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Authors

Gill, Thomas M
Bhasin, Shalender
Reuben, David B
et al.

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BRIEF REPORTS

Effect of a Multifactorial Fall Injury Prevention Intervention on Patient Well-Being: The STRIDE Study

Thomas M. Gill, MD,[*†] *Shalender Bhasin, MB, BS,*[††] *David B. Reuben, MD,*[‡†] *Nancy K. Latham, PT, PhD,*[†] *Katy Araujo, MPH,*[§] *David A. Ganz, MD, PhD,*[‡¶] *Chad Boult, MD, MPH, MBA,*[‖] *Albert W. Wu, MD, MPH,*[‖] *Jay Magaziner, MSHyg, PhD,*[**] *Neil Alexander, MD,*[††] *Robert B. Wallace, MD, MSc,*[‡‡] *Michael E. Miller, PhD,*[§§] *Thomas G. Travison, PhD,*[†¶¶] *Susan L. Greenspan, MD,*[‖‖] *Jerry H. Gurwitz, MD,*[***] *Jeremy Rich, DPM,*[†††] *Elena Volpi, MD, PhD,*[‡‡‡] *Stephen C. Waring, DVM, PhD,*[§§§] *Todd M. Manini, PhD,*[¶¶¶] *Lillian C. Min, MD, MSHS,*[††] *Jeanne Teresi, PhD,*[‖‖‖] *Patricia C. Dykes, RN, PhD, MA,*[****] *Siobhan McMahon, PhD, MPH,*[††††] *Joanne M. McGloin, MDiv, MS, MBA,*[*] *Eleni A. Skokos, BS, MS,*[*] *Peter Charpentier, MPH,*[§] *Shehzad Basaria, MD,*[†] *Pamela W. Duncan, PhD, PT,*[§§] *Thomas W. Storer, PhD,*[†] *Priscilla Gazarian, RN, PhD,*[****‡‡‡‡] *Heather G. Allore, PhD,*[§] *James Dziura, PhD,*[§] *Denise Esserman, PhD,*[§] *Martha B. Carnie, AS,*[****] *Catherine Hanson, BA,*[§§§§] *Fred Ko, MD, MS,*[¶¶¶¶] *Neil M. Resnick, MD,*[‖‖] *Jocelyn Wiggins, BM, BCh,*[††] *Charles Lu, MS,*[§] *Can Meng, MS, MPH,*[§] *Lori Goehring, BA,*[†] *Maureen Fagan, DNP, FNP-BC, FAAN,*[§§§§] *Rosaly Correa-de-Araujo, MD, MS, PhD,*[‖‖‖‖‖] *Carri Casteel, PhD, MPH,*[‡‡] *Peter Peduzzi, PhD,*[§] *and Erich J. Greene, PhD*[§]

BACKGROUND/OBJECTIVES: In the Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE) study, a multifactorial intervention was associated with a nonsignificant 8% reduction in time to first serious fall injury but a significant 10% reduction in time to first self-reported fall injury relative to enhanced usual care. The effect of the intervention on other outcomes important to patients has not yet been reported. We aimed to evaluate the effect of the intervention on patient well-being including

