

MoveSTroNg at Home:

MoveSTroNg at Home: A Model for Remote Delivery of Functional Strength and Balance
Training with Nutrition Education for Older Frail Adults in Ontario. A Feasibility Study

by

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AUTHOR'S DECLARATION

I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

I understand that my thesis may be made electronically available to the public.

Abstract

Background: The Coronavirus disease (COVID-19), caused by SARS-CoV-2 exacerbated the potential for physical inactivity¹, nutritional risk², and loneliness³ among older adults, especially in those with pre-existing health or mobility impairments. There is high quality evidence to suggest that functional training and balance exercises can prevent falls, improve functional capacity and increase levels of physical activity in vulnerable populations^{4,5}. Now and in the future, we need alternate ways to promote safe movement and proper nutrition that does not require participants to leave their homes.

Objectives: The primary aim was to assess the feasibility of an 8-week remotely delivered exercise and nutrition education program. The primary outcomes (and criteria for success) were recruitment (≥ 25 participants/12 weeks), retention (80% at follow-up), adherence ($\geq 70\%$ exercise & nutrition Q&A sessions).

Design: An 8-week feasibility study with 4-week follow-up (time series design).

Participants: Pre-frail and frail community-dwelling Ontario residents, ≥ 60 years of age, living with ≥ 1 diagnosed chronic condition; score of ≥ 1 on the FRAIL Scale.

Methods: MoveStrong was delivered to participants in their homes, using mailed program instructions and private training sessions through Physitrack®. Online nutrition Q&As and group sessions were hosted over Microsoft Teams®. Telephone was used for participants without internet access. Recruitment was determined by the number of participants who started the intervention. Retention was determined by the number of participants who completed the follow-up assessment. Adherence was calculated from a total of 36 exercise sessions (three per week for 12 weeks) and three nutrition Q&A sessions throughout the intervention. Secondary outcomes including the Physical Activity Screen (PAS), Modified Exercise Self-Efficacy Scale (ESES), Center for Epidemiology Studies Depression Scale (CES-D), Warwick-Edinburgh Mental Well-being Scale (WEMWBS), EuroQol 5 Dimensions 5 Levels (EQ5D5L), and Seniors in the Community Risk Evaluation for Eating and Nutrition (SCREEN©) were assessed by online questionnaire at program end and 4 weeks later to measure short-term sustainability. Physical function was assessed using adapted and self-administered versions of the SPPB 3-point balance test and 30s chair stand test. Adverse events and process outcomes were monitored and recorded throughout the study. Qualitative exit and follow-up interviews were used to capture participant experience, suggestions for future studies and identify facilitators of and barriers to sustainability.

Results: We enrolled 30 participants in 12 weeks with an average age of 74 (SD 7.29); 22 (73%) were pre-frail, 8 (27%) were frail. 28 participants (93%) completed program and follow-up assessments. Adherence to exercise was 84%, while adherence to nutrition was 82%. Exploratory analyses of secondary outcomes revealed significant improvements [program end, follow-up] in 30s chair stand test [3.5 (SD 6.1), 4.5 (SD 6.7)], physical activity [132 (SD 167), 82 (SD 150)], exercise self-efficacy [8.4 (SD 11.1), 9.7 (SD 12.1)], fatigue [0.70 (SD 1.17), 0.70 (SD 1.27)], health status [4.9 (SD 10.8), 9.1 (SD 11.9)], nutritional risk [10.0 (SD 5.4), 8.3 (SD 6.4)], and dietary protein intake [12.9 (SD 18.4), 9.2 (SD 22.7)]. No statistically significant changes occurred for other outcomes. 6 non-serious adverse events, not attributable to intervention, occurred. Overall participants were satisfied with the program and reported physical and psychological benefits. Barriers to maintenance were mapped to the TDF domains of Environmental Context and Resources, and Social Influences (opportunity).

Conclusion: We determined that remotely delivered one-on-one functional strength and balance training, combined with nutrition education was feasible according to *a priori* criteria. A larger pragmatic trial is necessary to confirm our findings.

Registration: This trial was registered in ClinicalTrials.gov under identifier [NCT04663685](https://clinicaltrials.gov/ct2/show/study/NCT04663685).

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Dedication

I dedicate this paper to the members of the MoveStrong implementation team (patient partners, health care providers and advocacy organizations) from across the country, without their feedback and support this study would not be possible.

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1.1 Introduction

Frailty can be best understood as a “syndrome” caused by an accumulation of deficits across multiple systems in the body¹⁵. For individuals living with frailty, every day stressors such as the common cold, can trigger rapid and dramatic deterioration due to a loss of resilience¹⁶. Indicators of frailty often include reduced physical activity, fatigue/exhaustion, muscle weakness, slow gait speed and unintentional weight loss^{13,17}. Although, there is no unanimous definition, the Fried frailty phenotype is the most widely used tool to assess physical frailty status¹⁸. Individuals presenting with ≥ 3 out of 5 criteria are considered frail, while those with ≤ 2 criteria are considered pre-frail¹⁷. Today it is estimated that frailty affects over 1.5 million Canadians; by 2025, over two million Canadians will be living with frailty¹⁹. If left unaddressed, frailty could have individual, social and economic consequences that affect the entire healthcare system¹⁹.

