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Research Article

Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE): A Cluster-Randomized Pragmatic Trial of a Multifactorial Fall Injury Prevention Strategy: Design and Methods

Shalender Bhasin, MB, BS,[1,*] Thomas M. Gill, MD,[2,*] David B. Reuben, MD,[3,*] Nancy K. Latham, PhD, PT,[1,*] Jerry H. Gurwitz, MD,[4] Patricia Dykes, RN, PhD, MA,[5] Siobhan McMahon, PhD, MPH, GNP-BC,[6] Thomas W. Storer, PhD,[1] Pamela W. Duncan, PhD, PT,[7] David A. Ganz, MD, PhD,[3] Shehzad Basaria, MD,[1] Michael E. Miller, PhD,[7] Thomas G. Travison, PhD,[8] Erich J. Greene, PhD,[9] James Dziura, PhD,[9] Denise Esserman, PhD,[9] Heather Allore, PhD,[9] Martha B. Carnie, AS,[5] Maureen Fagan, DNP, MHA,FNP-BC,[5] Catherine Hanson, BA,[10] Dorothy Baker, PhD,[2] Susan L. Greenspan, MD,[11] Neil Alexander, MD,[10] Fred Ko, MD, MS,[12] Albert L. Siu, MD, MPH,[12] Elena Volpi, MD, PhD,[13] Albert W. Wu, MD, MPH,[14] Jeremy Rich, DPM,[15] Stephen C. Waring, DVM, PhD,[16] Robert Wallace, MD, MSc,[17] Carri Casteel, PhD,[17] Jay Magaziner, MSHyg, PhD,[18] Peter Charpentier, MPH,[9] Charles Lu, PhD,[9] Katy Araujo, MPH,[9] Haseena Rajeevan, PhD,[9] Scott Margolis, MBA,[1] Richard Eder, BA,[1] Joanne M. McGloin, MDiv, MS, MBA,[2] Eleni Skokos, BS, MS,[2] Jocelyn Wiggins, BM, BCH,[10] Lawrence Garber, MD,[4] Steven B. Clauser, PhD, MPA,[19] Rosaly Correa-De-Araujo, MD, MS, PhD,[20] and Peter Peduzzi, PhD[9,*]

[1]Pepper Older Americans Independence Center, Research Program in Men's Health: Aging and Metabolism, Brigham and Women's Hospital, Boston, Massachusetts. [2]Pepper Older Americans Independence Center, Yale University, New Haven, Connecticut. [3]Multicampus Program in Geriatrics Medicine and Gerontology, David Geffen School of Medicine at UCLA, Los Angeles, California. [4]Meyers Primary Care Institute, Reliant Medical Group, Worcester, Massachusetts. [5]Brigham and Women's Hospital, Boston, Massachusetts. [6]School of Nursing, University of Minnesota, Minneapolis. [7]Wake Forest University, Winston-Salem, North Carolina. [8]Hebrew SeniorLife, Harvard Medical School, Boston, Massachusetts. [9]Yale Center for Analytical Sciences, Yale University, New Haven, Connecticut. [10]University of Michigan, Ann Arbor. [11]Pepper Older Americans Independence Center, Division of Geriatrics and Gerontology, University of Pittsburgh, Pennsylvania. [12]Mount Sinai School of Medicine, New York, New York. [13]University of Texas Medical Branch, Galveston. [14]Johns Hopkins University, Baltimore, Maryland. [15]HealthCare Partners, El Segundo, California. [16]Essentia Health, Duluth, Minnesota. [17]University of Iowa, Iowa City. [18]University of Maryland, Baltimore. [19]Patient Centered Outcomes Research Institute, Washington, District of Columbia. [20]National Institute on Aging, Bethesda, Maryland.

*The authors indicates that these authors contributed equally.

Address correspondence to: Shalender Bhasin, MB, BS, Professor of Medicine, Harvard Medical School, Director, Research Program in Men's Health: Aging and Metabolism, Brigham and Women's Hospital, 221 Longwood Avenue, Boston, MA 02115. E-mail: sbhasin@bwh.harvard.edu

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Abstract

Background: Fall injuries are a major cause of morbidity and mortality among older adults. We describe the design of a pragmatic trial to compare the effectiveness of an evidence-based, patient-centered multifactorial fall injury prevention strategy to an enhanced usual care.

Methods: Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE) is a 40-month cluster-randomized, parallel-group, superiority, pragmatic trial being conducted at 86 primary care practices in 10 health care systems across United States. The 86 practices were randomized to intervention or control group using covariate-based constrained randomization, stratified by health care system. Participants are community-living persons, ≥70 years, at increased risk for serious fall injuries. The intervention is a comanagement model in which a nurse Falls Care Manager performs multifactorial risk assessments, develops individualized care plans, which include surveillance, follow-up evaluation, and intervention strategies. Control group receives enhanced usual care, with clinicians and patients receiving evidence-based information on falls prevention. Primary outcome is serious fall injuries, operationalized as those leading to medical attention (nonvertebral fractures, joint dislocation, head injury, lacerations, and other major sequelae). Secondary outcomes include all fall injuries, all falls, and well-being (concern for falling; anxiety and depressive symptoms; physical function and disability). Target sample size was 5,322 participants to provide 90% power to detect 20% reduction in primary outcome rate relative to control.