From the *Yale Claude D. Pepper Older Americans Independence Center, Yale University, New Haven, Connecticut; †Boston Claude D. Pepper Older Americans Independence Center, Research Program in Men's Health: Aging and Metabolism, Brigham and Women's Hospital, Boston, Massachusetts; ‡Multicampus Program in Geriatric Medicine and Gerontology, David Geffen School of Medicine at UCLA, Los Angeles, California; §Yale Center for Analytical Sciences, Yale University, New Haven, Connecticut; ¶Geriatric Research, Education and Clinical Center; Veterans Affairs Greater Los Angeles Healthcare System, Los Angeles, California; ‖Johns Hopkins University, Baltimore, Maryland; **University of Maryland School of Medicine, Baltimore, Maryland; ††University of Michigan, Ann Arbor, Michigan; ‡‡University of Iowa, Iowa City, Iowa; §§School of Medicine, Wake Forest University, Winston-Salem, North Carolina; ¶¶Marcus Institute for Aging Research, Hebrew SeniorLife, Harvard Medical School, Boston, Massachusetts; ‖‖Pittsburgh Claude D. Pepper Older Americans Independence Center, Division of Geriatrics and Gerontology, University of Pittsburgh, Pittsburgh, Pennsylvania; ***Meyers Primary Care Institute, A Joint Endeavor of Reliant Medical Group, Fallon Health and University of Massachusetts Medical School, Worcester, Massachusetts; †††HealthCare Partners, El Segundo, California; ‡‡‡University of Texas Medical Branch Claude D. Pepper Older Americans Independence Center; Sealy Center on Aging, The University of Texas Medical Branch, Galveston, Texas; §§§Essentia Health, Duluth, Minnesota; ¶¶¶Department of Aging and Geriatric Research, University of Florida, Gainesville, Florida; ‖‖‖Research Division, Hebrew Home at Riverdale, RiverSpring Health, Bronx, New York; ****Brigham and Women's Hospital, Boston, Massachusetts; ††††School of Nursing, University of Minnesota, Minneapolis, Minnesota; ‡‡‡‡University of Massachusetts, Boston, Massachusetts; §§§§University of Miami Health System, Miami, Florida; ¶¶¶¶Icahn School of Medicine at Mount Sinai, New York, New York; and the ‖‖‖‖‖National Institute on Aging, Bethesda, Maryland.

Address correspondence to Thomas M. Gill, MD, Yale School of Medicine, Adler Geriatric Center, 874 Howard Avenue, New Haven, CT 06510. E-mail: thomas.gill@yale.edu, Twitter: @MrDisability

†These authors contributed equally.
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concern about falling, anxiety, depression, physical function, and disability.

DESIGN: Pragmatic cluster-randomized trial of 5,451 community-living persons at high risk for serious fall injuries.

SETTING: A total of 86 primary care practices within 10 U.S. healthcare systems.

PARTICIPANTS: A random subsample of 743 persons aged 75 and older.

MEASUREMENTS: The well-being measures, assessed at baseline, 12 months, and 24 months, included a modified version of the Fall Efficacy Scale, Patient-Reported Outcomes Measurement Information System (PROMIS) anxiety and depression scales, and Late-Life Function and Disability Instrument.

RESULTS: Participants in the intervention (n = 384) and control groups (n = 359) were comparable in age: mean (standard deviation) of 81.9 (4.7) versus 81.8 (5.0) years. Mean scores were similar between groups at 12 and 24 months for concern about falling, physical function, and disability, whereas the intervention group's mean scores on anxiety and depression were .7 points lower (i.e., better) at 12 months and .6 to .8 points lower at 24 months. For each of these outcomes, differences between the groups' adjusted least square mean changes from baseline to 12 and 24 months, respectively, were quantitatively small. The overall difference in means between groups over 2 years was statistically significant only for depression, favoring the intervention: −1.19 (99% confidence interval, −2.36 to −.02), with 3.5 points representing a minimally important difference.

CONCLUSIONS: STRIDE's multifactorial intervention to reduce fall injuries was not associated with clinically meaningful improvements in patient well-being. **J Am Geriatr Soc 69:173-179, 2021.**

Keywords: older persons; fall injury prevention; well-being; pragmatic trials

Falls are the leading cause of injury-related morbidity and mortality among older Americans.[1] Each year, about 30% of community-living older persons fall, and 20% to 30% of those who fall experience moderate to severe injuries.[1-6] Although the most serious sequalae include fractures, head injuries, and death, falls and fall injuries have also been linked to an array of other adverse outcomes including diminished fall efficacy (i.e., concern about falling), depressive symptoms, and worsening function and disability.[7]

In 2014, the Patient-Centered Outcomes Research Institute (PCORI) and the National Institute on Aging funded a pragmatic trial, Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE), to determine the effectiveness of a multifactorial individually tailored intervention implemented by nurse falls care managers (FCMs) in primary care settings. STRIDE was a cluster-randomized trial conducted at 86 primary care practices in 10 U.S. healthcare systems.[8] The main results, recently published,[9] showed no significant reduction in the primary outcome of adjudicated serious fall injuries but a statistically significant 10% reduction in the secondary outcome of time to first self-reported fall injury.

