the groups to which they were randomized?

5). Were both groups similar at the start of the trial?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Discussion

- How will this change my practice?

Questions/Comments?