**Overview of A Randomised Trial of a Multifactorial Strategy to Prevent Serious Fall Injuries (Bhasin et al, N Engl J Med 2020; 383:129-140)**

**Cameron Hicks, NeuRA**

The Strategies to Reduce Injuries and Develop Confidence in Elders (STRIDE) cluster-randomised trial was funded through a partnership between the Patient-Centered Outcomes Research Institute and the National Institute on Aging (USA). The aim was to determine the clinical effectiveness of a patient-centred 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 on serious fall injuries in people aged 70+ years.

**Characteristics of the Sample**

The trial was coordinated across 10 health care organisations at 10 clinical sites. Eighty-six primary care practices were selected from 162 within the participating health care systems, based upon size of practice, ability to implement the intervention, geographic proximity to other practices, accessibility of electronic health records and access to community-based exercise programs. Eligible practices were randomised with the use of covariate-constrained randomisation, 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 (non-white vs. white, and Hispanic vs. non-Hispanic).

Participants were eligible if they were 70 years of age or older and met one of the following criteria: 1) experienced a fall-related injury in the previous year, 2) experienced two or more falls in the previous year, 3) were afraid of falling because of problems with balance or walking. Participants were excluded if the person: 1) resided in a in hospice, 2) resided in a nursing home, 3) was not capable of providing informed consent and a proxy was not available, 4) did not speak English or Spanish. A person who was cognitively impaired (4 or more errors on six-item Callahan screening) was eligible if a proxy provided consent and assisted them during the trial.

The primary outcome for the trial was the time to first adjudicated serious fall injury, 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 hospitalisation for a head injury, sprain or strain, bruising or swelling, or other serious injury. A secondary analysis adjusted for a prespecified set of baseline covariates to examine their influence on the intervention effect (age [70-79years vs. ≥80 years], sex, fear of falling, at least two chronic conditions, previous hip fracture or other fracture after 50 years of age). Secondary outcomes included the time to first participant-reported fall injury, number of falls, number of fall injuries and measures of well-being.

Recruitment packets were mailed to 31, 872 positive screening patients. Then 18,571 persons were interviewed of which 5,451 were recruited and provided consent. Across the groups, the mean age was 80 years, 62% were women, 39% had experienced a fall with an injury during the previous year and 35% had experienced two or more falls during the previous year. Baseline characteristics of the randomised practices between the two groups were similar with respect to practice size, urban vs. rural locations and racial patronage. Baseline characteristics of the participants between the two groups were also similar regarding age, sex, race, education, chronic conditions, cognitive impairment, mobility aid usage, previous falls and fear of falling.

**Intervention and its implementation**

The intervention aimed to implement a multifactorial program to reduce fall risk across a range of domains. Falls Care Managers (FCM) in charge of implementing the program were nurses who had obtained a Bachelor of Science in Nursing and completed a 26-module online STRIDE training course with supplemented face-to-face sessions developed by STRIDE team experts and the John Hopkins School of Nursing.

Prior to initiating the intervention, the FCM reviewed participant's electronic medical record for fall risk factors, previous bone mineral density testing, cognitive function and medications related to falling and osteoporosis. An FCM made initial contact with participants over the telephone in order to introduce the intervention, develop a therapeutic relationship and to review the circumstances of any falls and data needed to calculate the risk of future fractures (FRAX score). The participant was then requested to complete baseline questionnaires, a home safety checklist and a travel safety checklist and undergo a face-to-face assessment.

The intervention included five components:

1) Standardised assessment of seven modifiable risk factors for fall injuries conducted by the FCM.
    i. Impairment of strength, gait or balance.
    Based upon the participants modified Short Physical Performance Battery results, cognitive function, pain level and preferences, exercise was implemented through the FCM referring to outpatient or home health physical therapy, community-based exercise programs, or home-exercises based on the Otago exercise program.

    ii. Medication use.
    Fall risk-increasing drugs, drug related side effects that may increase the risk of falling, medication use without clear reason, medication adherence and alcohol consumption were assessed by the FCM. If medication was being taken and symptoms or adherence problems are reported, medication was taken without clear indication or a medication to avoid was taken a referral to the pharmacist or site clinical director was made. A letter with suggestions for modification was sent to the primary care physician by the pharmacist or site clinical director along with an appropriate de-escalation handout. The primary care physician then decided whether to modify medications and how best to monitor.

    iii. Postural hypotension.
    Based upon a 3-minute lying to standing blood pressure measurement the FCM recommended the following interventions; 1) Education and behaviour changes and re-checked after 2 weeks. Indicated by a drop in systolic blood pressure of no more than 20mmHg and remains greater than 90mmHg but is symptomatic. 2) Education and behaviour changes and a prompt letter to the primary care physician. Indicated by a drop in systolic blood pressure of greater than 20mmHg or falls blow 90mmHg while standing but is asymptomatic. 3) Education and behaviour changes and an immediate notification of the primary care physician. Indicated by a drop in systolic blood pressure of greater than 20mmHg or falls blow 90mmHg while standing and is symptomatic. Education involved the FCM discussing the causes of postural hypotension, how it can cause falls and symptoms experienced with the participant.

iv. Problems with feet or footwear.
Indicated by foot pain, limited range of motion, numbness, weakness of toes or ankles and deformities such as bunions, hammertoes and long toenails. Also included footwear-related risks such as walking barefoot, using slippers, or other shoes that have inadequate fixation, high or narrow heels, or smooth, thick or soft soles. The FCM reviewed responses to foot-relevant questionnaires, examined both bare feet, evaluated footwear and observed the participant performing the Short Physical Performance Battery. Based upon this assessment the FCM was able to recommend safer footwear or safer footwear use, initiate referrals to podiatry for nail and foot care, other specialists for shoe and orthotic interventions or suggest to the primary care physician to consider evaluation and treatment by a physical therapist or work-up of peripheral neuropathy.