Results: Trial enrolled 5,451 subjects in 20 months. Intervention and follow-up are ongoing.

Conclusions: The findings of the STRIDE study will have important clinical and policy implications for the prevention of fall injuries in older adults.

Keywords: Fall prevention, Clinical effectiveness, Patient and stakeholders in fall injury prevention research, Nurse falls care managers.

Falls are the leading cause of fatal and nonfatal injuries among older adults, accounting for an estimated 424,000 deaths annually worldwide. Approximately one in three older Americans falls each year, and 20%–30% of those who fall suffer moderate to severe injuries (1–3). In 2010, 2.3 million nonfatal fall injuries were treated in emergency departments and more than 662,000 of these patients were hospitalized (4). Among those who fall but do not sustain an injury, many develop fear of falling and limit their activities (5). Therefore, strategies to prevent fall injuries are a major public health concern in the United States and worldwide.

There is abundant evidence that many falls in the elderly are preventable (6–8). Unfortunately, fewer than half of those who fall discuss fall prevention with a health care provider (9), and only a third of elderly patients are screened for fall risk. Thus, the quality of care for those at risk for falling has not improved in the past decade (10) and there is an unmet need for prevention strategies that are cost-effective and easily deployed at the site of clinical care.

Recognizing that fall injuries are a major public health problem, the Patient Centered Outcomes Research Institute (PCORI) and the National Institute on Aging (NIA) awarded a 5-year cooperative agreement to conduct a pragmatic trial to determine the effectiveness of a patient-centered intervention that combines elements of practice redesign and an evidence-based, multifactorial, individually-tailored intervention implemented by nurse Falls Care Managers (FCM) in primary care settings. We describe here the overall design of this pragmatic trial.

Methods

The trial is a pragmatic, multisite cluster-randomized, parallel group, superiority trial among noninstitutionalized older persons. The primary outcome of the trial is serious fall injuries.

The Brigham and Women's Hospital established a special Institutional Review Board (IRB), with a designated chair, that serves as the central IRB (cIRB) and approved the STRIDE protocol and amendments. A 9-member Data and Safety Monitoring Board (DSMB), established by the NIA, meets every 6 months to oversee the trial's progress and safety.

Pilot Phase

During the pilot phase in Year 1, we established organizational structure and trial infrastructure, drafted the trial protocol and the Manual of Procedures, and undertook training of investigators, study staff, and FCMs. We pilot tested the screening and recruitment procedures to determine feasibility and yields of different recruitment strategies.

Pilot testing was completed at one practice at each of the 10 trial sites. A total of 164 participants were identified using 5 screening questions to assess high risk for serious fall injuries; 82% of participants were identified on the basis of three core screening questions from an Assessing Care of Vulnerable Elders (ACOVE) study (11): "Have you fallen 2 or more times in the past year?", "Have you fallen and hurt yourself in the past year?", and "Are you afraid that you might fall because of balance or walking problems?" Two additional questions, "Do you have difficulty maintaining your balance when bathing, dressing or getting in and out of chair?" and "Do you usually use a cane, walker or other device when walking inside or outside your home?" were pilot tested but offered little additional information beyond that provided by the 3 core questions, and were subsequently omitted from the screening questionnaire. During the pilot phase, local and central screening were evaluated and based on feasibility, yields and costs, central screening was chosen as the primary strategy for the trial.

The FCMs, recruited by each trial site, completed a custom-designed 24-module training program. During the pilot phase, the FCMs, assisted by local patients and stakeholders, identified services and care providers within the health care system and in the community. The study team created structured notes for clinical assessment, materials that could be given to patients to enable them to access these health care services, and referral notes that could be sent to these services. The intervention was pilot tested at each trial site.

Design of Main Trial

STRIDE is a cluster-randomized, pragmatic clinical trial set in primary care practices, with practices stratified by health care system and patients nested within practices. The unit of randomization is the practice. This avoids the potential for contamination of controls, allows staff to be trained efficiently, and improves the feasibility of applying the intervention practice-wide. The trial's duration is 40 months, including 20 months of recruitment and a minimum of 20-months of follow-up. The primary outcome is time to first serious fall injury assessed at the patient level.

Trial Sites

The trial is being conducted at 86 primary care practices in 10 health care systems across the United States: Essentia Health; HealthCare Partners; Johns Hopkins Medicine; Mercy Health; Michigan Medicine, Mount Sinai Health; Partners Healthcare; Reliant Medical Group; University of Pittsburgh Healthcare; and University of Texas Medical Branch Galveston. These health care systems reflect the racial and ethnic diversity of the U.S. population, and include rural, urban, and suburban sites, and diverse reimbursement plans.

