**MoveStrong at Home:**
A feasibility study of a model for remote delivery of functional strength and balance training combined with nutrition education for older pre-frail and frail adults.

Registration: NCT04663685

Date: February 8th, 2023

## Protocol

The protocol was drafted in accordance with the CONSORT Statement for pilot studies [1] and the TIDieR checklist [2] and registered with ClinicalTrials.gov (NCT04663685). The study (ID: #42206) was reviewed and approved by the Office of Research Ethics at the University of Waterloo, Waterloo, ON.

### Intervention Development and Research Design

MoveStrong was originally designed to provide a framework for exercise professionals to tailor fundamental strength exercises for older adults of varying abilities using minimal equipment. The functional movements were informed by the GLA:D program for arthritis [3], BoneFit™ [4], and meta-analyses on resistance exercise and fall prevention [5]. Difficulty was meant to be progressed over time and ranged from simple seated exercises to compound movements with free weights. The nutrition component was developed following recommendations from the PROT-AGE group of 1.0-1.2g protein/kg of body weight/day for older adults, and more for active individuals or those living with acute or chronic illness [6]. Achieving target levels of dietary protein was supported with a 30-page booklet, which included information, tips, and recipes.

This project was built upon the MoveStrong pilot that was first delivered in person across five different sites in Ontario from March 2019 to March 2020 [7]. The original in-person study included twice-weekly exercise sessions and two nutrition sessions over an 8-week period. The small group classes (4-5 participants) were delivered by a registered kinesiologists or exercise physiologists, and registered dietitians in community centres and retirement homes. When the COVID-19 pandemic brought on a nation-wide lockdown, the protocol was adapted for remote implementation by engaging patient partners and key stakeholders. During the first wave of the pandemic, we identified team members including researchers and health care providers with

clinical expertise working with individuals living with frailty. Patient partners from Osteoporosis Canada and representatives from community organizations were contacted. By consulting diverse stakeholders, we were better able to understand issues and considerations for adapting MoveStrong to a virtual platform, identify priorities for the intervention, and come up with realistic solutions. A joint decision-making process was used during two hour-long meetings to modify the program.

**Sample Size**

We selected a recruitment goal of ≥25 people over 12 weeks as a pragmatic sample size to understand feasibility of intervention delivery and participant experience [30]. No formal sample size calculation was made as our aim was to assess the feasibility of the intervention, and not the effectiveness of the protocol.

**Recruitment**

A convenience sample was recruited from email contact lists of individuals who previously agreed to be notified of research opportunities. In addition, we asked colleagues and collaborators (Research Institute for Aging, Centre for Community Clinical and Applied Research Excellence, Osteoporosis Canada, Community Support Connections, YMCA) to forward the link to potential participants on their distribution lists. Research support staff and kinesiologists at three local retirement homes recruited participants using flyers and word of mouth. Primary care professionals were provided with electronic flyers and posters to use in their practice. Lastly, Twitter (Twitter Inc. 2020) and Facebook (Facebook Inc. 2020) were used to share the recruitment post with relevant professional groups and local neighborhood associations (e.g., Connected Kinesiologists, Eastbridge Neighborhood Association).

**Eligibility Criteria**

We recruited English speaking Ontario residents, ≥ 60 years of age, with ≥1 self-report chronic condition (e.g., diabetes, obesity, cancer, chronic lung disease, cardiovascular disease, hypertension, osteoporosis, arthritis, stroke), and ≥1 FRAIL scale score (fatigue, resistance, ambulation, illnesses, and loss of weight) [8]. For the purpose of telephone screening, the FRAIL Scale questionnaire was used as a time efficient tool. Individuals were ineligible if they were completing similar progressive strength training exercises ≥2x/week (or had completed similar training within <6 months of recruitment); were receiving palliative care; could not perform basic activities of daily living; had moderate to severe cognitive impairment (e.g., unable to follow two-step commands); planned to travel >1 week; or met any ACSM absolute exercise contraindications [8].

Upon screening, the consent form was mailed or emailed to all eligible individuals. The research assistant reviewed the form by telephone a week after the initial screening call or upon arrival of the documents by mail. Informed consent was obtained verbally and documented using a standardized form.

**Intervention Description**

**Overview**

MoveStrong at Home was delivered as an 8-week home-based exercise and nutrition program with a 4-week follow-up. The intervention and all data collection were implemented remotely via telephone and virtually to community-dwelling older adults in their homes, or to older adults living independently in a retirement home setting. We used the Knowledge-to-Action (KTA) framework to guide implementation [9] and addressed known barriers to participation using 28 Behaviour Change Techniques [10] that targeted 6 Intervention Functions [11].

