Official Title: Strength training and nutrition education for older adults (MoveStrong): A pilot randomized controlled trial

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History of Changes

July 12, 2019: Stair climb test was removed since not all sites had stairs.
July 14, 2019: Replaces the CHAMPS questionnaire with the Physical Activity Scale.
July 18, 2019: Minor editorial changes**.**

ABSTRACT

Background: Age-related loss of muscle mass and strength can lead to disability, frailty, and health instability. There is strong evidence certain types of exercise can prevent falls, disability, and bone loss but many older adults do not meet the physical activity guidelines. The purpose of this study will be to assess the feasibility of implementing workshops to teach functional strength and balance training and nutrition to older adults (MoveStrong) across diverse settings.

Design: This is a closed cohort stepped wedge design.

Setting: Northern (rural) and Southern Ontario sites in Canada

Participants: We will recruit 40 older adults considered pre-frail as measured by the FRAIL Scale, ≥60 years old, with at least one chronic condition, but who are currently not engaging in a regular exercise program.

Intervention: The MoveStrong program is an eight-week exercise and nutrition program. The program will include a kinesiologist-led twice-weekly functional strength and balance program, and two seminars delivered by a dietian on behavior change strategies to promote healthy eating and specifically increase protein intake.

Measurements: The primary outcome is feasibility of implementation, defined by recruitment, retention, and adherence rates. Secondary outcomes include frailty indicators, mobility and balance measures, quality of life, dietary protein intake, adverse events, and participant and provider experience. We will analyse feasibility objectives using descriptive statistics based on estimates with 95% confidence intervals. Secondary outcomes will be evaluated in exploratory intention-to-treat and per protocol analyses via independent Student *t* tests or logistic regression. Content analysis will be used to identify facilitators or barriers to implementation.

Conclusions: Our goal is to develop a scalable model for enabling older adults to participate in functional strength and balance training, and to consume adequate protein. The current study will inform the feasibility of a larger pragmatic trial in other diverse settings.

INTRODUCTION

With age, there are a number of changes in body composition including atrophy of the skeletal muscle, beginning around age 25 and accelerating after the age of 50 (1,2). Sufficient muscle strength is necessary to provide a reservoir of protein for the immune system, prevent falls and disability, and perform activities of daily living such as getting up from the bed. When age-related loss of muscle mass decreases beyond a defined threshold, this is termed sarcopenia (1). The European Working Group on Sarcopenia in Older People is one of several groups that has provided a working definition of sarcopenia as "a progressive loss of skeletal mass and strength that increases the risk of adverse outcomes such as physical disability, poor quality of life, and frailty" (3). The physical features of frailty include weakness, slowness, unintended weight loss, and low physical activity (4). Between 1 to 29% of community-dwelling older adults have sarcopenia, and this has direct consequences on personal, social, and healthcare costs, which will rise steadily with an increasing ageing population (1,5).

There is evidence that regular exercise [i.e., planned, structured, and repetitive bodily movement done to improve or maintain one or more components of physical fitness (6)] can improve muscle outcomes in older adults (5,7–9), and there is emerging data for significant psychological and cognitive benefits accrued from regular exercise (9). A narrative review, based on multiple meta-analyses, suggests exercise training improves functional capacity and muscle strength in individuals with different chronic diseases without having a negative effect on disease progression (10). These results are corroborated in a recent meta-analysis that reported exercise interventions significantly improve some, but not all, aspects of muscle strength and mass, and functional outcomes in older adults with sarcopenia (11). Specifically, resistance training alone, performed between 3 to 18 months, improved muscle mass and strength, and physical performance

variables, such as chair rise, stair climb, and the 12-minute-walk-test in older adults with sarcopenia (5). Similarly, progressive resistance training performed two to three times per week at a high intensity result in moderate to large significant improvements in gait speed, getting out of a chair, and muscle strength (12). Further, a recent Cochrane review reported that balance and functional exercises reduced the rate of falls by 24% in community dwelling older adults (13), and balance and functional exercises in combination with resistance training could potentially reduce the rate of falls by more than 30% (13).

The benefits accrued from exercise are evident, but over 75% of Canadian adults 18 years and older are not meeting the physical activity guidelines, and it gets worse with age, as 88% of adults over 65 years of age do not meet exercise guidelines (14). Thus, the biggest challenge is not a lack of evidence that exercise is beneficial, but the absence of effective, sustainable real-world implementation exercise models, especially for older adults with chronic conditions. In our previous work, we tested a model for delivering balance training for adults ≥75 years old in primary care who were not physically active (a 1:1 session followed by 4 group sessions) (15). We defined physical inactivity as individuals who are physically active occasionally or during certain seasons more than others or as not physically active beyond moving around or walking during activities of daily living (15). In exit interviews, participants stated they valued a familiar location (e.g., a doctor's office), small group classes, personal attention, social interaction, learning from others, free or low-cost classes, easy-to-read materials, and encouragement to attend with a caregiver/friend for social or physical support. Using what we learned, we collaborated with the YMCA, Community Support Connections, Osteoporosis Canada, and patient advocates to co-create MoveStrong – a model of service delivery that adapts functional strength training (e.g., squats, push-ups, step-ups, loaded carries) to support movements performed during activities of daily living. The MoveStrong model is

designed to be scalable in multiple settings, with training materials for instructors to tailor, teach, and progress functional moderate-high intensity strength and balance training. There are variations of each movement on a continuum from seated exercises to body weight exercises to more challenging versions with weights. The program uses fundamental strength training exercises aligned with functional movements to promote personal relevance; for example, step-ups build stair-climbing power while loaded carry exercises may translate to transporting groceries more efficiently. Balance challenges are included for fall prevention (16,17). MoveStrong also provides two dietian-led seminars and a booklet focused on using real food to improve protein intake. From past work, we identified meal preparation approaches with fresh ingredients are preferred over supplements.