The burden of frailty

In otherwise healthy individuals, frailty can present clinically as an increased risk of falls and diminished physical function²⁰. In more severe cases, individuals living with frailty are at an increased risk of poor health outcomes and mortality^{21,22}. For instance, older adults living with frailty experience a disproportionately greater number of falls and more severe consequences than non-frail counterparts²³. In fact, a recent study reported that frail women over the age of 75 were 2.5–3 times more likely to experience a reoccurring fall than age matched controls²⁴. Despite similar admission rates to the intensive care unit, pre-frail and frail patients aged 65 years and over had a significantly higher risk of poor health outcomes from COVID-19 when compared to fit patients²⁵. It has also been documented that individuals with high levels of dependency or disability can recover, however they remain at an elevated risk of mobility limitations²⁶. Three to five year follow-up from the 2013/2014 Canadian Community Health Survey revealed that frail older adults (65+) were three times more likely to die than those who were not frail (25% versus 7%)²⁷. The identification of sustainable and scalable interventions to prevent or delay the onset of frailty is one of the most important public health challenges faced today²⁸.

The incidence of frailty appears to escalate after the age of 70²⁹, along with muscle degradation³⁰, bone loss³¹ and the risk of developing chronic conditions³². This accumulation of age and disease-related deficits threatens older adults’ independence and their ability to live in

their own homes and community of choice³³. A systematic review and meta-analysis by Cane et al. found a consistent inverse relationship between frailty and quality of life³⁴. Beyond the individual, the dependency that results from frailty can impact informal caregivers³⁵, and add additional strain to care providers^{36,37}. Nonetheless, frailty is not synonymous with aging. The health status of individuals of the same age can differ drastically³⁸. It is well documented that modifiable factors such as inactivity³⁹, malnutrition⁴⁰, and social isolation/loneliness⁴¹ contribute to the development and the progression of frailty. Interventions targeted at reducing frailty may have the additional benefits of improving patient-level outcomes, while alleviating some of the burden placed on family members and patient-provider relationships.

Today, frailty individuals make up an estimated 22% of the Canadian population over the age of 65, while pre-frail individuals make up an additional 32%²⁷. This group is over-represented at all levels of the healthcare system including primary, residential, acute and end-of-life care⁴². In Ontario, the incremental cost of being frail (vs. robust) was \$12,360, a 52.9% relative increase. The incremental cost of being pre-frail (vs. robust) was \$5,393, a 23.1% relative increase⁴³. While healthcare resource use rises with age, more money spent does not improve health outcomes for older adults⁴². Unfortunately, the medical system is ill equipped to deal with complex issues that manifest differently in each individual⁴⁴. Although research on frailty has accelerated over the past two decades, translation into practice has been delayed⁴⁵. Common challenges include the lack of understanding of effective interventions, as well as the under prescription of proven strategies such as exercise and diet modification by health care providers⁴⁴. In addition, potential therapies are not adapted with sufficient consideration for the context, implemented in a timely manner or evaluated with adequate rigor. Therefore, health care providers, patients and the general public are often left with many misconceptions or simply unaware of the consequences of frailty^{46,47}.

Clinical practice guidelines and current best evidence

There is potential for frailty to be reversed, particularly in early stages known as pre-frailty^{48,49}. This can be better understood as a “transition” period along the spectrum of frailty where lifestyle interventions, including physical activity and diet may be the most effective⁵⁰. The 2019 ICFSR clinical practice guidelines recommend physical activity as a first line of defence against frailty⁵¹. Today, there is high quality evidence to suggest that both an increase in structured exercise or activities of leisure can positively affect health outcomes⁵². To add on, dietary protein can act as an important substrate in the maintenance of skeletal muscle mass

and physical function in older adults⁵³. Large cross-sectional studies have found a dose-response relationship between protein intake and frailty status^{54,55}. However, levels of physical activity and sports participation seem to decline with age^{56,57}; while the rate of muscle protein breakdown increases in older individuals⁵⁸. Only 17% of Canadians age 60 to 79 meet physical activity guidelines of 150 minutes of moderate to vigorous aerobic activity (completed in bouts of 10min or more) per week⁵⁹. A cross-sectional analysis of the Canadian Longitudinal Study on Aging found that only a third of active older adults reported engaging in strength training 1–7 days per week⁶⁰. In terms of diet, it is estimated that 35% of community-dwelling older adults (65+) are at risk of malnutrition²¹; while over 50% of institutionalized older adults fail to meet minimal protein requirements (0.8g protein/kg body weight/day)⁶¹.

Several high quality systematic reviews have found that physical activity started in later life can drastically improve health outcomes⁴. However, only a handful of interventions have demonstrated the potential of physical activity to halt the development or reverse later stages of frailty. One of the interventions that has demonstrated cost-effectiveness and adaptability is the OTAGO exercise program (OEP). OEP emphasizes strength training, challenging balance exercises, and regular walking to reduce falls. An initial home visit is used to tailor exercises; follow-up visits allow for progression and regular phone calls support long-term engagement. The two original RCTs by Campbell et al. reported a 35% reduction in falls and improvements in functional outcomes in frail older adults^{62,63}. Cost analysis of the OEP delivered in the United States to individuals 80 and older found a net benefit of \$429.08 and the return of investment of 127%, which was higher than values for older adults age 65 and older⁶⁴. Another highly effective program being the Lifestyle Interventions for Independence for Elders (LIFE), which is aimed at reducing mobility impairments⁶⁵. The tailored exercise program has elements of walking, strength, balance, stretching and behavioral counseling. The LIFE pilot program led by Pahor et al. was unique as it encouraged participants to learn activities and plan ways to integrate them into their daily routine instead of completing structured training sessions. In addition, the study began with in-person delivery and gradual transitioned to home-based training. After an average of 1.2 years, the prevalence and severity of physical frailty was diminished, with greater effects in participants who were frail at baseline⁶⁵. Remarkably, these results were mirrored in the full scale RCT where participants with lower physical function at baseline (i.e., SPPB < 8) were those who benefited the most⁶⁶. Although these interventions seem to differ in design and outcomes, a common element is the individualized multicomponent exercise training.