v. Osteoporosis and vitamin D deficiency.
An assessment determined whether existing treatments for osteoporosis were in place. If not, a bone mineral density test and history of a minimal trauma fracture taken to determine whether osteoporosis was present. If the individual had osteopenia or there was no bone mineral density test results, the FRAX risk calculator was used to determine recommendations for treatment. Supplementation with calcium and vitamin D was recommended for all people according to Institute of Medicine recommendations.

vi. Home safety hazards.
The FCM reviewed the participant's completed Home Safety Checklist and provided information flyers on the participant's specific fall risks, reviewed the participant's ability to get up from a fall and determined the participant's eligibility for Medicare coverage of a home safety evaluation by a home care agency or outpatient Occupational Therapist. The FCM evaluated the need for and made referrals based upon visual impairment, previous fall at home in the previous year, environmental risks at home and patient willingness to have a home evaluation, or otherwise highlighted specific fall risks and situations likely to result in injurious falls and provided an information flyer.

vii. Visual impairment.

The FCM reviewed the individual's history to determine whether a visit with an eye doctor had occurred during the past year and to identify any history of cataracts, macular degeneration, glaucoma or visual loss. If there was no record of a recent eye examination visual acuity was measured and recommendations were made accordingly.

2) Standardised protocol-driven recommendations.
Risk factors that were identified by the FCM were explained to the participant, caregiver, or both. Interventions for the identified risk factors were suggested and motivational interviewing was used to elicit preferences and readiness to participate in treatments.

3) Development of an individualised falls care plan.
The care plan was initially focussed on one to three risk factors, based upon the individual's preference and approved by the primary care physician.

4) Implementation of the individualised falls care plan.
   Implementation of the falls care plan depended on the type of fall risk factor or treatment option the individual prioritised. Interventions within a Registered Nurse's scope of practice (e.g. recommendations for safe footwear and instruction on simple home exercises) were managed between the FCM and individuals. Interventions outside a Registered Nurse's scope of practice (e.g. treatment of osteoporosis) were communicated to relevant providers. Interventions requiring specialised skills or programs were referred, as appropriate (e.g. to outpatient physical therapy or community-based exercise programs).

5) Follow-up care.
   A formal face-to-face follow-up visit was conducted by the FCM and according to the individualised fall care plan after ≤6 months, then annually along with at least one phone call within the first year. During these follow-up visits, risk factors were reassessed, and the care plan was evaluated and revised as needed.

The control group received enhanced usual care which included an information pamphlet about falls and were encouraged to discuss fall prevention with their primary care physician. Primary care physicians in both intervention and control groups were provided with a webinar on preventing falls. They did not receive the initial face-to-face assessment conducted by the FCM nor complete the initial questionnaires or Home Safety Checklist.

During the implementation of the trial, enrolment was slower than projected. The duration of the trial was therefore extended from 36 months to 40 months and the sample size was reduced from 6,000 to 5,322. After recruitment concluded, 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. An annual event rate in the control was projected at 14% to 18%. There was no record of compliance with the intervention during the trial.

**Main findings**

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). A practice-level analysis (i.e. an analysis performed comparing intervention and control primary care practices instead of individual participants) 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. Regarding secondary outcomes, 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 total number of adjudicated serious fall injuries (hazard ratio, 0.94; 95% CI, 0.81 to 1.10) and participant-reported fall injuries (hazard ratio, 0.96; 95% CI, 0.89 to 1.03) did not differ significantly between the groups. The most common types of adjudicated serious fall injuries were bone fractures and injuries leading to hospitalization. There was no significant difference between groups for hospitalisations resulting from serious adverse events (hazard ratio, 0.98; 95% CI, 0.92 to 1.04; P = 0.47) or deaths resulting from serious adverse events (hazard ratio, 1.01; 95% CI, 0.84 to 1.23; P = 0.88).

**Authors thoughts from the paper as to why the trial was not effective**

The finding of no significant reduction in the rate of time to first adjudicated serious fall injury was unexpected. The authors listed several reasons in the paper's discussion as to why it was not as effective as expected:

1) Adherence to the intervention may have been lower than in previous trials. This may be due to barriers faced by the participants in implementing the recommendations such as transportation, co-payments or insurance coverage.
2) Participants were referred to existing services provided by local health or community centres; the trial did not manage or evaluate these services.
3) Adherence to behaviour modification interventions (e.g. exercise) was not routinely monitored.
4) The falls care plan was participant focussed and the risk factors addressed were selected based upon their preferences. This meant that some valuable recommendations were not implemented. For example, only 29% of participants with a medication-related fall risk factor agreed to a medication review and only 50% of participants who had a home safety hazard identified agreed to address it.
5) Participants and their physicians together selected the modal of intervention and may have selected less effective approaches (e.g. calcium or vitamin D over osteoporosis medications or non-evidence based exercise modalities).
6) 14% of the intervention participants did not commence the intervention.
7) Improving quality of care for fall prevention may not be sufficient to reduce time to serious fall injuries.
8) Conducting the intervention within the health care system may have increased the awareness of the risk of falls among all participants and providers, influencing fall prevention practice and leading to a longer time to first serious fall injuries in both groups. Control group physicians were provided with a webinar on falls and participants were provided fall prevention information flyers and encouraged to speak to their physicians about fall prevention and this may have further influenced the result.

**Implications for future studies**

The authors suggested that additional measures such as interventions to improve adherence and more intensive strategies to encourage the application of medication reviews may be needed in the future.

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