Objectives

We aim to lead a pragmatic trial where settings (retirement homes, YMCAs, family health teams) are cluster randomized to timing of the MoveStrong implementation to evaluate the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM Framework) (18), including cost-effectiveness and sustainability. The pilot study will assess the feasibility, fidelity and adaptability of the MoveStrong model in diverse settings and responsiveness of outcomes. The primary objectives of the proposed pilot study will be to:

1. Evaluate the number of participants recruited to participate at the start of the study;
2. Determine retention rates at the end of the study; and
3. Calculate adherence rates to the MoveStrong program.

Secondary objectives will determine participants' and providers' experience with MoveStrong, adaptations to the model, the cost relative to the benefit, the short-term responsiveness of frailty

indicators, protein intake, quality of life, and if the exercise and changes in eating behaviour are maintained.

METHODS

The protocol was drafted in accordance with the SPIRIT 2013 checklist of information to include when reporting a pilot or feasibility trial (https://www.spirit-statement.org/). In addition, we followed the TIDieR checklist for describing interventions in sufficient detail to allow their replication (http://www.equator-network.org/wp-content/uploads/2014/03/TIDieR-Checklist-PDF.pdf).

Trial design

This is a pilot single-blinded multicentre RCT to determine the feasibility of implementing a twice-weekly exercise program with a nutritional component for 8 weeks. We will use a closed cohort stepped wedge design at four sites across Ontario. At regular intervals (the "steps") one cluster (i.e., one site) is randomized to cross from the control to the intervention (see Figure 1) (19). This process continues until all clusters have crossed over to the intervention and at the end of the study all clusters will have received the MoveStrong program.

Study Setting

One Northern and three Southern Ontario sites were chosen to ensure diversity in city population, structure, services, and other variables. Participants will be recruited from local primary care practices, retirement homes and via advertisement. We will evaluate the MoveStrong program at three distinct settings; retirement home, YMCA, and a family health team. The MoveStrong program will be implemented and delivered at a kinesiologist-led clinic partnered with the City of Lakes

Family Health Team (Sudbury), Arbour Trails Retirement & Independent Living (Guelph), Village of Winston Park (retirement home & independent living, Kitchener), and two of the YMCA's of Cambridge and Kitchener-Waterloo (CKW YMCA, each YMCA is part of one cluster). The Sudbury site is located in Northern Ontario, while the others are in Southern Ontario. Data collection will occur at these four sites. The University of Waterloo will be the coordinating site. The Sudbury implementation site will have a kinesiologist led clinic (Kinnect to Wellness) partnered with a family health team.

Eligibility Criteria

Residents are eligible to participate in the study if they: speak English or attend with a translator; ≥ 60 years; have a FRAIL Scale score ≥1; and have ≥1 primary care diagnosed chronic condition [e.g., diabetes, obesity, cancer (other than minor skin cancer), chronic lung disease, cardiovascular disease, congestive heart failure, hypertension, osteoporosis, arthritis, stroke, or kidney disease]. Participants will be encouraged to attend with a caregiver/friend for social or physical support, and the caregiver/friend can choose to complete the screening and assessment process if eligible. Residents cannot participate in the study if they: are currently doing similar resistance exercise ≥2x/week; are receiving palliative care; cannot perform basic activities of daily living; have severe cognitive impairment (e.g., unable to follow two-step commands); travelling >1 week during the MoveStrong program; and have absolute exercise contraindications. Absolute exercise contraindication will be assessed using the Get Active Questionnaire, and if a participant selects "YES" to any question on this questionnaire, they must seek physician approval before exercising.

Intervention

The MoveStrong program has two main components, an exercise program and nutrition education.

Exercise (functional strength and balance training): MoveStrong is designed to provide a scalable framework for exercise professionals to tailor fundamental strength training exercises for older adults of varying abilities, using minimal equipment. The exercises are aligned with functional movements to promote personal relevance; jump, step-ups, reach, squat, pull, lift and carry, and push. The MoveStrong framework guides exercise selection, prescription details (e.g., intensity, volume, time under tension) and progression (Table 1). Seated exercises are provided only for participants who cannot perform the lowest level of difficulty (Level 1) with or without external support (e.g., walker, cane, wall, table). Exercises are informed by the GLAD program for arthritis (20), BoneFit™ (21), and meta-analyses on resistance exercise and fall prevention (8,12,16,17,22) that emphasize functional strength and balance exercise. Each participant will have a 1:1 session with a kinesiologist who will select a starting level and variations for each functional movement, intensity, and the number of repetitions and sets. Then, participants will attend a kinesiologist-led exercise workshop (5 attendees, 1:5 kinesiologist to participant ratio) twice a week for 8 weeks. Each site will receive a standardized toolkit with materials for participant workbooks and a trainer manual. The manual provides guidance on how to deliver the workshop, select and progress exercises, adapt exercises for common impairments, cueing tips, and discussion topics. Participant workbooks will be assembled to include pictures of each exercise (i.e., the variation of each movement selected for them) with instructions so they can take home to practice and exercise logs and planning worksheets. For the pilot study, we will run four workshops a week to accommodate ten participants. The exercise program starts with a warm up (5-7 minutes) that include a reactive