The potential of individualized multi-component exercise training

At the molecular level, regular exercise is thought to combat frailty by reducing muscle inflammation that is associated with aging⁶⁷. Even a single bout of exercise can acutely stimulate muscle protein synthesis, however benefits are lost if exercise is discontinued⁶⁸. A 2019 Cochrane review and meta-analysis of 81 RCTs that included 19,684 participants reported that sustained exercise has the potential to reduce falls by up to 23% in community-dwelling older adults⁶⁹. In terms of physical function, exercise can significantly improve results on performance-based tests such as the Timed Up and Go test (TUG), Short Physical Performance Battery (SPPB) and Sit-to-Stand test (STS)⁷⁰. However, an increase in physical performance does not necessarily translate to activities of daily living (ADLs). A systematic review found no significant changes in ability to perform specific ADLs, despite improvements on physical function assessments⁷¹. A possible explanation may be that ADL scales display weak sensitivity to change and large ceiling effects when compared to performance-based measures^{72,73}. At the same time, not all forms of exercise are equally effective at improving functional independence. The principle of specificity predicts that the closer the training routine is to the requirements of the desired outcome (e.g., putting on shoes, getting into bed) the better the outcome⁷⁴. Simply put, it is necessary to practice movements that mimic real-life tasks in the environment in which they are meant to be executed.

Individualized multicomponent interventions that combine strength training, functional exercise and balance are well suited to confront the issue of frailty^{75,76}. Walking interventions are well accepted and can help to preserve gait patterns, but alone may not offer adequate musculoskeletal benefits to combat age-related muscle and bone loss⁷⁷. Progressive strength training has been found to improve muscle strength, power and function, yet barriers such as perceived risk and fear of harm continue to restrict participation among older adults^{78,79}. Today, there is high quality evidence to suggest that functional exercise and balance are safe and effective at improving physical function in community-dwelling older adults⁶⁹. Movements that are aligned with ADLs can promote personal relevance^{80,81}. Individually tailored and continuously monitored exercise training programs are able to address the needs of individuals living with chronic conditions^{82,83} and improve adherence⁸⁴. In the future, exercise interventions must be comprised of elements that work synergistically to improve physiological resilience across different systems. Furthermore, they must be delivered in ways that are accessible and practical for vulnerable populations.

The need for complex interventions

Findings from a recent systematic review suggest that an incremental and sustained increase in daily protein intake (0.1 g/kg BW/d) can help to build or maintain muscle mass⁸⁵. Several systematic reviews and meta-analysis suggest that pairing strength training with high protein intake may result in greater gains in muscle mass and strength in healthy adults^{86–88}. In the context of frailty, a systematic review by Liao et al. examined RCTs of strength training with nutrition supplementation or multicomponent exercise with nutrition supplementation. They found that both study designs improved lean mass, strength, mobility and frailty status in older adults⁸⁹. Subgroup analyses revealed that strength training plus nutritional supplementation further improved lean mass; whereas multicomponent training with nutritional supplementation exerted greater effects on frailty indicators⁸⁹. Travers and colleagues conducted an evidence synthesis of 46 primary care interventions aimed at delaying or reversing frailty. Their results showed that strength training combined with protein supplementation was not only the most effective intervention, but the easiest to implement when compared to health education, home visits, hormone supplementation, counselling or any other combination of interventions⁹⁰. One cross-sectional study of community-dwelling older adults found no association between dietary protein intake and frailty status. Instead authors noted that protein distribution was significantly different between frail, pre-frail and non-frail participants⁹¹. Some researchers have proposed a dietary plan that includes 25 to 30g of high quality protein three times a day (spread feeding) to combat age-related muscle loss⁹². It can be agreed that well powered and extensively reported studies are necessary to evaluate the potential of complex intervention designs for individuals living with frailty.

Barriers to change

A commonly cited barrier to physical activity for older individual is poor health, which includes the presence of chronic conditions, acute illness, disability or injury⁹³. Lack of company/social support is another prominent barrier to participation in both middle-aged and older individuals^{93,94}. A recent qualitative study examined the meaningfulness and risk of harm associated with physical activity from the perspective of frail older adults⁹⁵. For many participants being physically active supports independence. However, participants expressed a lack of knowledge of how to perform exercise; many did not recall receiving information from healthcare professionals. In addition, patients perceived pain and fatigue as barriers, along with impaired balance, fear of falling, and fear of doing activities that could potentially harm them⁹⁵. Those with severe mobility limitations have also reported poor health and fear of injury as

barriers to participation⁷⁹. Together, these findings stress the importance of adapting physical activity interventions to address the characteristics of specific health conditions and functional limitations (physical capability)⁹⁶. Furthermore, providing opportunities for social interaction and personalized education may help to address opportunity (social) and capability (psychological) barriers to participation⁹⁷.

Recognised barriers to eating well among community-dwelling older adults include the accessibility and affordability of food⁹⁸. Living alone and social isolation are known to affect one's ability to acquire food, motivation to eat, and appetite⁹⁹⁻¹⁰¹. The Old People Eat Well project recognized that individuals with mobility impairments and those who lacked cooking skills were at greater risk of malnutrition⁹⁸. Older adults who are able to prepare their own meals often lack the desire to do so¹⁰², and cooking a single serving is often more costly¹⁰³. A 2012 study conducted in Canada found that a lack of financial resources could hinder an individual's ability to resolve obstacles that reduced food quality¹⁰⁴. With the cost of food on the rise¹⁰⁵, nutritiously dense options seem more out of reach than before^{106,107}. From another perspective, health professionals struggle to modify established eating habits in their frail elderly patients¹⁰⁸. Practitioners acknowledge that individuals would often be misled by outdated information. This was further complicated by the presence of restrictive diets for certain health conditions¹⁰⁸. Disseminating knowledge and raising awareness of malnutrition may not be enough to promote change. Greater recognition of opportunity barriers (physical & social) is warranted. Realistic solutions are required to help older adults purchase, transport, prepare and enjoying nutritious meals.