In this article, we report results for five prespecified secondary outcomes of patient well-being that were identified based on input from patient advisors and other stakeholders: concern about falling, anxiety, depression, physical function, and disability.[8]

METHODS

The study's protocol, recruitment and retention strategies, interventions, and primary outcome results have been reported.[8-12] A single institutional review board approved the STRIDE protocol and amendments. Input from stakeholders was integrated into the trial's planning and implementation. Recruitment, enrollment, and assessments were completed over the phone by the Yale Recruitment and Assessment Center.[10] Verbal consent was obtained from participants or from their proxy/caregiver with participant assent.[8] A Data and Safety Monitoring Board reviewed the trial's progress and safety every 6 months. All study materials and interviews were available in English and Spanish.

Randomization and Eligibility Criteria

The trial was conducted at 86 primary care practices in 10 U.S. healthcare systems that included diverse reimbursement plans and rural, urban, and suburban sites. The practices were randomized to intervention (n = 43) or enhanced usual care, that is, control (n = 43), using stratified covariate-constrained randomization to balance practice characteristics within and across the healthcare systems (Supplementary Figure S1).[13] Participants within these practices had to be aged 70 and older, community living, and at increased risk for serious fall injuries based on a "Yes" response to one or more of three screening questions: (1) Have you fallen and hurt yourself in the past year? (2) Have you fallen two or more times in the past year? and (3) Are you afraid that you might fall because of balance or walking problems?[7,14,15] Persons with significant hearing impairment or substantial cognitive impairment, defined as four or more errors on the six-item Callahan screener,[16] were included if they had a proxy/caregiver willing to provide consent and assist them in the study. Persons were excluded if they did not receive primary care at the assigned practice, planned to move out of the area in the coming year, resided in a nursing home, were enrolled in hospice or reported being too ill to participate, or did not speak English or Spanish.

Participants and Baseline Assessment

Over the course of 20 months, 5,451 participants were enrolled.[10] Baseline information was collected on sociodemographic characteristics, self-rated health, chronic conditions, and use of mobility aids. Among a subsample of 743 participants, who were selected randomly within

clusters and enrolled earlier in the trial before the age criterion was lowered from 75 to 70 years (Supplementary Figure S2),[10] information was collected on the well-being outcomes.[8]

Treatments

STRIDE's intervention was delivered by specially trained registered nurse (RN) FCMs who co-managed fall risk in partnership with patients and their primary care providers (PCPs).[11] The intervention's components included (1) standardized assessment of seven modifiable risk factors (strength, gait, and balance impairment; medications; postural hypotension; feet and footwear; vision; osteoporosis and vitamin D; and home safety); (2) developing recommendations for managing risk factors using standardized protocols; (3) motivational interviewing to explain the assessment results and engage patients and/or caregivers in risk reduction; (4) developing individualized falls care plans that were approved by PCPs; and (5) implementing the falls care plans including referrals to community-based programs, if indicated. The FCMs reassessed the participants' falls risk annually and revised the falls care plans as needed. Some variation in intervention implementation at trial sites was allowed, depending on availability of local resources or other site-specific factors. The fidelity of the intervention (Supplementary Table S1) was comparable with that previously reported in all STRIDE participants.[9]

Participants in the control practices received a falls-information pamphlet created by the Centers for Disease Control and Prevention and were encouraged to discuss fall prevention with their PCPs, who received their patients' responses to the fall-risk screening questions.

A webinar about fall prevention was made available to the PCPs and staff in all participating practices (https://www.cdc.gov/steadi/training.html).

Outcomes

Outcomes were assessed at baseline, 12 months, and 24 months using instruments that were brief, could be administered by phone, and were responsive to change in studies of comparable populations.

Concern about falling was ascertained using a modified version of the Fall Efficacy Scale[17,18] that was used in prior fall prevention studies.[19] Participants were asked, "How concerned are you that you might fall while" performing each of 10 activities, such as cleaning the house and walking around in your neighborhood. Each item was rated on a 4-point scale (not at all, somewhat, fairly, very), yielding a total score of 10 to 40.

Symptoms of anxiety and depression, referred to elsewhere simply as anxiety and depression, were assessed using Patient-Reported Outcomes Measurement Information System (PROMIS) scales[20] that are responsive to change over time.[21] The eight-item anxiety scale asks about the frequency of feeling fearful, worried, or anxious (among others), and the eight-item depression scale asks about the frequency of feeling worthless, hopeless, or having nothing to look forward to (among others). Scores for each range from 8 to 40.