stepping game (http://clockyourself.com.au) or other balance and agility activities. Participants then complete the MoveStrong exercises in a circuit (jump, step-ups, reach, squat, pull, lift and carry, and push) where they perform 2-3 sets of 3-8 repetitions of each exercise with time under tension per repetition of 2:0:4 seconds for concentric:rest:eccentric). During the first week, the focus is on form rather than intensity. Exercise difficulty, resistance used, or volume (up to 3 sets, up to 8 reps) is progressed over time, with a target intensity of < 8 repetitions maximum (RM). At the end of each workshop session is a 10-minute group discussion where participants select an "Exercise of the Week" to plan when and where to practice it at home, or in a setting of choice. Schlegel Villages will provide kinesiologists for the Guelph and Kitchener sites and we will contract independent kinesiologists for the CKW YMCA and Sudbury sites to deliver the intervention (not blind to cluster allocation).

Nutrition Education: Participants receive an education booklet and participate in two dietitian-led group seminars that discuss strategies to increase protein intake. Presentations topics will consider the cost of preparing high protein foods and the ability of retirement home residents to alter their diet when food is provided, guide how and why to spread protein intake through the day, how much protein is in their usual diet, low cost options, easy-to-consume protein-rich snacks with minimal preparation, high quality protein supplements (e.g., rapidly digested, high leucine like whey), and how to prioritize high-protein choices in retirement home menus or restaurants. Other activities include sampling of protein-rich snacks. Seminars will occur at weeks 2 and 5 to allow time in between to review material and revisit topics and address questions. We will promote a protein intake greater than 1.2 g/kgBW/day, 20-30g/meal. In the pilot study, two sites will have sessions led by an in-person dietian and the other two sites will be led online by a dietian to assess the challenges and successes of an in-person versus virtual strategy. The dietitian is not blind to cluster allocation.

Recruitment

We will send posters and referral forms to local primary care providers, retirement homes, and fracture clinics for recruitment. We will also use social media (Facebook and Twitter) to advertise the MoveStrong study and share our recruitment posters with local contacts.

Data Collection Methods

A research assistant from the University of Waterloo and two nurses from the Sudbury site (all blinded to allocation) will recruit participants and collect data. They will record the number of eligible participants, the number of individuals willing to be randomized in the study, and retention rates; these rates will be reported in a standard excel sheet. An independent biostatistician will then develop a computer-generated randomization sequence at St. Joseph's Healthcare in Hamilton and randomize sites to implement MoveStrong at one of four start times, each three weeks apart. The randomization sequence will be maintained and concealed by a co-investigator at a site independent from those recruiting participants or delivering the intervention. The co-investigator will communicate allocation to a researcher or clinician at the central site who is not blind to group allocation at the end of pre-rollout. Clusters one and three will receive the nutrition education sessions in person, and clusters two and four will receive skype-led sessions.

The kinesiologist at each site will use a standardized calendar to record adherence rates. After the participant provides written informed consent (Appendix B), a research assistant will complete all baseline assessments. We aim to recruit all participants prior to randomizing sites to MoveStrong program start time. The same research assistant will conduct an additional three assessments each six weeks apart. Questionnaires may be conducted over the phone, if it is not possible to complete them in a visit. We will record and report any assessor that is unblinded as part of the feasibility evaluation.

Data Management

Each recruiting site will be required to keep accurate and verifiable source notes relevant to each study participant, and a protocol deviation log. Participants will be de-identified by assigning an ID to be used on all forms and in the data management spreadsheet. Identifiable information (i.e., full name, date of birth, site number, and contact details) from the southern Ontario sites will be kept in a locked cabinet at the University of Waterloo. Records at the Sudbury site will be stored in a password protected electronic medical record located at the City of Lakes Family Health Team. Only the principal investigator and nurses in the Sudbury location will be able to view both the participants' data and identifiers' spreadsheet. When the research trial is complete, it is a requirement of the Research Governance Framework and Sponsor Policy that the records are kept for 20 years.

Outcomes

Primary outcome: The primary research question is feasibility of implementation, defined by recruitment (number of participants recruited at the end of rollout), retention (number retained at post-rollout end), and adherence (percentage of exercise sessions completed). Our criteria for success are to recruit 10 participants at each of the four sites (40 total), retention of 90% at post-rollout end, and adherence of ≥70% (15,23).

Secondary outcomes: We will measure the following secondary outcomes: frailty indicators, quality of life and resource use, dietary protein intake, participant and provider experience, adverse events, and whether behaviour change was maintained (see Table 4 for a timeline).