The impact of COVID-19 on physical activity and diet

For older adults who were previously active, stay-at-home orders made it more difficult to achieve physical activity and dietary recommendations. During the first wave of the pandemic, Ammar and colleagues surveyed participants around the world using the International Physical Activity Questionnaire¹⁰⁹. They reported that isolation decreased the quantity of physical activity for all exercise intensities and increased daily sitting time. Duration of vigorous activity dropped from 38.7 to 26.0 min/week, moderate activity from 32.1 to 21.4 min/week and walking from 37.2 to 24.6 min/week. Total physical activity duration was reduced by 33%, while sedentary time increased by 28%. Although the survey results may not seem alarming, literature suggests that as little as 14 days of step reduction in older adults can induce changes in cardiorespiratory function, glucose and insulin metabolism, skeletal muscle protein synthesis,

and pro-inflammatory cytokines¹¹⁰. While it is possible to counteract the effects of physical inactivity, re-conditioning may be incomplete, take longer to achieve or require more intensive training in older adults or those with chronic conditions when compared to young healthy adults^{110,111}. In addition, authors of the survey evaluated food consumption and meal patterns, and found that individuals were more likely to make unhealthy choices than prior to the pandemic¹¹². Being confined to home could lead to irregular eating patterns and frequent snacking, both of which are associated with higher caloric intake and increased risk of obesity¹¹³. On the other hand, emotions such as fear or sadness are associated with less desire and enjoyment during eating which could lead to insufficient caloric intake¹¹⁴. The variability of dietary patterns was reflected in a study conducted in the UK which found that nutritional behaviours during lockdown simultaneously predisposed individuals to both overnutrition (20.3–32.4%) and undernutrition (6.9–15.1%)¹¹⁵. Together, findings display the impact that COVID-19 has had on the lifestyle of many individuals around the world. Evidence-based and theory-driven solutions are needed to reach older adults that are isolated at home.

Evidence gaps and implementation plan

Evidence-based interventions that are built upon theoretical frameworks and engage key stakeholders in the planning process have the potential for greater effectiveness^{116–118}. The Knowledge-to-Action (KTA) framework is used to guide the translation of research evidence into real life settings. It is composed of several dynamic and iterative steps that include the “*synthesis, dissemination, exchange and ethically-sound application of knowledge*”⁶. The cycle starts in the middle with knowledge creation and then proceeds into the action cycle. Today, there is high quality evidence to suggest that functional exercise and balance can prevent falls, improve functional capacity and increase levels of physical activity^{4,5}. Furthermore, high protein intake has been found to protect against age-related muscle loss^{119,120}. The main problem is that there is poor adherence to Canadian physical activity guidelines and minimal protein requirements^{21,121}. Very little is known about effective approaches to promote and sustain physical activity and dietary behaviours in older adults living with frailty. We know even less about how to implement interventions remotely during a time of elevated stress and worry^{122,123}.

To date, the majority of exercise interventions have examined the effectiveness of the intervention rather than the mechanisms that allow certain interventions to be effective¹²⁴. Behaviour change theories allow researchers to identify and target determinants of change, however they are often poorly applied. Prestwich et al. found that while 56% of interventions

reported a theory base, only 10% reported links between behaviour change techniques and theoretical constructs¹²⁵. Likewise, there is often a misalignment between the implementation strategy applied and evidence of effectiveness in a particular setting. A Cochrane review led by Wolfenden and colleagues found that commonly used implementation strategies in a workplace setting for targeting physical activity and diet was educational materials and meetings¹²⁶. Yet, there is limited evidence on the effectiveness of education-based strategies in a workplace setting. Lastly, there have been reports of “improvement evaporation” up to 70% by follow-up, even in the most effective interventions¹²⁷. Systematic reviews and meta-analyses of long-term physical activity trials have found that the majority of individuals will relapse to a less active status after 12 months^{128,129}. Researchers should devote special attention to sustainability during the design process. Greater engagement with knowledge translation frameworks is necessary to further the quality of research findings.

The Behaviour Change Wheel (BCW) was developed by Michie and colleagues after an extensive review and synthesis of 19 different frameworks. The BCW is made up of three layers¹⁰. The centre consists of the COM-B model, which is the observation that a particular behaviour will only occur when three conditions are met: Capability, Opportunity, and Motivation. In the case of functional strength and balance training, capability is achieved when the individual is physically able and has the necessary knowledge and skills to complete prescribed exercises. Opportunity is defined as factors within a person’s environment that support or prompt adherence to exercise. Finally, motivation is defined as that individual’s intrinsic commitment or extrinsic desire to act. To promote behaviour change, developers can select, and tailor "active ingredients" called behaviour change techniques (BCTs) to target specific intervention functions (IFs). Closely related is the Behaviour Change Technique Taxonomy v1 (BCTTV1)¹¹ which provides a systematic method of describing and categorising BCTs, and allows for testing and future replication¹³⁰. Together with the Transtheoretical Domains Framework (TDF), researchers can uncover which facilitators are most effective at supporting change and which barriers hinder progress¹³¹.