Upon enrollment, program instructions, a nutrition education booklet, and an exercise band were mailed to participants. A research assistant delivered a 60-minute technology session to each participant to help familiarize them with the Physitrack/Physiapp® (Physitrack PLC. 2021), and Microsoft Teams® (Microsoft Corporation. 2021) platforms. The exercise physiologist was given an instructor manual that provided guidance on chronic conditions, common movement impairments, safety reminders, cueing tips, and procedures for reporting adverse events. The exercise physiologist then delivered 11 one-on-one sessions to each participant. A registered dietitian completed an orientation session on the protein focus of the intervention and was provided with the MoveStrong nutrition education booklet and access to five online videos. The dietitian led three group nutrition sessions with the purpose of addressing participants questions on how to increase protein content in their diet.

**Meet & Greet**

Before starting the intervention, participants received a 60-minute consultation with the exercise physiologist to review program instructions. Together, the exercise physiologist and the participant decided when they would meet weekly for their one-on-one sessions. Participants were encouraged to dedicate space in their home and leave their materials and equipment in the designated location.

**One-on-one Exercise Training**

Using what they gathered from the Meet & Greet session and baseline measures, the exercise physiologist created an individualized program for each participant on Physitrack® or mailed a printed copy to their home. Physitrack® is a commercially available platform which the exercise physiologist used to prescribe exercises, monitor adherence, and respond to incoming

messages. An add-on subscription provided teleconferencing minutes on a secure and user-friendly interface. Each individualized training program included at least 7 functional movements and alternated between upper and lower body to enhance recovery – Balance, Pull, Squat, Push, Hinge, Lift & Carry and Calf Raise. Participants were asked to perform 8-10 repetitions of each functional movement with time under tension per repetition of 4:0:2 seconds for eccentric:isometric:concentric phases. Exercise variation, resistance, or volume (up to 3 sets) were progressed over time. Participants were able to access their program through the participant portal – Physiapp®, where they reported adherence (i.e., reps, sets, RPE) and provided feedback (e.g., pain).

In addition to the Meet & Greet session, the exercise physiologist met each participant twice during weeks 1-2, and then once from weeks 3-8 (11 sessions total). At the start of every one-on-one session, the exercise physiologist inquired about changes to health status. The exercise physiologist then confirmed weekly exercise adherence (as reported on Physiapp®) and reminded participants to remove tripping hazards and ensure a support object was nearby. Warm up consisted of 2-4 dynamic range of motion movements that target major muscle groups and joints in the body. The exercise physiologist led participants through 1-2 static and dynamic balance exercises that reduced base of support, shifted focus, or required multitasking. Then the exercise physiologist demonstrated functional movements, discussed the importance of each exercise and what muscles it engaged. Cool down consisted of 3-4 static stretches that were held for 30-60 seconds on each side and repeated.

**Group Nutrition Question & Answer Sessions**

Participants received a nutrition booklet that included detailed guidance, useful tips, and high protein recipes. Five educational videos were available on a private YouTube® channel (Google

LLC. 2021) to help reinforce key topics (Reading nutrition labels, Plant-based proteins vs. animal proteins, Protein foods, Ways to incorporate protein into your meals and snacks, Spreading protein throughout the day). In addition, individuals participated in three 60-minute dietitian-led nutrition discussion sessions over Microsoft Teams® on weeks 2, 4, and 6. The purpose was to review content from the booklet and videos and discuss more personalized strategies to increase protein intake.

**Group Discussion Sessions**

Optional group discussion sessions were delivered over Microsoft Teams® by a research assistant, and took place on weeks 3, 5 and 7. The intention was to foster a sense of community, consider strategies to support adherence to the intervention, and introduce behavior change techniques. A PowerPoint presentation was used to present key concepts, share motivational quotes, and pose discussion questions during the 60-minute sessions. Individuals took turns sharing their experiences and responding to one another.

**Outcomes (Primary, Secondary, Process, Qualitative Interviews)**

The primary outcomes were feasibility of community and network recruitment, retention at follow-up, and adherence to the exercise and nutrition components. During supervised sessions, adherence was assessed by an exercise physiologist or research assistant. For independent exercise sessions, adherence was self-reported through Physiapp® or recorded using the sheets provided.

Secondary outcomes were measured by telephone, an online survey platform (Qualtrics®) or virtually over Microsoft Teams® at three time points – baseline, program end and at follow-up (4 weeks after program cessation). Questionnaire responses were stored in the Qualtrics® data

centre (SAP. 2020) and Food Recall entries were stored on the ASA24 database (National Cancer Institute. 2018).