Physical function and disability were assessed using the computer adaptive test version of the Late-Life Function and Disability Instrument[22,23] that was validated psychometrically and is responsive to change over time.[24] The physical function domain includes items such as getting in/out of a car and walking around one's home; the disability domain includes items such as doing personal errands and preparing meals. Scores for each range from 0 to 100.

Statistical Analyses

The prespecified statistical analysis plan was followed.[9] Sample size was determined for a clustered design using PASS v.12 (Kaysville, UT). For the well-being outcomes, the target sample size was 720 participants to detect a standardized effect size of .3 between intervention and control groups at 12 and 24 months, assuming a type I error of 1% (two-sided), 80% power, equal allocation, 10% annual death rate, 5% annual loss-to-follow-up rate and an intracluster correlation coefficient of .007.[8]

All analyses were intent-to-treat and assumed that data were missing at random. Each outcome was analyzed as change from baseline using a longitudinal linear mixed model with two discrete time points (12 and 24 months) and a random effect for participant nested within a random effect for practice. The model included a treatment × time interaction and was adjusted for baseline score, the practice-level randomization constraint variables (practice size, practice location [urban vs rural], race/ethnicity of most persons in the practice [non-Hispanic White vs other]), and baseline covariates that were predictive of outcome-specific missingness (age at enrollment, use of outdoor mobility aid, history of congestive heart failure or myocardial infarction, number of positive responses to the serious fall injury screening questions, and poor self-reported health [for concern about falling, anxiety, and depression], Hispanic ethnicity [for anxiety, depression, physical function, and disability], ever married [for physical function and disability], and consent provided by proxy/caregiver [for physical function and disability]). To control overall type I error, a significance level of .01 (two-sided) was used for each of the outcomes. Results are presented as adjusted least square mean changes from baseline at 12 months, 24 months, and overall by treatment group.

RESULTS

The characteristics of participants in the two groups were similar at baseline with some minor exceptions (Table 1). The prevalence of female sex, Hispanic ethnicity, high school graduate or less, hypertension, and chronic lung disease was higher in the control group, whereas the prevalence of postgraduate education, hip fracture, and Parkinson's disease was higher in the intervention group. Overall, the mean age was 82 years, 59% were women, and 36% had an injurious fall in the past year.

As shown in Supplementary Table S2, losses to follow-up were similar in the intervention and control groups, with one exception: at 24 months, a higher proportion of participants in the control group could not be contacted (6.7% vs 3.1%), leading to a slightly lower proportion available to complete the well-being assessment.

Table 1. Baseline Characteristics of Study Participants[a]

Characteristic	Intervention N = 384	Control N = 359
Age, y, mean	81.9 ± 4.7	81.8 ± 5.0
Female, n (%)	214 (55.7)	223 (62.1)
Race, n (%)		
White	351 (91.4)	332 (92.5)
Black	19 (4.9)	15 (4.2)
Other	12 (3.1)	12 (3.3)
Unknown	2 (.5)	0 (.0)
Hispanic ethnicity, n (%)	21 (5.5)	33 (9.2)
Education, n (%)		
High school graduate or less	94 (24.5)	102 (28.4)
Some college or equivalent	100 (26.0)	102 (28.4)
College graduate	70 (18.2)	72 (20.1)
Postgraduate	120 (31.3)	82 (22.8)
Unknown	0 (.0)	1 (.3)
Self-rated health, n (%)		
Excellent	37 (9.6)	30 (8.4)
Very good	114 (29.7)	102 (28.4)
Good	151 (39.3)	146 (40.7)
Fair or poor	82 (21.4)	79 (22.0)
Unknown	0 (.0)	2 (.6)
Chronic conditions,[b] mean	2.2 ± 1.4	2.3 ± 1.3
Hypertension, n (%)	250 (65.1)	255 (71.0)
Fracture other than hip since age 50, n (%)	133 (34.6)	131 (36.5)
Cancer, n (%)	104 (27.1)	100 (27.9)
Arthritis, n (%)	65 (16.9)	73 (20.3)
Diabetes, n (%)	80 (20.8)	72 (20.1)
Chronic lung disease, n (%)	47 (12.2)	63 (17.5)
Myocardial infarction, n (%)	47 (12.2)	46 (12.8)
Stroke, n (%)	27 (7.0)	29 (8.1)
Congestive heart failure, n (%)	33 (8.6)	32 (8.9)
Hip fracture, n (%)	25 (6.5)	13 (3.6)
Parkinson's disease, n (%)	19 (4.9)	8 (2.2)
Cognitively impaired,[c] n (%)	10 (2.6)	8 (2.2)
Use of mobility aid or nonambulatory,[d] n (%)	155 (40.4)	145 (40.4)
Screening questions for fall injuries, n (%)		
Fell ≥2 times in past year	143 (37.2)	128 (35.7)
Fell and hurt self in past year	137 (35.7)	134 (37.3)
Afraid of falling because of balance or walking problems	329 (85.7)	312 (86.9)
No. positive fall screening questions, n (%)		
One	228 (59.4)	209 (58.2)
Two	87 (22.7)	85 (23.7)
Three	69 (18.0)	65 (18.1)
Eligible based on fear of falling alone, n (%)	185 (48.2)	178 (49.6)