Selection of Practices

A Practice Selection Committee evaluated 116 primary care practices and selected 86 practices to be randomized using pre-specified eligibility criteria, including practice size, the ability to implement the intervention, and availability of electronic medical record (EMR) data. Eligible practices were required to have access to one or more community-based exercise programs aimed at preventing falls within reasonable proximity. The geographic proximity of practices was also considered to mitigate the potential for contamination of intervention and to minimize FCM's travel. Practices that were primarily geriatric medicine clinics were excluded. Practices that shared physicians were excluded to avoid contamination bias that could result if these practices were randomized to different treatment groups.

Cluster Randomization

Eighty-six eligible practices were randomized to either the intervention or the control group using covariate-based, stratified, constrained randomization (12,13) to balance practice characteristics within and across the 10 health care systems. The randomization was stratified by health care system and the balancing covariates were practice size, urbanicity (urban vs rural), and race/ethnicity (whether the practice was predominantly White or non-White). Randomization was completed prior to participant enrollment. Only the biostatisticians participated in randomization and practice names were masked.

Participants

After 9 months of recruitment, the initial age limit of 75 was lowered to 70 to increase the recruitment pool. Patients were eligible if they were identified as being at increased risk of fall injuries by answering yes to one or more of the three fall-related questions, and if they were able to provide telephone consent or proxy consent with patient assent (Table 1). To enhance generalizability, the exclusion criteria were kept to a minimum. Patients found to have significant cognitive impairment, defined as four or more errors on the 6-item Callahan screener (14), were required to have a proxy/caregiver willing to provide consent and assist the participant in the study.

The mean age of the enrolled participants was 80 years; 62% were women, 13% were African American or Hispanic. The participants reported an average of 2.1 chronic conditions; the most common chronic conditions were hypertension (65%), cancer (26%), arthritis (21%), and diabetes (20%). Thirty-nine percent had a fall with injury during the past year and 35% had two or more falls during the past year.

Screening and Recruitment

Based on the results of the pilot phase, our primary recruitment strategy was centralized screening through the Yale Recruitment and Assessment Center (RAC) at 9 of the 10 trial sites. The clinic sites provided the RAC with the names and addresses of age-eligible patients in each practice. These patients were sent a letter addressed from their primary care providers asking them to complete the falls screening questionnaire, which included the three questions in Table 1, and mail it back to the RAC. Additional mailings were sent to non-responders to improve response rates.

A clinic screening strategy was used at the Reliant Medical Group in which practice staff screened all age-eligible patients during primary care visits as a part of standard vital signs.

Recruitment

All patients who screened positive were mailed a recruitment packet which included an invitation letter from the patient's practice and a study information sheet. The invitation letter indicated that the subject could opt out from being contacted about the study by returning a self-addressed postcard within 2 weeks.

All screen-positive patients who did not opt out were called by a RAC staff member masked to treatment allocation. During this telephone interview, the interviewer confirmed the absence of any exclusion criteria; administered the Callahan screener; reviewed study's purpose; and answered any questions. After obtaining verbal consent, baseline data, including demographics, chronic conditions, falls history, self-rated health, and height and weight, were collected. Written consent was not obtained. Information about secondary outcomes also was collected among a random subset of 714 participants (see sample size estimates).

Intervention

The intervention, described in detail in another manuscript (15), is an individually tailored set of recommendations/interventions (16,17) based on multifactorial risk assessment that utilizes a primary care comanagement model implemented by a nurse FCM (Table 2). The maximum duration of intervention is 40 months and minimum 20 months, for an average intervention duration of 30 months. The

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	
i.	The patient is at least 70 years of age.
ii.	The patient must answer "yes" to one or more of the following questions:
A	Have you fallen and hurt yourself in the past year?
B	Have you fallen two or more times in the past year?
C	Are you afraid that you might fall because of balance or walking problems?
Exclusion Criteria	
i.	The patient is enrolled in hospice.
ii.	The patient resides in a nursing home.
	The patient is not capable of providing informed consent (or assent), and a proxy is not available.
iv.	The patient does not speak English or Spanish

Table 2. Key Elements of the Intervention

1. Risk assessment by a FCM using standardized history-gathering and physical examination documented in a structured visit note.
2. Use of evidence-based algorithms to identify recommended treatments that are discussed with participants
3. Explanation of identified risks to the patient (and caregiver, when appropriate) and suggested interventions, using motivational interviewing to elicit patient preferences and readiness to participate in treatments
4. Cocreation, with FCMs and patients (and caregivers, as appropriate), of an individualized Falls Care Plan that is presented to the patient's PCP for modification and approval, to include:

a. Fall risk reduction interventions that the FCM can directly implement;
b. Recommendations that the PCP can implement (eg, medication changes);

5. Referrals to health providers or community-based organizations for more detailed assessment or implementation of specific components identified in the Risk Assessment.
6. Ongoing monitoring of response to treatment as indicated in the Care Plan and reassessment of risk factors at scheduled intervals by the FCM with revision of the Care Plan as needed.

Note: FCM = Falls Care Managers; PCP = Primary care provider.

FCMs are registered nurses, who completed a 24-module fall prevention and management program custom-developed by the STRIDE team, along with individualized training in the management of patients at risk for falls. A FCM Nursing Director provided ongoing support and supervision through scheduled weekly conference calls and annual in-person training sessions.