**Analysis**

Primary outcomes of recruitment, retention, and adherence were reported using descriptive statistics and compared to *a priori* criteria to determine feasibility. Baseline sociodemographic and health information was reported using descriptive statistics including mean (95% CI) for continuous or frequency (%) for categorical variables. Secondary outcome data was cleaned, organized, and inputted into SPSS 27 (IBM Corp. 2020). We conducted exploratory analyses of baseline to end of study and baseline to follow-up differences using paired (dependant) samples t-tests. We used complete case analyses. We presented effect estimates as mean differences (95% CI). We reported adverse events at a patient level (# of events, # of people who had events) and process outcomes via count (#) and percent (%).

We transcribed interviews verbatim and analyzed them using NVivo version 12 Pro (QSR International Pty Ltd. 2020). We followed an inductive qualitative description approach to code perceived benefits and suggestions for future studies [12]. The inductive process began with open coding where units of meaning were organized into fluid code categories. We used nine transcripts to create a basic framework which was then applied to the remaining transcripts (EW). The codes were analyzed and reviewed by two research assistants and discrepancies were settled through discussion (EW & AS). In conjunction, we used content analysis to identify facilitators of and barriers to behaviour maintenance which were mapped to Transtheoretical Domains Framework (TDF) [13,14]. The deductive process involved identifying and grouping related codes (facilitators and barriers) together into appropriate sub-categories to condense

text while staying close to the data (EW). Finally, the sub-categories (constructs) were mapped to 11 domains of the TDF (EW).

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**Appendix 1: Participant Information Sheet and Consent Form**

**Title of Project:** *MoveStrong at Home*

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**Students or Trainees**: *Ellen Wang*
**Sponsors:** *Network for Aging Research*

**Introduction**

You are being invited to participate in our research study. This letter will explain what the study is about, the possible risks and benefits, and your rights as a research participant. If there is something in this letter that you do not understand, please ask one of the study staff. Please feel free to discuss this with your family, friends, or family physician before you decide to participate.

Your participation is voluntary. It is up to you to decide whether or not you wish to take part. If you decide to participate, you are still free to withdraw at any time and without giving any reasons for your decision. Your decision to participate or not will not affect your relationship with the study staff or the university.

**Who is conducting this study?**

This study is being conducted by researchers at the University of Waterloo. The study is sponsored by the Network for Aging Research.

**Why is this research being done?**

We lose muscle mass and strength as we age. Exercise can help maintain muscle and improve balance, especially in pre-frail and frail individuals. Eating the right kinds of foods to support muscle is also important. However, getting enough physical activity and protein can be a challenge, especially with mandated social distancing practices. Alternate ways to promote safe exercise and proper nutrition are more needed than ever before.

**What is the purpose of the study?**

We want to evaluate if it is possible to deliver exercise and nutrition education over the phone or computer. In addition, we wish to understand barriers, facilitators, and participant experiences with remote delivery. We also

want to see if there are changes in your mobility, physical activity levels, diet, mental health, and quality of life after participation in the program.

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

The study takes place over 12 weeks (about 3 months). You do not need to leave your house to participate in the study. You can choose to communicate with us via telephone, or online using your computer, or a little of both – it is up to you.

We will complete each of the following assessments of your health, physical activity, physical function and nutrition over the phone or computer at the beginning of the study, after the 8-week intervention, and one month later (12-weeks). These assessments will allow you and the research team to monitor changes in physical function, nutrition and well-being that result from this education program.

- We will call you to complete questionnaires physical activity beliefs and participation, dietary habits, fatigue, mental health, and quality of life (60 minutes). You can choose to complete the questionnaires and physical function assessments on your own and mail them in.

- We will call or video call you to assess your physical function. We will assess whether you can maintain balance in different standing positions and how many times you can get in and out of a chair in 30 seconds (~15-30 minutes).

-

  **An undergraduate student will be present during your baseline assessments to observe the physical function assessments. They will ask you to share your expectations, difficulties you faced and suggestions to improve the balance and chair stand tests using a brief online survey using Microsoft Forms. We ask your permission to record the physical function assessment (at baseline) as a video or voice recordings over Microsoft Teams so we may evaluate and improve the process.*

- We will call you over 3 days to ask you about the foods and drink you have consumed (~30-45 minutes each)

You will be asked to participate in web conference or telephone sessions to learn about exercise and nutrition. The exercise sessions will be led by an exercise physiologist, who will tailor exercises to your needs and answer any questions you may have. In addition, they will inquire about illnesses or injuries at the beginning of every session, monitor your progress throughout, and remind you to practice on your own at the end of every session. The private exercise sessions will happen twice a week on non-consecutive days to start, with each session lasting 30 minutes. As you progress, you will be encouraged to complete more exercise independently outside of the structured session. Every participant will be continuing to receive one private session per week after the first two weeks of the intervention. If attending by phone, there is an option to continue with a second private session. You will also receive nutrition and exercise education materials in the mail. At weeks 2, 4, and 6 of the study, you will be invited to attend a virtual group seminar led by a dietitian to learn about nutrition and protein intake. At weeks 3, 5, and 7 of the study, you will be invited to attend an optional group session to discuss and practice behavior change strategies to help you sustain your new exercise and nutrition habits.