[a]All means are expressed ± standard deviation.
[b]Listed in order of overall prevalence from highest to lowest.
[c]Four or more errors on six-item Callahan cognitive screener or interview completed entirely by proxy.
[d]The number of nonambulatory participants was 3 (.8%) in the intervention group and 4 (1.1%) in the control group.

Table 2. Scores on Well-Being Measures over Time by Treatment Group[a]

Time point	Treatment group	Concern about falling[b]		Anxiety[c]		Depression[c]		Physical function[d]		Disability[d]	
		N (missing)	Mean (SE)	N (missing)	Mean (SE)	N (missing)	Mean (SE)	N (missing)	Mean (SE)	N (missing)	Mean (SE)
Baseline	intervention	372 (12)	15.4 (.28)	371 (13)	12.5 (.26)	372 (12)	12.1 (.26)	380 (4)	60.2 (.46)	380 (4)	57.3 (.53)
	Control	351 (8)	15.7 (.29)	350 (9)	12.4 (.27)	350 (9)	12.0 (.26)	358 (1)	58.9 (.47)	358 (1)	56.2 (.51)
12 months	Intervention	320 (1)	15.2 (.30)	319 (2)	11.6 (.25)	319 (2)	11.5 (.26)	313 (23)	59.8 (.54)	313 (23)	56.4 (.64)
	Control	300 (4)	15.3 (.35)	293 (11)	12.3 (.32)	295 (9)	12.2 (.32)	284 (30)	58.9 (.57)	283 (31)	55.8 (.66)
24 months	Intervention	286 (27)	15.8 (.37)	282 (31)	11.6 (.27)	282 (31)	11.6 (.25)	290 (23)	59.1 (.61)	290 (23)	56.7 (.76)
	Control	262 (17)	15.5 (.36)	260 (19)	12.2 (.31)	260 (19)	12.4 (.34)	257 (22)	58.0 (.53)	256 (23)	55.8 (.63)

Abbreviation: SE, standard error.
[a]At baseline, the intervention group included 384 participants; the control group included 359 participants. Information about losses to follow-up at 12 and 24 months is provided in Supplementary Table S2. Missing values represent participants who completed at least part of the assessment.
[b]Assessed with a modified version of the Fall Efficacy Scale, with scores ranging from 10 (low) to 40 (high).
[c]Assessed with 8-item PROMIS scales, with scores ranging from 8 (low) to 40 (high).
[d]Assessed with the computer-adapted test version of the Late-Life Function and Disability Instrument, with scores ranging from 0 (worst) to 100 (best).