Results from a meta-regression suggest that interventions with a greater number BCTs are not necessarily associated with better outcomes^{132,133}. Instead, certain BCTs or groupings may be more potent than others at effecting behaviour change; however it depends on the context^{134,135}. A qualitative study by Frost et al. used semi-structured interviews to identify acceptable components for home-based interventions for pre-frail older adults¹³⁶. Health care

providers, caregivers and patients agreed that interventions should target physical capability (mobility) and social opportunity (social support). Furthermore services should aim to increase reflective motivation by promoting functional independence¹³⁶. Gardener and colleagues found that home-based interventions which included instructions on how to perform the behavior, added objects and restructured the physical environment appeared to have the greatest improvements on physical function¹²⁴. In terms of exercise maintenance, a recent systematic review in young and middle aged adults found that prompting self-monitoring of behavioral outcomes and use of follow-up prompts to be effective at achieving exercise maintenance at 6 and 9 months¹³⁷. Additionally, feedback, in combination with other BCTs, appears to be a top candidate for promoting long-term adherence. MoveStrong at Home was designed using 28 BCTs to target 6 Intervention Functions (Education, Persuasion, Training, Environmental Restructuring, Modelling, and Enablement)¹¹⁷. These BCTs are integrated into the 12-week study design to address barriers to participation and promote sustainability (Table 8).

Bridging the gap through remote delivery

With the advances in communication technology, telehealth and telerehabilitation have become more viable and well accepted by both clients and health care providers. An increasing number of older adults now own smartphones, tablets or laptops, and have access to highspeed internet¹³⁸. However, the effectiveness of a remote model compared to an in-person delivery is still unclear. A previous pilot of MoveStrong took place from October 2019 to March 2020 across four sites in Ontario. From the original intervention, we learned that physical capability (illness and disability) and physical opportunity (transportation) were key barriers to participation for pre-frail and frail older adults¹³⁹. In theory, remotely delivered interventions have the potential to promote equitable access to those who are unable to leave their home and address travel-related issues. Systematic review of non face-to-face interventions found that 14 out of 16 studies were successful at increasing self-reported levels of physical activity, with 8 out 9 studies reporting maintenance of physical activity at follow-up¹⁴⁰. Tele-rehabilitation has been found to be effective at promoting physical activity and improving measures of functional capacity in patients with cardiovascular disease¹⁴¹, stroke¹⁴², arthritis¹⁴³, and multiple non-communicable diseases¹⁴⁴. Similarly, the application of telehealth to the delivery of nutrition care has the potential to improved health outcomes, lower no-show rates and increase retention¹⁴⁵. To date, preliminary evidence supports the use of technology to enhance the uptake of lifestyle interventions while meeting the needs of both clients and providers¹⁴⁶.

Commonly reported challenges to remote delivery include a lack of support¹⁴⁴, perceived lack of effectiveness or skepticism regarding effectiveness¹⁴³, and technological difficulties¹⁴². Many have suggested individualized and tailored exercise programs to improve safety and adherence¹⁴⁷, while others have emphasized the need for proper training and education of team members¹⁴⁸. One study found that consultation time tended to be longer for telerehabilitation professionals¹⁴⁹, while dietitians reported that communication difficulties were a hinderance to care¹⁵⁰. To add on, telehealth services may require additional staff to support administration and information technology¹⁴⁵. To date, the majority of home-based interventions have excluded participants with chronic conditions¹⁵¹, as well as those with cognitive¹⁵², visual and auditory impairments^{153,154}. Furthermore, studies prior to the pandemic often required in-person assessments or home visits by a physiotherapist^{155,156}. Thus, former intervention designs may not lend well to older adults living with frailty or a state of lockdown.

Telephone visits can improve accessibility for older adults who are inexperienced with technology or lack internet access. However telephone calls are known to be suboptimal for care that requires visual assessment¹⁵⁶ or anthropometric measurements¹⁵⁰. Furthermore, research on telephone-assisted counseling for physical activity has generally been limited to aerobic exercise that requires limited guidance and monitoring^{151,157,158}. When led by a trained physiotherapist, telephone-delivered counselling only modestly improved physical function, with no improvements in knee pain for individuals with osteoarthritis¹⁵⁹. In a similar study, patients with knee osteoarthritis that underwent telephone-based physiotherapy admitted that they did not view telerehabilitation as a substitute for face-to-face care, but rather a more accessible option for follow-up¹⁶⁰. Seeing as remote delivery is an emerging field, the feasibility of functional strength and balance training for populations living with frailty has yet to be established. Our current study aims to address this gap.

MoveStrong at home was an 8-week remotely delivered model for functional strength and balance training combined with nutrition education to pre-frail and frail older adults. MoveStrong was originally developed by Dr. Giangregorio and Keller with the help of patient partners, health care professionals and advocacy organizations (Research Institute for Aging, Centre for Community Clinical and Applied Research Excellence, Osteoporosis Canada, Community Support Connections, YMCA). Due to the COVID-19 pandemic, MoveStrong was adapted for virtual and telephone delivery to older adults in their homes, using mailed program instructions and a nutrition education booklet, one-on-one exercise training sessions through

Physitrack®, and online nutrition Q&As and group sessions hosted through Teams®. Known barriers to participation were addressed using BCTs embedded in the study design. Our overall aim was to assess the feasibility and acceptability of the intervention rather than the effectiveness of the protocol. Given stay-at-home orders, it was sensible to test the intervention with a small sample of participants to determine if telephone and web conference delivery was possible and what implementation strategies to use. Furthermore, feasibility studies allow researchers to determine if there is potential to reach a greater proportion of the eligible population and gather insight to increase the likelihood of effectiveness¹⁶¹. The results from MoveStrong at Home will be used to develop a sustainable and scalable model for implementation in a larger pragmatic trial in community centres, retirement homes, family health teams and other settings across Ontario.

1.2 Objectives

Our study assessed the feasibility of virtual and telephone delivery of the MoveStrong model, and short-term sustainability of behavior change. The primary objectives were to:

1. Evaluate the feasibility of recruitment over 12 weeks.
2. Determine retention rates at the end of the study.
3. Calculate adherence rates to the MoveStrong program
4. Capture participant experience, suggestions for future studies and identify facilitators of and barriers to sustainability.