The FCM assesses each participant for 7 modifiable falls risk factors (17) (Table 3), explains the identified risks to the patient (and caregiver, as appropriate), and suggests interventions, based on the person's risk factors and STRIDE algorithms for each risk factor. The FCM uses motivational interviewing to elicit patient preferences and readiness to participate in treatments. The FCM creates an individualized Falls Care Plan and presents it to patient's primary care provider (PCP) for approval. This individualized Falls Care Plan includes fall risk reduction interventions that the FCM can independently implement, recommendations that the PCP can implement (eg, medication changes), and referrals to health providers or community-based organizations for implementation of specific components identified in the Risk Assessment. During regularly scheduled follow-up visits or phone calls, the FCM evaluates patients' progress in Falls Care Plan implementation and response to intervention; reassesses risk factors; and revises the Falls Care Plan as needed. After the initial evaluation by the FCM, follow-up visits take place at least once annually. Additional phone calls take place at least once during the first year and every 6 months in subsequent years.

The principal components of the intervention—the FCM, systematic assessment of risk factors, patient engagement, the linkage with health care providers, and referrals to community-based programs—are consistent across practices. However, some variation in the implementation of the intervention at the trial sites was necessary, depending upon local resources, availability of community-based programs, or other site-specific factors.

Structured notes from the initial and follow-up visits and clinical documents (eg, previsit questionnaire, home safety checklist) are entered into an electronic health record and into a specially designed FCM software application. The falls events are managed by the primary practice and FCM according to standards of care.

Table 3. Fall Risk Factors and Triggers for Intervention

Risk Factor	Triggers
Strength, balance, gait impairment.	All patients
Medications	FRIDs or symptoms identified from Previsit Questionnaire
Vitamin D deficiency	All patients not currently taking Vitamin D
Home safety	Risk factors identified by the FCM on home safety checklist filled by all patients prior to initial visit
Orthostatic hypotension	Orthostatic hypotension identified during initial visit
Visual impairment	Patients who have not been seen by eye doctor in past year, or Patients who have vision risk factors (macular degeneration, glaucoma, diabetic eye disease, near or far vision loss) even if they have seen an eye doctor within the past year.
Foot problems or unsafe footwear	All patients depending upon assessment findings
Osteoporosis	All patients

Note: FCM = Falls Care Managers; FRID = Fall Risk Increasing Drugs.

Adherence to the intervention is measured by the percentage of persons randomized to the intervention arm who receive an initial evaluation for risk factors, the percentage of risk factors assessed for each participant, and the percentage of identified positive risk factors for which an action is taken according to the clinical protocols.

Control intervention

The participants in the control practices receive enhanced usual care. These participants receive a falls informational booklet, entitled "Stay Independent", which is part of the STEADI toolkit, and they are encouraged to discuss fall prevention with their PCP at their next clinic visit. Their physicians receive the results of the screening questions and are referred to a training webinar about fall prevention adapted from the STEADI toolkit (16).

Outcomes

The primary outcome is time to first serious fall-related injury, defined as falls leading to medical attention, including nonvertebral fractures, joint dislocation, head injury, lacerations, and other major sequelae (eg, rhabdomyolysis, internal injuries, hypothermia) (Table 4). In a supportive analysis, all serious fall injuries will be evaluated.

Secondary outcomes include all fall injuries and all falls, defined as an unexpected event in which the participant comes to rest on the ground, floor, or lower level (18). We collect data on falls, serious fall injuries, and other fall injuries every 4 months in all participants (Table 5) using a structured telephone interview, conducted by masked interviewers, which also asks about hospital admissions, emergency department (ED) visits, and other health care utilization. To facilitate recall, participants are provided a monthly fall calendar to record their falls and injuries. The ascertainment of these outcomes is conducted by the RAC.

Secondary well-being outcomes include concern about falling, anxiety and depressive symptoms, and physical function and disability. Concern about falling is ascertained using the Fall Efficacy Scale (FES) (19); physical function and disability using the computer

Table 4. Primary and Secondary Outcomes of the STRIDE Study

Outcome level	Outcome Measure	Ascertainment
Primary	Serious fall injuries defined as falls leading to medical attention, including nonvertebral fractures, joint dislocation, head injury, lacerations, and other major sequelae (eg, rhabdomyolysis, internal injuries, hypothermia)	Every 4-month interviews aided by monthly fall calendars; encounter and claims data; electronic medical records
Secondary	Fall-Related	Every 4-month interviews aided by monthly fall calendars; encounter and claims data
	All fall injuries	
	All falls*	
	Wellbeing measures	Measured at baseline, 12 and 24 months
	Concern for falling	Fall efficacy scale
	Depressive symptoms	PROMIS scales for depressive symptoms and anxiety
	Anxiety	CAT version of Late Life Function and Disability Instrument
	Physical function and disability	
Tertiary	Hospitalizations	Every 4-month interviews; encounter and claims data; electronic medical records if needed
	Nursing home admissions	

Note: *A fall was defined as an unexpected event in which the participant comes to rest on the ground, floor, or lower level. A modified caregiver FES was used in patients who had a caregiver. CAT = Computer Adaptive Testing; FES = Fall Efficacy Scale; PROMIS = Patient-Reported Outcomes Measurement Information System.