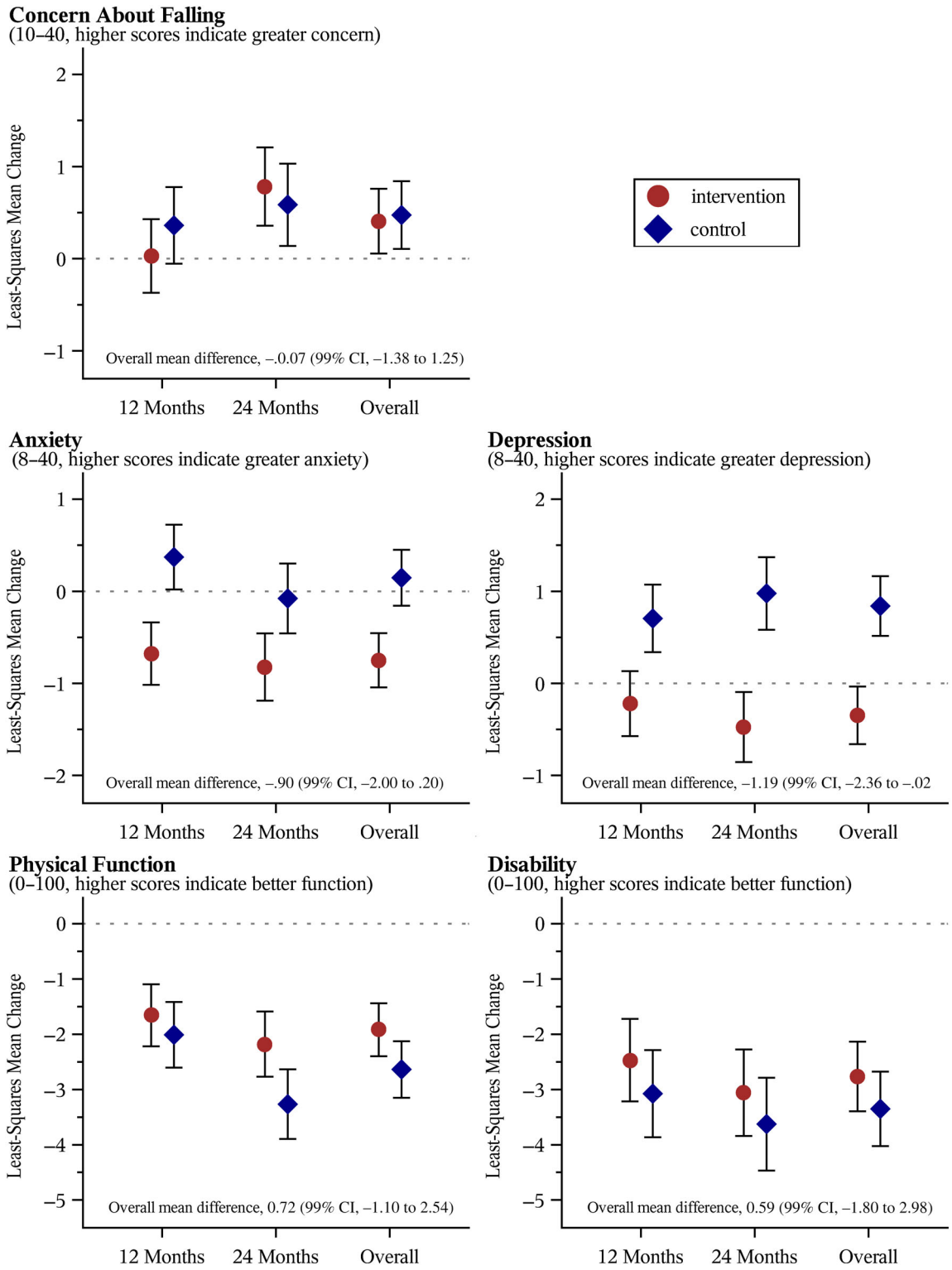

Figure 1. Adjusted least-squares mean changes from baseline at 12 months, 24 months, and overall for each of the well-being outcomes by treatment group. The I bars represent standard errors. Models were adjusted for baseline score, the practice-level randomization constraint variables (practice size, practice location [urban vs rural], and race of most of the persons in the practice [non-Hispanic White vs other]), and baseline covariates that were predictive of outcome-specific missingness (age at enrollment, use of outdoor mobility aid, history of congestive heart failure or myocardial infarction, number of positive responses to the serious fall injury screening questions, and poor self-reported health [for Concern about Falling, Anxiety and Depression], Hispanic ethnicity [for Anxiety, Depression, Physical Function, and Disability], ever married [for Physical Function and Disability], and consent provided by proxy/caregiver rather than participant [for Physical Function and Disability]).Differences were considered to be statistically significant if the 99% confidence interval did not include 0. Positive changes represent improvements for Concern About Falling and Physical Function, but worsening for Anxiety, Depression, and Disability.