Frailty indicators: Fried Frailty Index components will be used to guide selection of frailty indicators (24). We will measure change in body weight with a calibrated scale, walking speed via the 10-metre walk test (25), fatigue with the Center for Epidemiologic Studies Depression Scale-fatigue questions (26), and physical activity levels using the Physical Activity Scale (PAS) previously developed by our lab. To assess handgrip strength, we will follow the 2016 National Institute for Health Research (NIHR) Southampton protocol and use a digital Jamar Hand Dynamometer to measure isometric grip force in the non-dominant hand (27,28). To assess lower body strength and dynamic balance we will use a number of standardized tests including the 30 Second Chair Stand Test and the Four Square Step Test (29). To test leg strength and endurance, we will use the 30-second chair stand test that requires a chair with a straight back against a wall, 17 inch high, without armrests and rubber tips on the legs (30). Participants will be asked to sit in the middle of the chair, place their hands on the opposite shoulder crossed at the wrist, feet flat on the floor with a straight back (30). When the research assistant says, "go", the participant will rise to a full standing position and then sit back down again as quickly as possible for 30 seconds (30). Foot clearance is an important function in everyday life and the ability to accomplish this in different directions is essential when reacting to stimuli in the real world (i.e., navigating a busy street or walking on uneven pavement) (31). The Four Square Step Test incorporates rapid stepping whilst changing direction; a square is formed using four 90 cm long canes resting flat on the floor and the participant will step in each square as fast as possible (32). Each square is labelled 1 to 4. The participant will start in square 1 facing square 2 and then step forward into square 2, sideway to square 3, backward to square 4, sideway to square 1, sideway to square 4, forward to square 3, sideway to square 2, and backward to square 1 (32).

Quality of life and resource use: The EuroQol Group 5 Dimension 5 Level (EQ-5D 5L) questionnaire is a multi-attribute health related quality of life tool that we will use to achieve a quality-adjusted life year (QALY) estimate per intervention (33). We will use a questionnaire, developed by our team in conjunction with health economic experts from the University of Toronto, to assess healthcare resources, including direct medical (e.g., personnel, hospitalization, medications, rehabilitation, tests), direct non-medical (e.g., out of pocket expenses, transportation), and indirect resources (e.g., Productivity and Activity Index), used over the last 6 weeks. Multiplying resources collected by jurisdictional unit costs will determine the total cost per exercise program.

Dietary energy/protein intake: We will use the Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool (epi.grants.cancer.gov/asa24/) to conduct interviewer administered diet recalls for 2 weekdays and 1 weekend day. Nutrient analysis is automated and will be used to quantify and compare protein and energy intakes at baseline (week 1) and at follow-up (week 36).

Participant and provider experience and satisfaction, adaptations, fidelity: We will use a semi-structured interview guide to conduct exit interviews with each participant and the kinesiologists (see Table 2 for examples). Interviews will be audio-recorded and transcribed verbatim. One researcher will perform content analyses to describe participant and provider experience and satisfaction, adaptations, and learning needs. Analyses will be verified by another research through member checking. Kinesiologists and staff will be given a spreadsheet to record any protocol adaptations, challenges and successes to inform a future trial. We will video record sites to observe a MoveStrong session and evaluate fidelity via fidelity checklist.

Adverse Events: We will ask participants to report adverse events such as falls, fractures, muscle pain, etc., using Health Canada definitions (34). Any major adverse events (e.g., fracture, death, hospitalization event) will be reported to the principal investigator and to a Data Safety Monitoring Committee (DSMC).

Demographic information: Questionnaires will be used to collect demographic data and medical history (e.g., co-morbidities). Weight will be measured using a calibrated scale and height will be measured via stadiometer or wall mounted measuring tape.

Statistical analyses

Demographic data and outcomes will be summarized using descriptive measures such as mean and standard deviation or mean and confidence intervals for continuous variables, and count and percent for categorical variables. Recruitment, retention and adherence will be reported as a mean and standard deviation or estimates based on 95% confidence intervals (Table 3). To assess responsiveness of frailty indicators, we will calculate standardized response means, or mean change in score divided by the standard deviation of the changed scores. We will conduct exploratory analyses of secondary outcomes using linear regression, adjusted for period, time by exposure interaction and intra-cluster correlation (SASv9.2, North Carolina), and sensitivity analyses with/without caregiver or friend participation. Clusters will be analyzed according to their randomized exposure, regardless of whether exposure was achieved at the correct time. We will compare groups using per protocol analysis and exploratory intention-to-treat analysis and we will impute missing data using multiple imputation. The criterion for statistical significance will be set at alpha = 0.05. To analyse the exit interviews, we will do thematic analysis to identify positive or

negative experiences, and suggested adaptations using NVivo version 12 Pro or higher (QSR International Pty Ltd, 2019). Adverse events will be reported with descriptive statistics or estimates based on 95% confidence interval.

Sample size

Although Sim and Lewis recommend at least 50 participants (35) and Julious, 12 per group (36), we have selected a recruitment rate of 10 participants at each site because of the proposed class ratio of one instructor to five participants. Recruiting 10 participants will allow us to observe feasibility of delivery of two full workshops of five people each.

Data Safety Monitoring Committee (DSMC)

A DSMC of three arms' length members (a physician, a physical therapist and a biostatistician) will review adverse events after two clusters have completed half of the program to review adverse events and study progress. The DSMC will have unblinded access to all data, will report to the primary investigator, and will guide how we might roll participants into a larger trial. No interim analyses are planned and there are no stopping guidelines for the pilot trial.