Criteria for success were:

1. Recruitment of 25 participants over 12 weeks.
2. Retention of >80% from baseline to follow-up assessment.
3. Adherence of $\geq 70\%$ exercise and nutrition sessions.

**Exercise adherence was defined by attendance of one-on-one exercise sessions and completion of independent sessions (Total 3 per week)*

**Nutrition adherence was defined by attendance of Nutrition Q&A sessions (Total of 3 during the intervention).*

Our secondary objective was to explore levels of physical activity, physical function, exercise self-efficacy, quality of life, mental well-being, fatigue, dietary habits at baseline, post intervention and at follow-up using a variety of questionnaires. We also tracked protein and total energy intake using a 24-hour food recall to better inform participants of their personal needs and areas of improvement. Adverse events were recorded to evaluate safety. We monitored process outcomes for Physitrack® (Physitrack PLC., London, UK), Teams® (Microsoft

Corporation, Redmond, WA) and YouTube® (Google LLC., San Bruno, CA) to help us understand the uptake and usability of technology among older adults living with frailty. Lastly, we documented all modifications made to the study protocol to inform a future trial and advance scientific inquiry.

We hypothesized that remotely delivered exercise and nutrition was feasible according to the *a priori* criteria for success and well received by participants. A Logic Model can be found on (Table 4).

1.3 Methods

The protocol was drafted in accordance with the CONSORT pilot studies extension to guide reporting⁷ (Table 5). In addition, the TIDieR checklist (Template for Intervention Description and Replication) was used to promote full and accurate description of the intervention⁹ (Table 6).

1.3.1 Study Design

MoveStrong at Home was an 8-week single arm prospective feasibility study with a 4-week follow-up (Table 1). The first phase with 9 participants began on October 26th, 2020. The second phase with 21 participants started on January 18th, 2021 (Table 2). This study was funded by the Network of Research Aging from the University of Waterloo.

1.3.2 Study Setting

The MoveStrong at Home program and all data collection was implemented remotely by web conference or telephone to community-dwelling older adults and those living independently in a retirement home setting.

1.3.3 Sample size

We selected a recruitment goal of ≥ 25 people over 12 weeks (two participants per week or 8 participants per month) as a pragmatic sample size to understand the feasibility of remote intervention delivery and participant experience, given the available resources and timeline. We overrecruited by 5 participants to account for possible dropouts. No formal sample size calculation was made.

1.3.4 Recruitment

Participants were primarily recruited from email or telephone contact lists of individuals who previously agreed to be contacted for research purposes. 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 two Schlegel Villages and one Luther Villages recruited participants using flyers and word of mouth. Primary care professionals were provided with electronic flyers and posted to use in their practice. Lastly, Twitter (Twitter Inc., San Francisco, CA) and Facebook (Facebook Inc., Menlo Park, CA) were used to share the recruitment post with relevant professional groups, and local neighborhood associations. The recruitment period went from October 5th, 2020, to December 28th, 2020 (Table 2).

1.3.5 Eligibility Criteria and Informed Consent

We recruited English speaking, Ontario residents, ≥ 60 years of age; ≥ 1 primary care diagnosed chronic condition (e.g., hypertension, cardiovascular disease, stroke, diabetes, obesity, cancer, osteoporosis, osteoarthritis, kidney/liver/thyroid condition, pulmonary conditions, autoimmune disease, and depression); ≥ 1 FRAIL Scale score. For the purpose of screening, the FRAIL Scale was used as a time efficient tool¹³. The 5-item questionnaire considers fatigue (over the past 4 weeks), resistance (difficulty going up 10 stairs), ambulation (difficulty walking several hundred yards), illnesses (≥ 5 chronic conditions), and loss of weight ($\geq 5\%$ body mass in the past 6 months) to determine the physical frailty status.

Individuals could not participant if they were completing similar progressive strength training $\geq 2x/week$ within 6 months (cardiorespiratory/endurance activities did not preclude eligibility); could not perform basic activities of daily living; had moderate to severe cognitive impairment (e.g., unable to follow two-step commands); were receiving palliative care; planned to travel >1 week during the MoveStrong program; and had absolute exercise contraindications (ACSM)¹⁶². In the case of uncertainty due to the presence of a medical condition, a physician on the study team was consulted or participants were asked to contact their physician to confirm eligibility.

Upon recruitment, all eligible individuals were mailed or emailed the Participant Information and Consent Form to read independently [Appendix 2]. The research assistant

reviewed the form with each eligible individual by telephone a week after the initial screening call or upon arrival of the documents by mail. Informed consent was obtained verbally over the telephone and documented using a standardized form. Ineligible individuals received an email containing links to the YMCA and Community Support Connections exercise programs across Ontario.

1.3.6 Intervention Development

MoveStrong was originally 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 were aligned with functional movements like a squat that mimic activities of daily living such as getting out of a chair. Difficulty ranged from simple seated exercises to compound movements with free weights. MoveStrong exercises were informed by the GLA:D program for arthritis¹⁶³, BoneFit™¹⁶⁴, and meta-analyses on resistance exercise and fall prevention^{165–169}. The nutrition component was developed following recommendations from several expert groups (PROT-AGE, ESCEO, ESPEN) for 1.0-1.2g protein/kg body weight/day for older adults and more for active or frail individuals^{119,170,171}.