Table 2 provides mean scores on the well-being measures over time. Values were similar between groups for concern about falling, physical function, and disability. However, mean scores for anxiety and depression were .7 points lower at 12 months and .6 to .8 points lower at 24 months in the intervention group than the control group. Figure 1 compares the adjusted least square mean changes from baseline at 12 months, 24 months, and overall between treatment groups. The overall mean differences all favored the intervention but were small to very small. The largest differences were observed for anxiety (−.90 [99% confidence interval [CI] = −2.00 to .20]) and depression (−1.19 [99% CI = −2.36 to −.02]), each on a 33-point scale, although only the latter difference was statistically significant.

DISCUSSION

In this pragmatic cluster-randomized trial conducted in real-world U.S. primary care practices, an RN-delivered fall injury prevention strategy led to small improvements in anxiety and depression over 2 years, but minimal improvement in concern about falling, physical function, and disability relative to enhanced usual care. Only the benefit for depression was statistically significant.

We hypothesized that a reduction in serious fall injuries would be accompanied by improvements in patient well-being. Before the start of the trial, patient advisors and other stakeholders identified several aspects of well-being that are important consequences of having a fall injury including concern about falling, anxiety, depression, and worsening function and disability. These consequences were operationalized using validated instruments and included as prespecified secondary outcomes. Although statistically significant, the observed difference of 1.19 points on the depression scale between the intervention and control groups was considerably smaller than the minimally important difference of 3.5 points.[25] This small benefit could be attributable to a supportive relationship between the FCMs and participants.

A likely explanation for the largely null findings on patient well-being is the lower than expected reduction in serious fall injuries. The multifactorial intervention led to a nonsignificant 8% reduction in first serious fall injury, whereas a 20% reduction had been hypothesized.[9] An alternative explanation is that these measures of well-being are not tightly linked to reductions in fall injuries; although prior interventions reduced falls,[26] none demonstrated improvements in well-being. Other contributing explanations include less than optimal intervention fidelity; possible ceiling effects, especially for concern about falling, depression, and anxiety; and some benefit of the enhanced usual care intervention.

This study had several strengths. The intervention integrated practice redesign, co-management, motivational interviewing, and individualized risk factor–guided care into primary care practices of 10 diverse healthcare systems across the United States. There were few exclusion criteria, enabling enrollment of a fairly representative population of older persons at increased risk of fall injury including cognitively impaired participants. Finally, the intervention was patient centered, and the trial's design and implementation were guided by substantial input from patients' advisors and other stakeholders.

The study also had some limitations. Participants were more highly educated than the general population and had only modest representation of Blacks and Hispanics. Practices were randomized, leading to some baseline imbalances between treatment groups. Finally, follow-up data were not available in about 13% and 15% of the nondecedents at 12 and 24 months, respectively.

In summary, the modest benefit of STRIDE's multifactorial intervention on fall injuries was not associated with meaningful improvements in measures of patient well-being.

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Conflict of Interest: The authors have declared no conflicts of interest for this article.

Author Contributions: Erich J. Greene and Thomas M. Gill had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors met the criteria for authorship stated in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Study concept and design: Gill, Bhasin, and Reuben. Acquisition of

data: Gill, Araujo, and McGloin. Analysis and interpretation of data: Araujo, Gill, and Greene. Preparation of manuscript: Gill. Critical revision of the manuscript for important intellectual content: All authors.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

Supplementary Figure S1: CONSORT diagram for STRIDE practices.

Supplementary Figure S2: CONSORT diagram showing flow of participants through the study

Supplementary Table S1: Number and Percentage of Participants in the Intervention Group with Risk Factor Assessments, Positive Assessments, Prioritized Risk Factors, and Agreed-Upon Plans to Reduce Each Factor.

Supplementary Table S2: Status of Participants at 12- and 24-Month Follow-up Assessments.

Supplementary Document S1: Acknowledgments.