Table 5. The Trial's Schedule of Events

Activity/Assessment	Screen	Baseline	4 mo	8 mo	12 mo	16 mo	20 mo	24 mo	28 mo	32 mo	36 mo	40 mo
Screen												
Screen for high fall risk	X											
Telephone interview		X										
Consent/Assent		X										
Demographic characteristics		X										
Cognitive screen		X										
Chronic conditions		X										
Fall history		X										
Self-rated health, height/weight		X										
Physical function and disability[a]		X			X			X				
Concern about falling[a]		X			X			X				
Anxiety/depressive symptoms[a]		X			X			X		X		
Phone interviews for fall ascertainment[a]			X	X	X	X	X	X	X	X	X	X
Falls, fall injuries, serious fall injuries			X	X	X	X	X	X	X	X	X	X
Health care utilization			X	X	X	X	X	X	X	X	X	X

Note: After the initial visit with the FCM, follow-up visits take place at least once annually. Additional FCM phone calls take place at least once during the first year and every 6 months in subsequent years. The exact timing of the FCM visits and telephone calls depends on the patient and FCM availability and other factors. FCM = Falls Care Managers.

[a]Among a random subset of 714 participants.

adaptive technology version of Late Life Function and Disability Index (20,21); and anxiety and depressive symptoms using the PROMIS scales (22). Wellbeing outcomes are being collected in a 13% subsample at 12 and 24 months.

Fall Injury Adjudication

The primary outcome—serious fall injuries—will be adjudicated by an Adjudication Committee using three sources of information: 4-monthly RAC interviews, informed by monthly fall calendars; encounter data from the clinical trial sites or claims data from Center for Medicare Services (CMS); and specific information from the EMR. One physician from each of the ten sites, plus two physicians from the central STRIDE team, will be involved in adjudication of the primary outcome. An injury will be deemed to meet the definition of the primary outcome if the injury is related to a fall, the injury leads to use of health care services, and the injury falls into a predefined list of types (nonvertebral fractures, joint dislocation, head injury, lacerations, or "other major sequelae").

Two site-based adjudicators will be responsible for initial adjudication of each case. The central STRIDE team of two adjudicators will review a stratified random sample of 5% of all cases to assure consistency in adjudication. If the two site-based adjudicators do not agree, a third adjudicator may be enlisted to break the tie.

Statistical Design

STRIDE was designed as a pragmatic trial with the following adaptive features: (i) modifying the eligibility criteria if enrollment is lower than expected (eg, by lowering the eligibility age); (ii) modification of primary outcome definition if there is evidence of ascertainment bias because of interactions between the FCMs and participants; (iii) changing the primary outcome from first serious fall injury to all serious fall injuries if the former rate is too low, affecting statistical power; (iv) interim monitoring for efficacy or futility, if necessary and (v) refining the analytic methods based on the validity of assumptions. All adaptations, except for interim look, will be done masked to treatment.

Analytic approach

All analyses will consider practices according to their randomized assignment regardless of adherence to protocol, and will account for cluster design with the participant as the unit of analysis. The analysis of the primary outcome, time to first serious fall injury, will use a survival model that incorporates clustering and competing risk of death (23–25). The model will be adjusted for stratified randomization of practices by health care system and include the balancing covariates used in assignment of practices (practice size, location, and ethnicity). Participants without a serious fall injury will be censored either at the date of their withdrawal or at the end of follow-up. In a secondary analysis, we will adjust for a prespecified set of baseline covariates to examine their influence on treatment effect: age, race/ethnicity, education, number of chronic conditions, and number of positive screening items. Model fit will be assessed using standard approaches (eg, examination of Martingale residuals and the proportional hazards assumption). The effect of intervention relative to control will be estimated as a subdistribution hazard ratio with corresponding 95% confidence intervals. Also, we will obtain an estimate of the intervention effect at the practice level. If the intervention is effective in reducing the risk of serious fall injuries, its effect will be evaluated in subgroups of participants using appropriate tests of homogeneity (eg, interaction) defined by prespecified covariates. The cumulative incidence of serious fall injuries will be estimated using nonparametric maximum likelihood methods (24) and used to estimate freedom from falling over the entire follow-up period. In a supportive analysis, we will evaluate serious fall injuries as a recurrent event using a joint frailty model that accounts for clustering, censoring and competing risk (26). An overall type I error rate of 0.05 (two-sided) will be used as the level of significance for primary endpoint.

Analysis of the secondary outcomes

The time-to-event analysis of the secondary outcomes—all fall injuries and all falls (regardless of injury)—will be performed similar to the primary outcome. Indicators of well-being (fall efficacy, physical function, anxiety and depressive symptoms) measured in the 13% subsample will be analyzed using generalized linear mixed models assuming missing at random (MAR) with adjustment for factors that are found to be predictive of missingness. Sensitivity analyses will be conducted to investigate the MAR assumption, such as methods that model jointly the missingness and outcome distributions. Adjustments for multiplicity will be used to control type I error for the secondary endpoints (eg, Hochberg procedure).