Before the start of study, you will complete demographic information and various questionnaires online using Qualtrics. A link to their privacy policy can be found here: https://www.qualtrics.com/privacy-statement/. You may also to choose to complete them over the phone or by mail. Then, we will schedule a 30-minute

technology consultation to teach you how to attend private training sessions by web conference and telephone using Physitrack, a telehealth system that offers secure communication between participants and exercise leaders. Physitrack abides by the safety and access standards set forth by the Information and Privacy Commissioner of Ontario. All data is stored in the Canadian databases on Amazon Web Services in Montreal. A link to their privacy policy is available here: https://www.physitrack.com/privacy. Microsoft Teams, an externally hosted cloud-based service, will be used to deliver all group trainings sessions including nutrition seminars and virtual support groups. The Canadian Data Centre for Microsoft Teams is located in Quebec City and Toronto. A link to their privacy policy is available here: https://www.microsoft.com/en-ca/trust-center/privacy?rtc=1 . In the case that participants are unable to use Physitrack® due to incompatibilities with their electronic device, Cisco WebEx® will be used instead [https://trustportal.cisco.com/c/dam/r/ctp/docs/privacydatasheet/collaboration/cisco-webex-meetings-privacy-data-sheet.pdf].

At the end of the study and at follow-up, we will invite you to share your experience during a 30-minute interview. We would like to audio record the interviews using Microsoft Teams so we can revisit your responses and transcribe them for analysis.

**Who may participate in the study?**

Our study will recruit 25 older adults in Ontario. You are **eligible to participate if you** are aged 60 or over; speak English; receive a score of 1 or greater on our FRAIL Scale (chronic fatigue, difficulty walking 100 yards, difficulty with stairs, >5 chronic conditions, weight loss >10lbs within the last year); and have 1 or more diagnosed conditions (e.g., diabetes, cancer, heart failure, arthritis).

**Who is not be eligible?**

You are **not eligible to participate if you** are doing similar exercises 2 or more times per week; cannot do basic activities of daily living or follow 2-step commands; are receiving palliative care; or have contraindications to exercise. If you have health conditions that may get worse if you participate in exercise, or if you think your physician may have concerns about your participation, we may need to consult your physician prior to including you in the study.

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

You will receive advice and materials on nutrition and exercise. The exercise and nutrition materials are yours to keep. We will provide you with the results of your assessments at the end of the study, so you can see how you did. Our study will help society in that we will learn about how to deliver exercise and nutrition remotely.

**What are the possible risks and discomforts?**

There is a potential for exercise-related changes to occur during the assessments or exercise sessions, such as muscle soreness and changes in blood pressure or heart rate. Any physical exertion, including performance-based tests, are associated with a risk of falls, injuries, or cardiovascular complications. It is possible for you to sustain a fracture or injury during physical activity. We aim to minimize the risks by training our staff and having the exercises selected by an exercise physiologist. You may choose not to perform an exercise or request a modified version at any time.

**What information will be kept private and confidential?**

Some of the exercise or nutrition sessions may take place in a live, virtual group setting on Microsoft Teams, to promote interaction and learning from each other. Other participants in the study may be able to see your name or your face on screen or hear you during the session. We ask that you keep other's identities or things we discuss in the sessions private. We cannot guarantee the confidentiality of anything you say during group sessions, so please do not say anything that you would not feel comfortable saying in public. You may choose not to participate in the group sessions.

Your data will not be shared with anyone except with your consent or as required by law. All personal information will be removed from your data and will be replaced with an ID code. Data stored this way is referred to as "de-identified data". Paper and electronic records will be retained for 7 years after the study is complete. All de-identified forms and study data will be stored in a locked cabinet in our private office or on a secure network drive. All data collection files will be password-protected. Only approved members of the research team will have access to the lab, network drives, and further, the passwords for encrypted documents.