Ethics and confidentiality

The research will be conducted according to the 2014 Tri-Council Policy Statement, (http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/default/). The study has received approval from the University of Waterloo Integrated Research Ethics Board. Any future amendments will be submitted to the ethics board by the principal investigator and updated in the registered clinical trials protocol.

DISCUSSION

There is a substantial body of evidence demonstrating that physical activity improves heart health, muscle and bone strength, and prevents falls, pain and disability among older adults. The MoveStrong trial is a pilot RCT of an exercise and nutrition intervention designed to teach functional movements and improve nutrition intake among pre-frail older adults living in the community. Given the association between frailty, functional limitations, and nursing home admissions, identifying a pragmatic model to teach functional exercises may improve the uptake of physical activity and slow the progression of frailty; however, it remains unclear how best to engage older adults in community exercise programs. To our knowledge, the MoveStrong trial is the first pilot RCT to implement an exercise and nutrition model in alignment with the Strategy for Patient Oriented Research. This is important because the design is based on patient-identified priorities, which ultimately lead to better patient outcomes. Another unique feature of our program is the selected intervention for participants is service provision. It incorporates a delivery model to translate exercise evidence that is adaptable and scalable in different community settings (e.g., family health team, retirement home, YMCA, community programs, etc) and promotes sufficiently dosed functional strength and balance training. We designed the MoveStrong program so it results in sustainable behaviour change where people are not dependent on the program in the long-term and this may be cost-effective at the healthcare level.

The HOPE trial was one of the first pilot studies evaluating the effectiveness of a home-based exercise program in the frail population (37). The authors reported only one-fifth of those approached were successfully recruited and their recruitment rates were lower than the majority of RCTs but their retention rates were high (92%) with only three of the 84 participants lost to follow-up (37). Recruiting pre-frail and frail older adults in community based intervention programs is a

complex process and older people may be suspicious of research studies because of feelings of vulnerability or prior experiences (38). However, it is important to realize that if someone made an informed decision to refuse to participate and was comfortable with that decision, this should not be considered as a lack of success (38). To improve our level of recruitment in this population, we have adapted some lessons based on prior experience from other researchers: 1) before talking to the participant, find out a little about them; 2) offer an accurate, concise explanation and overview of the MoveStrong program, and 3) provide the participant enough time to consent. In the HOPE trial, adherence was low (mean 46%), although the authors believe the home-based exercise frequency of 3 times per day for five days over the course of 12 weeks was not realistic for some older adults. For our study, we propose an exercise frequency of 2 times per week for 8 weeks, which may be more realistic for pre-frail older adults. In addition, our program provides a social network that is important for older adults. In a qualitative study of older adults with cardiac events, factors that influenced uptake of exercise and short term adherence included social support (e.g., health professionals, family, and friends), structured classes (novel exercises, specialist staff, routine, purpose), health (belief in health benefits), and high self-efficacy (39). Strategies to increase future uptake and adherence included support (a reasonable staff-to-participant ratio and group meetings/discussions) and motivation (challenge and variety, goal setting and feedback) (39). The MoveStrong program was designed to increase uptake and adherence by providing a 1:5 kinesiologist to participant ratio and by offering exercises on a continuum to maintain motivation. There is a need to continue to develop and refine strategies to increase the uptake of exercise among pre-frail and frail older adults, and, accordingly, the proposed study protocol hopes to extend the current knowledge in this area by specifically examining the feasibility of the MoveStrong model.

The MoveStrong trial has a few strengths. One, it incorporates behavior change techniques, such as a kinesiologist led exercise sessions and social engagement, to promote higher uptake and adherence. It also uses a eligibility criteria consistent with a pragmatic trial (40) such that we will include a wide range of participants to meaningfully assess the feasibility of and implementation for our trial. Lastly, the stepped wedge design provides the advantage that all participants will eventually receive the intervention making recruitment easier (41). A limitation of our pilot trial is the short follow-up period, which prevent us from examining the long-term maintenance of our program. The stepped wedge design also has a limitation; for example there is concern that an intervention implemented in all clusters has not yet been proven effective (41). However, despite this limitation we chose to use a stepped wedge design since there is mounting evidence that exercise and good nutrition can improve health outcomes in this population. It can also be argued that there are some circumstances where the stepped wedge trial is preferable to the parallel RCT (42) since the stepped wedge design is superior both scientifically and ethically as more data can be obtained and all groups can receive the intervention.

In summary, our goal is to implement and evaluate a sustainable and pragmatic model for delivering functional strength and balance training and promoting adequate protein intake among older adults. Future research can examine whether a model like this could be implemented at scale.

OTHER INFORMATION

Registration: This trial is registered in ClinicalTrials.gov Identifier NCTO20190401.

Funding: Funding for this project was provided by The Canadian Institutes of Health Research (CIHR-SPOR grant) [CIHR Funding Reference Number SCT-162968].