Interim monitoring

An interim monitoring plan, which encompasses the adaptive design features described earlier, has been approved by the DSMB. The DSMB also has approved a revision to the plan specifying that a formal interim analysis for efficacy or futility with the potential for early termination may not be necessary, and that a final decision about a formal interim analysis can be made sometime in 2018.

Sample Size

Sample size was first determined for an unclustered design with a time-to-first event outcome in the presence of a competing risk due to death using PASS software, and then inflated for clustering and interim monitoring. A target sample size of 6000 participants was selected based on the following assumptions: (i) 18-month recruitment period and a trial duration of 36 months with minimum follow-up of 18 months; (ii) type I error = 5% (two-sided) and 90% power; (iii) uniform accrual; (iv) equal allocation to intervention and control groups; (v) no adjustment for nonadherence to intervention (accounted for with conservative treatment effect); (vi) all patients followed to trial's end; (vii) 7% annual death rate without experiencing a serious fall injury (ie, competing risk); (viii) 3% annual loss-to-follow-up in the absence of serious fall injury or death (expected to be low due to the use of multiple sources, including claims data); (ix) 3% inflation for the proposed interim monitoring for efficacy and futility; and (x) 53% inflation for the design effect (DE) of clustering, based on 86 practices each enrolling 70 participants and an ICC of 0.0076 estimated from an analysis of serious fall injuries in the LIFE Study (27). The target effective number of serious fall injuries to detect a 20% reduction for intervention relative to control at 90% power is 844.

Because of slower than expected enrollment in the initial 6 months of the trial, the DSMB approved the extension of recruitment period to 20 months and the minimum follow-up period to 20 months for a total 40-month trial duration. These extensions reduced sample size requirements to 5,322 participants given the above assumptions.

At the completion of the 20-month recruitment period, the trial had accrued 5,451 subjects, and the enrollment was stopped, as planned; 714 were enrolled in the subsample.

Safety Monitoring

Because the intervention was considered standard of care and not research, the consent form did not include language for consent to an intervention, only for collecting data. However, the study is monitoring for two serious adverse events, hospitalizations and death using the RAC interviews conducted every 4 months, EMR review, and encounter data from the trial sites or CMS claims data.

Integration of Patient and Stakeholders in Trial's Planning and Implementation

A unique aspect of the STRIDE study is the inclusion of input from a patient and stakeholder group to facilitate the bidirectional process of engaging patients and other stakeholders both locally at the 10 trial sites, and centrally at the central project management level. This engagement started during the planning of the project and has continued throughout the trial's implementation. A National Patient and Stakeholder Council (NPSC) which includes patients, caregivers, representatives from patient and family-centered care programs, representatives of local or national government agencies on aging, and from the NIA and PCORI, is led by two cochairs, one of whom is a patient. The NPSC then worked with the leadership of the trial sites to establish 10 Local Patient and Stakeholder Councils (LPSCs), one at each trial site. The membership of NPSC and LPSCs is diverse in

terms of the type of stakeholder, sex, race, ethnicity, and geographic region. The LPSCs includes patients, caregivers, representatives from the local community; health care professionals, advocates for consumer groups, and local area Agencies on Aging. Each LPSC is cochaired by a facilitator and a patient stakeholder.

The NPSC serves in a consultative capacity to study leadership, local councils and site PIs, and provides input from the 10 local councils to the trial's PIs and committees. All STRIDE committees have at least one NPSC member. The NPSC and the LPSCs have provided important input into screening, recruitment, intervention, and retention strategies; crafting recruitment packages; reviewing patient-facing materials; and in selecting study outcomes. The LPSCs have also supported FCM(s) by facilitating connections with community resources needed for intervention implementation.

Discussion

As one of the largest trials of fall injury prevention, the STRIDE Study has important clinical and public health implications. The trial addresses barriers to quality falls care by identifying the best available evidence, redesigning practice to ensure that evidence-based care is provided, and involving researchers, clinicians, patients, and other key stakeholders in the implementation of the study. The resulting approach to preventing fall injuries follows three principles that should ensure its success and dissemination; it is (i) evidence-based, (ii) patient-centered, and (iii) scalable.

The trial tests strategies with proven efficacy on falls quality of care and outcomes into one cohesive intervention that can be adopted by many health systems. These strategies include multifactorial, individually-tailored, evidence-base interventions) (6,7,11) selected by activated, engaged patients. The design of the study incorporates strategies to overcome challenges in implementation of a pragmatic trial conducted in large and diverse health systems. Thus, the core pillars of the intervention are implemented faithfully across trial sites but the sites are afforded some latitude in varying the implementation of specific components based on local practices and resources. Cluster randomization with practice serving as the unit of randomization avoids the potential for contamination of controls, allows staff to be trained efficiently, and improves the feasibility of applying the intervention practice-wide.