During the first wave of the pandemic, MoveStrong was adapted for remote delivery by a team of researchers, patient partners, health care providers, and representatives of advocacy organizations. By working closely with various stakeholders throughout the adaption process, we were better able to identify priorities for the intervention and come up with realistic solutions within the context of COVID-19¹⁷². A joint decision-making process was used during two hour-long meetings to adapt components of the intervention design and protocol for remote delivery. During the first discussion, a lack of internet access in rural areas was brought up and the option of telephone delivery was incorporated into the study design. A 30-minute technology consultation was suggested to familiarize participants with various platforms (Physitrack® and Teams®). During the second meeting, it was concluded that safety was the highest priority due to the nature of remote supervision and the inability to spot participants during exercise. We discussed that the group session may not offer the same cohesive benefits remotely as would in-person. Instead, team members agreed on one-on-one exercise sessions to promote tailoring of functional movements and support participant engagement. In the past, MoveStrong nutrition seminars often ran overtime due to the high volume of questions; thus, three participant-directed nutrition Q&A sessions were arranged. Lastly, team members individually

provided feedback on mailed materials such as the program instructions package [Appendix 3]. Revised versions were sent back to team members for further input.

Physitrack® was a commercially available platform which offered a wide variety of narrated exercise videos and allowed the research team to include specific written instructions. Participants were able to access their program through the patient portal – Physiapp®, where they recorded adherence (reps, sets, RPE) and provided feedback (e.g., pain), all in real time. The exercise physiologist used Physitrack® to monitor participants and respond to incoming messages. An additional add-on subscription provided teleconferencing minutes on a secure and user-friendly interface. The Teams® application by Microsoft allowed multiple participants to attend nutrition Q&As and group discussion sessions, and it possessed audio/visual recording capability. Furthermore, Teams was well-rated in terms of privacy, security and end-to-end encryption which made it suitable for research¹⁷³. Both applications were free to download in the Apple and Google Play store and allowed users to join via the mobile app, over their browser or by dialing in.

1.3.7 Intervention Description

1.3.7.1 Overview

Participants completed all baseline assessments and a technology consultation prior to the start of the intervention. Program instructions, a nutrition education booklet and an exercise band were mailed to participants. The main components of the intervention included a meet & greet with the exercise physiologist, weekly one-on-one exercise sessions, three 60-minute nutrition Q&As and three 60-minute group discussion sessions to build a sense of community. Assessments were completed at the end of the intervention and again four weeks later (Table 3). The exercise physiologist was given an instructor manual that provided guidance on specific chronic conditions and common movement impairments. The manual also contained safety reminders, cueing tips and procedures for reporting adverse events [Appendix 3]. The registered dietitian completed an orientation session and was provided with the nutrition education booklet.

Table 7: MoveStrong at Home Enablement Strategies

Enablement Strategies	
Mailed Materials (Program Instructions, Nutrition Education Booklet & Exercise Band)	Program instructions contained a decision aid that helped participants navigate unpleasant symptoms of illness/injury, exercises tracking sheets to record progress, as well as pages dedicated to goal setting, action planning and problem solving.
Technology Consultation	Upon enrollment, participants completed a 30-minute technology consultation to learn how to operate Physiapp and Teams. In addition, the research assistant inspected the exercise space, placement of the device, and ensured the participant's body was in frame during movement.
Reminders	Participants were reminded of one-on-one and group sessions by email at the beginning of each week (Sunday). Participants had the option to enable daily reminders to complete exercises through Physiapp.
Baseline Assessment Results	An individualised feedback report which included results from the baseline physical function assessment (interpretation of the score, areas of improvement) and food recall (total energy and macronutrient intake, individual protein recommendations) was distributed during week 2.

1.3.7.2 Meet & Greet

Intervention Functions (IFs): Education, Training, Modelling, Environmental restructuring, Enablement

Prior to the start of the intervention, participants received a 60-minute consultation with the exercise physiologist to review program instructions and sample a variety of exercises (IFs: education, training, modelling). Together, the exercise physiologist and the participant decided when in their daily routine and where in their home to complete the functional movements (IFs: enablement). Participants were encouraged to dedicate a specific space in their home, rearrange furniture and leave their materials and equipment nearby (IF: environmental restructuring). In addition, the exercise physiologist answered questions and listened to participant concerns. Using what they gathered from the Meet & Greet session, the exercise physiologist created an individualized program for each participant on Physitrack® or mailed a printed copy to their home.

1.3.7.3 Exercise Training

Intervention Functions (IFs): Education, Training, Persuasion, Modelling, Enablement.

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 performed 8-10 repetitions of each functional movement with time under tension per repetition of 4:0:2 seconds for eccentric:isometric:concentric phases. Exercise difficulty/variation, resistance, or volume (up to 3 sets) were progressed over time.

At the start of every one-on-one session, the exercise physiologist inquired about changes to health status (IF: enablement). The exercise physiologist then confirmed weekly adherence to exercise 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. Then, balance was challenged using both static and dynamic exercises that reduced base of support, shifted focus, or required multitasking. During the session, the exercise physiologist demonstrated functional movements, discussed the importance of each exercise, what muscles it worked and encouraged participants (IFs: education, training, persuasion, modelling). Cool down consisted of 3-4 static stretches that were held for 30-60 seconds on each side and repeated.

1.3.7.4 Nutrition Education

Intervention Functions (IFs): Education, Persuasion, Training, Enablement

Participants received the nutrition booklet which included information, tips and recipes by mail. Educational videos were available on a private YouTube® channel for the duration of the study to help reinforce key topics (IFs: education, persuasion):

- 1. Reading nutrition labels.**
- 2. Plant-based proteins vs. animal proteins (benefits/sources of each).**
- 3. Which foods are protein foods?**
- 4. Ways to incorporate protein into your meals and snacks.**
- 5. Spreading protein throughout the day.**

In addition, individuals participated in three dietitian-led nutrition Q&A sessions on weeks 2,4 & 5 (Wednesday) to review content from the booklet/videos and discuss more personalized strategies to increase protein intake (IFs: education, training, enablement, persuasion). The dietitian considered the cost of preparing high protein foods and accessibility during the pandemic when answering questions. A research team member was present at all sessions to provide technical support and address participant concerns. The 60-minute sessions were recorded and transcribed into a frequently asked questions document for participants who were unable to attend.