Voice, video recordings & survey responses will be immediately moved to a password protected folder on the University of Waterloo network drive and deleted from the Microsoft server. While this service is approved for collecting data by the University of Waterloo Research Ethics Board, there is a small risk for the data collected on external servers to fall outside the control of the research team. Likewise, when information is transmitted over the internet, privacy cannot be guaranteed. There is always a risk your responses may be intercepted by a third party (e.g., government agencies, hackers). University of Waterloo researchers will not collect or use internet protocol (IP) addresses or other information which could link your participation to your computer or electronic device without first informing you.

We may use the data to answer research questions other than those described here. 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. By consenting to participate in this study, you are providing permission for future use of your data.

**Can I end my participation early?**

Participation in this research is voluntary. If you do not wish to take part, you don't have to. If you volunteer to be in this study, you may withdraw at any time by notifying a member of the research team. 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 so, or if the results have already been analyzed or published. We will not withdraw any safety data.

If you are withdrawing for personal or health-related reasons and we cannot confirm your direct consent (e.g., a family/friend informs us they are withdrawing) we will not contact you further, but we will include de-identified data collected to that point.

**Will I be paid to participate in the study?**

You will not be paid to participate in this study.

**Will the study cost me?**

You will not be charged for any activities in the study.

**What happens after completion of the study?**

We will inform you of your individual results and the overall study results after we have analyzed all data. This will be in the form of a letter to you.

**What happens if I have a research-related injury?**

If you sign this consent form, it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigators, institutions and/or sponsors from their legal and professional responsibilities. If you are found to be harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

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:

Anytime number for general question, to report concerns or injuries, or to make changes/cancellations to scheduled meetings: 519-904-0660 ***extension 5021.***
For all other questions contact Lora Giangregorio at phone 519-888-4567 ***extension 46357.***

**Consent of Participant**

- I have read the information presented in the information letter about the study, *MoveStrong at Home,* being conducted by Lora 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.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#42206). If you have questions for the committee, contact the Chief Ethics Officer, Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca. For all other questions, contact Lora Giangregorio at phone 519-888-4567 extension 46357.

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.

On _____, _____ gave verbal consent to participate.
Date Name of participant

The person stated above has provided verbal consent to have their interviews audio recorded.
☐YES ☐NO

The person stated above has provided verbal consent to have their physical function assessment video recorded. ☐YES ☐NO

The person stated above has provided verbal consent to the use of anonymous quotations in any thesis or research paper related to this research project. ☐YES ☐NO

The person stated above has provided verbal consent to the use of their data in future research. ☐YES ☐NO

**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 |

**Informed Consent Checklist**

# INFORMED CONSENT CHECKLIST

Name of Trial: MoveStrong at Home  Participant ID: _____

## SCREENING & RECRUITMENT

Date of Screening & Recruitment interview: _____
dd-mmm-yyyy

Was VERBAL consent received to conduct the Screening & Recruitment interview? ☐ Yes ☐ No

Completed by Research Team Member: _____

## INFORMED CONSENT

When was the consent form first given to the participant?

Date: _____ Time: _____
dd-mmm-yyyy

When was VERBAL consent given by the participant?

Date: _____ Time: _____
dd-mmm-yyyy

Please initial next to each row to verify that the consent interview addressed the following aspects of the trial:

| | |
|---|---|
| The purpose of the trial was explained to the participant | |
| The procedures of the trial were explained to the participant | |
| The possible risks and benefits of participation were explained to the participant | |
| The scope of privacy and confidentiality was explained to the participant | |
| The voluntary nature of the trial and its components were explained to the participant | |

## QUESTIONS (list all questions asked, and the responses given)

## COMMENTS

Signature of Research Team Member: _____  Date: _____
dd-mmm-yyyy

**Confidence to Explain Research Study (Capacity to Consent)**

**Questions to ask potential participants who are suspected to be cognitively impaired:**
*"I want to make sure that you understand what the study is about. Would you mind describing in your own words what we are asking you to do as part of the study?"* (The potential participant should be able to recite relevant details regarding the study)

Prompts**:**

- What are we asking you to participate in?
- What does the study involve?
- How long is the study?

Participant answers must include:

- ☐ An exercise and nutrition education program, delivered by phone or video conference
- ☐ A variety of questionnaires and assessments
- ☐ 8 weeks in length or a total time commitment of 12 weeks

_____ Participant answers include all relevant details; they are **eligible** to participate

_____ Participant answers lack relevant details; they are **ineligible** to participate

☐ Complete the Ineligibility Script

**Reason for ineligibility:** Inability to explain research study (lack capacity to consent)
**Explanation:** For the safety and well-being of participants, MoveStrong at Home requires that individuals have the ability to listen, reflect and execute complex commands that involve coordinating the entire body.