Recognizing that no single method for fall injury ascertainment is perfect, the trial combines three strategies—every 4-month phone interviews aided by fall calendars, CMS claims and health system encounter data, and electronic medical records—to adjudicate serious fall injury.

The STRIDE trial was designed with a keen focus on the scalability of its intervention strategies to other health care systems and populations. The trial has been integrated into 86 primary care practices of 10 diverse "real world" health care systems. The processes for practice redesign, patient co-management, and intervention for each risk factor have been successfully woven into the practices and their EMRs. Each practice has developed the needed collaborations with community resources. The STRIDE team has developed tools that can be used by other health care systems and clinicians; examples of such tools include manuals and videos for training of FCMs, rehabilitation therapists, and providers; algorithms for identifying persons at risk of falls and for prevention of fall injuries at a systems level; and information technology platforms that facilitate intervention's integration with EMR.

The project has drawn upon a diverse set of patients, caregivers and other stakeholders, who have participated in all the committees and in-person focus groups to craft the recruitment strategy, intervention, and outcomes. The STRIDE study's successful experience in integrating patients and stakeholders into the study team can inform the design and implementation of other patient-centered outcomes research.

The 10 trial sites reflect the diversity of the U.S. health care system with respect to models of care and payment, geography, and race/ethnicity. The successful implementation of the intervention in such diverse healthcare systems would provide strong evidence of its scalability. Although small group practices were not included, the lessons learned here may inform smaller practices. The intervention has been designed to be replicable within other health systems (eg, the Department of Veterans Affairs) and in small practices that participate in independent practice associations or Accountable Care Organizations.

The trial enlisted the expertise of scientists, patients, and stakeholders from across the country, including many NIA-funded Claude D. Pepper Older Americans Independence Centers. Thus, the STRIDE study represents an important national effort, whose results will greatly impact clinical practice as it relates to fall injury prevention.

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Acknowledgments

The STRIDE Study Team

Joint Principal Investigators:

Shalender Bhasin, MB, BS, Communicating PI and Chair of the Steering and Publications Committees, and Central Project Management (Brigham and Women's Hospital, Harvard Medical School, Boston, MA)

Thomas M. Gill, MD, PI and Chair of Protocol and Recruitment Committees (Yale School of Medicine, New Haven, CT)

David B. Reuben, MD, PI and Chair of Intervention Committee (David Geffen School of Medicine at UCLA, Los Angeles, CA)

School of Nursing, University of Minnesota

Siobhan McMahon, PhD, MPH GNP-BC (Nursing Director)

Central Project Management, Brigham and Women's Hospital, Boston, MA:

Shalender Bhasin (PI), Nancy K. Latham, PhD PT (Study Director), Shehzad Basaria, MD (Chief Medical Safety Officer), Richard Eder, BA (cIRB Liaison), Amy Larson, MHA (Administrative Director), Lori Goehring, BA (Study Manager), Molly Lukas, BS, Scott Margolis MBA, Thomas W. Storer, PhD, Priscilla Gazarian, PhD, RN, Maureen Fagan, DNP, MHA, FNP-BC, Martha B. Carnie, AS