Appendix A

	Study start-up, training	Pre-rollout period -	Rollout, Exposure and Maintenance																	Data cleaning, analysis, dissemination
Time in weeks	*1 to 8*	*9 to 16*	*17 to 18*	*19*	*20*	*21*	*22*	*23*	*24*	*25*	*26*	*27*	*28*	*29*	*30*	*31*	*32*	*33*	*34*	*35*	*36*	*37 to 52*
Cluster 1			x						x						x						x	
Cluster 2			x						x						x						x	
Cluster 3			x						x						x						x	
Cluster 4			x						x						x						x	

Training of staff, orientation to study and materials

During the pre-rollout period, study sites will initiate advertisement and recruitment.

Roll-out period: Intervention is rolled out every three weeks

Exposure to MoveSTroNg workshop

Maintenance period: MoveSTroNg workshop is complete. Participants are encouraged to sustain behaviour change

x Repeated measurements from individuals at fixed time points, allowing assessment of period effect

Figure 1: MoveStrong study design and allocation strategy

Table 1: MoveStrong Movements with Progressions

Warm-up	Seated Version	Level 1	Level 2	Level 3
Clock Yourself – Balance challenge activity	Heel and toe taps to clock numbers	Reactive stepping to numbers	Increase speed	Add challenge e.g., step+bicep curl
Exercise: Functional movement	**Seated Version[3]**	**Level 1**	**Level 2**	**Level 3**
Jump		Heel drops, hops	Jump squat, foot stomp, low drop jump with soft landing	Progressively higher drop jumps
Step ups	Weighted[1] calf raises Weighted[1] leg extension	Low step up Weighted[1] low step up	Progressive increase in riser height or increased weight	Increase riser height and weight
Reach	Resisted[1] thoracic extension	Back to wall shoulder flexion Resisted[1] cross-body thoracic extension	Thoracic/lumbar extension (bird-dog) at wall or counter Resisted[1] overhead press	Thoracic/lumbar extension on hands/knees (bird-dog)[2] Weighted[1] overhead press
Squat	Seated press ups, use arms Resisted[1] leg press	Sit to stand (can use arms) High box[1] unassisted sit-stand Medium box[1] unassisted sit to stand	Low box[1] unassisted sit-to-stand Half squat Body weight squat	Weighted[1] squat, sit to stand or half squat Split squat or one-leg squat
Pull	Resisted seated row	Standing resisted row Resisted pull apart	Resisted pull down or pull apart Increase resistance, bent over row	1-arm resisted/weighted pull down or row TRX row Chin-up
Hinge	Hip hinge, perched posture with pressure through feet	Supine glute bridge[2] Standing Wall tap hip hinge	Single leg supine glute bridge[2] Standing resistance band hip hinge[1]	Weighted hip hinge[1] Romanian hip hinge (1 leg, or modified golfer's reach)
Push	Resisted[1] Chest Press	Wall push up or plank to push up Standing resisted chest press	Counter/table push up	Floor push up or plank to push up
Stand tall, carry your stuff	Seated back extension with tall posture	2x10m weighted[1] carry, "Farmer's walk"	Increase distance up to 20m	Complete 4 x 20m Increase weight
Cool-down	**Seated Version**	**Level 1**	**Level 2**	**Level 3**

[1]Resisted movements use elastic tubing or bands. Weighted movements use household objects, held close to body e.g., water bottles, 4L jugs of water, weighted grocery bags. Ankle/wrist weights can be used if needed e.g., paralysis in one hand/arm. Form and alignment are prioritized over intensity. Participants with access to exercise equipment can choose to learn how to practice with that instead e.g., kettle bell. We will purchase boxes of different heights, fitness steps and risers, kettle bells and weighted bars for sites to use with participants that progress to weighted exercises. [2]We will also include forward and backwards chaining of getting on and off floor if that is participant's goal, with or without chair or support object.

Table 2: Interview guide to conduct exit interviews with each participant and the exercise professional.

Predetermined Questions	
Questions for the participant:	**Questions for the kinesiologist:**
Why did you decide to join this study?	Tell me about your experience delivering the MoveStrong program?
What, if any, benefit are you getting/did you get out of your involvement in the study?	What did you like about the manual? What did you dislike about it?
What did you like about the exercise program?	Which exercises did you find more challenging to teach?
What did you like about the nutrition sessions?	How would you feel about delivering the MoveStrong program in future? What might need to change?
Related to your participation in the exercise program, what could we have done better?	How is this program different from your current practice?
What overall changes would you recommend to improve this program?	Can you list certain exercises that participants enjoyed more than other exercises?
	What did you dislike about the exercise program?

Table 3: Variables, hypotheses, outcomes and methods of analysis

[1] where relevant, adjusted for period, time by exposure interaction & intra-cluster correlation. [2] Sensitivity analyses: with/without caregiver/friend.