Data Coordinating Center, Yale University, New Haven, CT:
Peter Peduzzi (Director), PhD, James Dziura, PhD, Denise Esserman, PhD, Erich J. Greene, PhD, Geraldine Hawthorne-Jones, Heather Allore, PhD, Margaret Doyle, Brian Funaro, Nancy Lorenze DNSc, Bridget Mignosa, Michael E. Miller, PhD (Wake Forest), Thomas G. Travison, PhD (Harvard), Peter Charpentier, MPH (Chair of Data Management Committee), Katy Araujo, MPH
Yale School of Medicine, New Haven, CT:
Geriatric Medicine:
Dorothy Baker, PhD
Recruitment and Assessment Center:
Joanne M. McGloin, MDiv, MS, MBA, Charles Lu, PhD, Haseena Rajeevan, PhD, Liliya Katsovich, MA, MBA, CCRP, Rixin Wang, PhD, Amy Shelton, MPH, Eleni Skokos, BS, MS, Sui Tang, BS, Mara Abella, Carol Gordon, Teresita Pennestri, Luann Bianco, Rina Castro, Sabina Rubeck, Kenneth Rando, Barbara Foster, Karen Wu, David Nock, Crysta Collins, Eloisa Martinez (UTMB), Leo Sherman (Mt. Sinai)
Clinical Trial Sites
Essentia Health, Duluth, MN
Site Principal Investigator: Stephen C. Waring, DVM, PhD, Fall Care Manager: Erica Chopskie, RN, BS, Allise Taran, MPH, Joseph Bianco, MD, Margaret Hoberg, CNP, Hillary Henzler
HealthCare Partners, El Segundo, CA
Site Principal Investigator: Jeremy Rich, DPM, Fall Care Manger: Vivian Chavez, RN, Christine Moore, Janelle Howe, Rosario Garcia, Jocelyn Nunez, Samuel Ho, MD, Yan Chen, MD
Johns Hopkins Medicine, Baltimore, MD
Site Principal Investigator: Albert W. Wu, MD, MPH, Jeremy D. Walston, MD, Fall Care Manager: Tiffany Campbell, BSN, RN, BMTCN, OCN, Patti Ephraim, MPH, Yuri Agrawal, MD,
Mercy Health Network (Des Moines, IA*) and University of Iowa* (Iowa City, IA)
Site Principal Investigator: Robert Wallace, MD, MSc, Co-Site Principal Investigator: Carri Casteel, PhD, Fall Care Manager: Angela Shanahan, RN-BC, BSN, Julie Weldon MSN RN, Anita Leveke, RN, BSN, CEN, Charles Keller, MD, Jeffrey Reist PharmD
Michigan Medicine, University of Michigan, Ann Arbor, MI
Site Principal Investigator: Neil Alexander, MD, Jocelyn Wiggins, BM, BCh, Fall Care Managers: Karen Burek, RN, MS, ANP-BC and Tina Ledesma, RN, BSN, Linda V. Nyquist, PhD, Nancy (Amby) Gallagher, PhD, APRN-BC, Catherine Hanson, BA
Mount Sinai Health System, New York, NY
Site Principal Investigator: Fred Ko, MD, MS, Albert L. Siu, MD, MPH, Rosanne M. Leipzig, MD, PhD, Christian Espino, BA, Ravishankar Ramaswamy, MD, MS, Fall Care Managers: Deborah West, RN, BS and Deborah Matza, RN, MPH
Partners Healthcare, Boston, MA
Site Principal Investigator: Patricia Dykes, RN, PhD, MA, Hilary Stenvig, Kety Vanda, Alejandra Salazar, PharmD, Laura Frain, MD, Ariela Orkaby, MD, MPH, Jonathan Bean, MD Fall Care Managers: Yvette Wells, RN and Cathy Foskett, RN
Reliant Medical Group, Worcester, MA
Site Principal Investigator: Jerry H. Gurwitz, MD, Allison Richards, Lawrence Garber, MD, Fall Care Managers: Peggy Preusse, RN and Anne McDonald, RN
University of Pittsburgh Medical Center, Pittsburgh, PA
Site Principal Investigator: Susan L. Greenspan, MD, Fall Care Manager: Mary Anne Ferchak, RN, BS, Madeline Rigatti, Joseph Madia
University of Texas Medical Branch at Galveston, Galveston, TX
Site Principal Investigator: Elena Volpi, MD, Fall Care Manager: Summer Chapman, RN, MSN, Roxana Hirst, MS, CCRP, Eloisa Martinez, BS, CCRP, Mukaila Raji, MD, MS
STRIDE Committee Chairs:
Clinical Trial Sites: Jerry H. Gurwitz, MD;
Outcomes: Jay Magaziner, MSHyg, PhD (University of Maryland) and Albert L. Siu, MD, MPH; ***Adjudication***: David A. Ganz, MD, PhD (UCLA);
Steering: Shalender Bhasin, MB, BS
Protocol: Thomas M. Gill, MD
Screening; Recruitment and Retention: Joanne M. McGloin, M Div, MS, MBA and Thomas M. Gill, MD
Data Management and IT: Peter Charpentier, MPH
Intervention: David B. Reuben, MD
Safety: Shehzad Basaria, MD
Falls Care Managers: Siobhan McMahon, PhD, RN (University of Minnesota);
National Patient and Stakeholder: Maureen Fagan, DNP, MHA, FNP-BC (Chair), Martha B. Carnie, AS (Co-Chair), Catherine Hanson, BA
Physical Components: Pamela W. Duncan, PhD, PT (Wake Forest University) and Thomas W. Storer, PhD
FCM Training: Chad Boult, MD, MPH, MBA (Johns Hopkins) and Priscilla Gazarian, PhD, RN
Ancillary Studies: James Goodwin, MD (UTMB) and Todd Manini, PhD (University of Florida) ***Publications***: Shalender Bhasin, MB, BS and Peter Peduzzi, PhD
Wake Forest University, Winston-Salem NC
Kevin P. High, MD, MS, Lea Harvin, Cindy Stowe
National Institute on Aging, Bethesda, Maryland:
Program Officer: Sergei Romashkan, MD, Scientific Officer: Rosaly Correa-De-Araujo, MD, MS, PhD, Lyndon Joseph, PhD, Marcel Salive, MD, MPH, Evan C. Hadley, MD
Patient Centered Outcomes Research Institute (PCORI), Washington, D.C.
Steven B. Clauser, PhD, MPA
Data and Safety Monitoring Board
A 9-member Data and Safety Monitoring Board, appointed by the National institute on Aging, oversaw study's progress and safety, and included:
David Buchner, MD, MPH(Chair); Terry Fulmer, PhD, RN, FAAN; Susan Ellenberg, PhD; Bonita Lynn Beattie, MPT, MHA; Abby C. King, PhD; Cynthia J. Brown, MD, MSPH; Laurence Rubenstein, MD; Mary Anne Sterling, CEA; Thomas Prohaska, PhD; Laurence Friedman, MD

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