Variable	Hypothesis	Outcome Measures	Methods of Analysis
Primary			
Recruitment	We will recruit 40 individuals, 10 per site	Number recruited at each site	Descriptive statistics or estimates based on 95% confidence intervals
Retention	We will retain 90% of our sample.	Number of participants that we can gather data from at study end	
Adherence	The average proportion of exercise sessions completed will be ≥70%.	Average proportion of completed exercise sessions	
Secondary			
Frailty indicators	Body weight, walking speed, chair stand performance and Four Square Step Test will be responsive to the intervention. Exposure will result in: • maintained or increased body weight; • faster walking speed • less fatigue • improved chair stand, Four Square Step test and grip strength • increased physical activity level	• body weight in pounds • 10-metre walk test (seconds • Center for Epidemiologic Studies Depression Scale-fatigue questions • Stair Climb Test (seconds) • 30 Second Chair Stand (# of stands) • Four Square Step Test (seconds) • hand dynamometer (lbs) • Physical Activity Scale for the Elderly score (0-793)	*Responsiveness:* standardized response means, or mean change divided by the standard deviation of the changed scores. *Exploratory intention to treat (ITT) and per protocol (PP) analyses:* linear regression[1,2]
Quality of Life	Exposure will increase Quality Adjusted Life Years (QALYs)	EQ5D5L – QALY	*Exploratory ITT and PP analyses:* linear regression[1,2]
Cost per life-year gained	No hypothesis at this time	Questionnaires to assess resource use, documentation of costs of intervention	*Exploratory ITT and PP analyses:* Ratio of incremental costs of intervention & QALY[1,2]
Protein and energy intake	Exposure will result in an increase in protein intake	Nutrient analyses to estimate grams of protein and kilocalories, based on 3-day 24-hour recall at baseline and final visit only	*Exploratory ITT and PP analyses:* linear regression[1,2]
Participant, provider experiences	Themes indicate positive experience, and identify needed adaptations	Exit interviews	Thematic analyses
Harms	No serious adverse events due to intervention	Self-report of harms	Descriptive statistics or estimates based on 95% confidence interval

ITT = intention-to-treat analysis. Based on the initial treatment assignment and not on the treatment eventually received; PP = Per Protocol Analysis. Comparison of treatment groups that includes only those participants who completed the treatment originally allocated.

Participant Timeline

Table 4: Time schedule of enrolment, interventions, assessments, and visits for participants.

Activity	Staff Members	T-1 (Screening/Consent)	T0 (Study visit 1)	T1	T2	T3 (Study visit 2)	T3	T4 (Study visit 3)	T5 (Study visit 4)
Recruitment and Screening									
In-clinic screening and referral	Physician/delegate	X							
Inclusion/exclusion form	Outcome assessor blinded	X							
Informed consent, contacts	Outcome assessor blinded	X							
Refusal questionnaire	Outcome assessor blinded	X							
Assessments									
FRAIL Scale	Outcome assessor blinded	X							X
Demographic questionnaire	Outcome assessor blinded		X						
Physical Activity Scale	Outcome assessor blinded		X			X		X	X
Verification of chronic disease(s)	Outcome assessor blinded		X						
Verification of frailty	Outcome assessor blinded		X						
Medical history and Mini-Cog	Outcome assessor blinded		X						
Medication review	Outcome assessor blinded		X			X		X	X
EQ5D5L	Outcome assessor blinded		X			X		X	X
Body weight	Outcome assessor blinded		X			X		X	X

10 Meter Walk Test	Outcome assessor blinded		X			X		X	X
Stair Climb Test	Outcome assessor blinded		X			X		X	X
30-Second Chair Stand Test	Outcome assessor blinded		X			X		X	X
4 Square Step Test	Outcome assessor blinded		X			X		X	X
Grip Strength	Outcome assessor blinded		X			X		X	X
Center for Epidemiologic Studies Depression Scale-fatigue Questions	Outcome assessor blinded		X			X		X	X
Resource Use	Outcome assessor blinded		X			X		X	X
Automated Self-Administered 24-Hour Dietary Assessment Tool	Outcome assessor blinded		X			X		X	X
Adverse Events Protocol	Kinesiologist		X			X		X	X
Exit Interview	Outcome assessor unblinded								X

Appendix B

Participant Information Sheet and Consent Form

Title of Project: MoveStrong: A Model for delivering Strength Training and Nutrition education for older adults

Primary Investigator: Dr. Lora Giangregorio
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Co-investigators: Professor Heather Keller, Dr. Angela Cheung, Dr. Wanrudee Isaranuwatchai, Dr. Maureen C. Ashe, Dr. Alexandra Papaioannou, Dr. Marina Mourtzakis, Dr. Lehana Thabane, and Dr. Sharon Straus, Dr. Jamie Milligan, Mr. Larry Funnell, Ms. Sheila Brien, Dr. Zachary Weston
Students or Trainees: Isabel Rodrigues, Justin Wagler
Sponsors: Canadian Institutes of Health Research

Your primary contact:
Day Emergency Contact: ***(insert research assistant name and contact information for each site)***

Introduction

You are being invited to participate in a research study. We have outlined the study here, and will discuss it with you. Please read this information carefully. Ask questions about anything that you want to know more about.

Why is this research being done?

Staying active and eating well can improve overall health and many people would benefit from learning how to exercise properly and eat healthy as they get older. This study will test a new method to teach functional strength and balance exercises and encourage good nutrition among older adults with chronic diseases.

What is the purpose of the study?

Our team wants to investigate a new exercise and nutritional education program to see if it is a realistic way to deliver education on exercise and nutrition in the community. In order to do this, we need to do a small study first to see if it is possible to achieve this goal. The current study will recruit 40 individuals from across Ontario. The current study will be the first step to

evaluating whether it is possible to deliver an education program like MoveStrong in the community.

What will your responsibilities be if you decide to take part in the study?

You will be asked to participate in one visit to *(insert site here)* at the beginning of the study, and three additional visits during and at the end of the program. The study visit will take approximately two hours, and will include the assessments listed below. If you cannot complete an assessment, or do not wish to, you can still remain in the study. The only assessments that are mandatory are the assessments at the start to confirm that you are eligible to participate. We may also ask you to describe the study back to us in your own words so we can be sure you understand what we are asking you to do.

Study assessments:

1. A physical assessment that includes assessing your height, weight, and walking speed over 10 meters. Balance and mobility tests include your ability to get up from a chair and sit back down for 30 seconds, and your ability to step over low objects while moving forward, backward, and sideway. We will also provide you with a number of questionnaires to assess your mood, quality of life, and diet.
2. We will ask questions about your health and medical history, your perceived quality of life, the health services you use, your physical activity levels and your diet. We will also ask about illness or injuries that happen during the study. We may complete some of these over the phone.

Other assessments:

1. A phone number will be provided so that you can report any falls, injuries or health problems. We will ask you to sign a form so that we can retrieve health records related to any injuries or illnesses you have.

There are four locations taking part in this study. Each location will be randomly assigned a start date to the program. So, some people will start the program right away while others will start 3, 6, or 9 weeks later. You will have a 1-on-1 session with a kinesiologist to determine which exercises are best for you. Then you will attend two group exercise sessions per week for 8 weeks. Each session will have 3-6 participants. A kinesiologist will supervise the sessions. At the end of each sessions, there is a group discussion about how to perform exercise at home. If you have a friend or caregiver who is eligible to participate, or who would like to support you with your exercise, you are welcome to bring them. You will also attend two nutrition education seminars led by a dietitian. You will receive a booklet about nutrition and some snacks.

What are the possible benefits of the study for me and/or society?

We will provide you with the results of your assessments at the end of the study, so that you can see how you did. You will be allowed to keep all of the exercise and nutrition materials and you

will receive an exercise program from the kinesiologist. You will exercise in small groups where you will meet other participants.

What are the possible risks and discomforts?

There is a potential for exercise-related changes to occur during the assessments or exercise, such as muscle soreness and changes in blood pressure and heart rate. Any physical exercise or performance-based test is associated with a risk of falls or cardiovascular complications. We aim to minimize the risks by having the exercise prescription done by a certified kinesiologist, and by having training for all our staff.

What information will be kept private and confidential?

Your data will not be shared with anyone except with your consent or as required by law. All personal information will be removed from the data and will be replaced with an ID code. Your information will be stored at the study site in a locked cabinet. Any data that is stored in the computer will be encrypted and password protect. Paper and electronic records will be retained for 7 years after the study is complete, and study data will be retained for 20 years. All anonymized forms and study data will be stored in a locked office. Only the research team will have access to the data. Some of the data may be examined by students doing thesis projects or research internships, but your name or other identifying information will not appear with the data. Data will be secured in accordance with UW policies available at http://ist.uwaterloo.ca/security/policy/.

Information about you will be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the University of Waterloo or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published or presented in a variety of forums. The results will be presented in such a way that you cannot be identified, except with your permission. You may be asked if you would like to have your photo taken during study activities for use in oral presentations, training information or publications. This is voluntary and not a requirement of the study. If you are to be photographed you will be asked to sign a separate consent form.

Information about your participation in this research project may be recorded in your health records.

Can I end my participation early?

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you volunteer to be in this study, you may withdraw at any time. If you withdraw, you will be asked if there are some parts of the study you are still willing to complete (e.g., phone assessments only). You can opt out of only some parts of the study, or withdraw altogether. We will not withdraw previously collected data unless you request that we do. If you decide to withdraw from the project, please notify a member of the research team.

Will I be paid to participate in the study?

You will not be paid to participate in the study. We will reimburse parking or bus transportation costs for travel to study visits. If you lose your receipt you will be reimbursed for parking or bus based on the time you spent at the clinic visit. If you do not have access to transportation, we will pay for a taxi within a reasonable distance from our centre.

What happens if I have a research-related injury?

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you **do not** give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

If you have any urgent medical problem, injury or illness that is related to your participation in this study or have any questions, concerns or would like to speak to the study team for any reason please call:

This project has been reviewed by, and received ethics clearance through, the Office of Research Ethics at the University of Waterloo. If you have any comments or concerns resulting from your participation in this study, contact **Dr. Vanessa Buote at the Office of Research Ethics at 519-888-4567 ext. 30321 or by email at vbuote@uwaterloo.ca**

Consent of Participant

I have read the information presented in the information letter about a study, a model for delivering strength training and nutrition education for older adults (MoveStrong), being conducted by Dr. Giangregorio and colleagues or I have had it read to me in a language that I understand. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I requested. I understand the purposes, procedures and risks of the research described in the project.

I am aware that I may withdraw from the study without penalty at any time by advising the researchers of this decision. With full knowledge of all foregoing, I agree, of my own free will to participate in this study. I have been advised that I will receive a signed copy of this form

Consent Statement

Name of Participant

_____

Signature of Participant Date

_____ _____

Person obtaining consent:

I have discussed this study in detail with the participant. I believe the participant understands what is involved in this study.

_____

Name, Role in Study Signature Date

Name of Translator, if applicable *Language translated into*

_____ _____

Signature of Translator *Date*

_____ _____

NOTE: This page should be given to the participant to keep

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