1.3.7.5 Group Session

Intervention Functions (IFs): Education, Persuasion, Training

Optional group discussion sessions took place on weeks 3, 5 & 7 (Wednesday). The intention was to foster a sense of community, stimulate thought 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 session (IFs: education, persuasion, training). Individuals took turns sharing their experiences and responding to one another. Topics included:

1. **Plan for success:** Goal setting (behaviour & outcome), Action planning, Problem solving.
2. **Make movement a part of your day:** Habit formation, Prompts and cues, Framing/reframing, Self-identity.
3. **Stay committed and focused:** Review behavior goal(s), Discrepancy between current behavior and goal, Feedback (behavior & outcome), Self-monitoring.

Table 8: MoveStrong at Home Behaviour Change Techniques

	Intervention Function	Mode of delivery	Example
1. Goals and planning			
1.1. Goal setting (behavior)	Enablement	Group session #1, Program instructions (goal setting sheet)	Group session #1 facilitated SMART goal setting, planning for action and problem solving.
1.2. Problem solving	Enablement	Group session #1, Program instructions (goal setting sheet)	
1.3. Goal setting (outcome)	Enablement	Group session #1, Program instructions (goal setting sheet)	
1.4. Action planning	Enablement	Group session #1, Program instructions (action planning sheet)	
1.5. Review behavior goal(s)	Enablement	Group session #3, Program instructions (goal setting sheet)	Group session #3 encouraged participants to revisit and revise goals for the follow-up period.
1.6. Discrepancy between current behavior and goal	Enablement	Group session #3, Program instructions (goal setting sheet)	Group session #3 reflected on adherence and considered additional strategies to promote maintenance.
2. Feedback and monitoring			
2.2. Feedback on behaviour	Education Training	1:1 – Instructor, Nutrition Q&A – Dietitian	Exercise instructor provided constructive feedback on proper exercise form during 1:1 sessions.
2.3. Self-monitoring of behaviour	Enablement Training	Program instructions (tracking sheet and calendar), Physiapp exercise tracking	Participants tracked exercise completion through Physiapp or using the tracking sheets provided.
2.7. Feedback on outcome(s) of behavior	Education Persuasion	1:1 – Instructor, Nutrition Q&A – Dietitian, Research Team	Researchers provided written personalized feedback on the physical function assessment and food recall at baseline.
3. Social support			

3.1. Social support (unspecified)	Enablement	1:1 – Instructor, Nutrition Q&A – Dietitian, Group session #1-3	Exercise instructor and dietitian listened to participant concerns and provided words of encouragement.
4. Shaping knowledge			
4.1. Instruction on how to perform the behavior	Education	1:1 – Instructor, Nutrition Q&A – Dietitian, Physiapp instructional content, Program Instructions, Nutrition booklet/videos	Mailed materials contained exercise instructions, tips, and safety precautions.
5. Natural consequences			
5.1. Information about health consequences	Education	1:1 – Instructor, Nutrition Q&A – Dietitian, Group session, Nutrition booklet/videos	Dietitian informed participants of the risks associated with inadequate protein intake and advance age.
5.6. Information about emotional consequences	Persuasion	1:1 – Instructor, Group sessions #1-3	Exercise instructor explained how physical activity promotes quality of life and mental well-being.
6. Comparison of behaviour			
6.1. Demonstration of the behavior	Modelling	1:1 – Instructor, Physiapp exercise videos, Program instructions (pictures)	Exercise instructor physically demonstrated each exercise.
7. Associations			
7.1. Prompts/cues	Environmental Restructuring	1:1 – Instructor, Nutrition Q&A – Dietitian, Group session #2, Program instructions (action planning sheet)	An exercise was associated with a specific location in the home, time of day or task.
8. Repetition and substitution			
8.1 Behavioural practice/rehearsal	Training	1:1 – Instructor, Nutrition Q&A – Dietitian, Group sessions #1-3	Exercise instructor encouraged participants to complete exercises outside of 1:1 sessions.
8.2 Behaviour substitution	Enablement	1:1 – Instructor, Nutrition Q&A – Dietitian, Group session #1	Dietitian suggested replacing certain foods with high protein alternatives.
8.3. Habit formation	Training	1:1 – Instructor, Nutrition Q&A – Dietitian, Group session #2, Program Instructions (action planning sheet), Nutrition booklet/videos	Exercise instructor encouraged participants to complete the program every second day at the same time.
8.6. Generalisation of target behavior	Enablement	1:1 – Instructor, Group sessions #2	Exercise instructor suggested completing balance exercises in a variety of settings and on different surfaces around the house.
8.7. Graded tasks	Training	1:1 – Instructor, Nutrition Q&A – Dietitian	Exercise instructor progressed exercise difficulty over time by adding strength or balance challenge.
9. Comparison of outcomes			
9.1. Credible source	Education Persuasion	1:1 – Instructor, Nutrition Q&A – Dietitian, Group sessions #1-3, Nutrition booklet/videos	Nutrition videos featured a leading researcher who shared information on the protective benefits of protein and the harms of malnutrition.
12. Antecedents			
12.1. Restructuring the physical environment	Environmental Restructuring	1:1 – Instructor, Nutrition Q&A – Dietitian, Mailed Materials (exercise band)	Participants were sent an exercise band to keep.
13. Identity			
13.2 Framing/reframing	Persuasion	1:1 – Instructor, Nutrition Q&A – Dietitian, Group session #1-3	Exercise instructor urged participants to think of exercise as a form of self-care.
13.4 Valued Self-Identity	Enablement	Group session #1, Program instructions (goal setting sheet)	The goal setting sheet included scales for participants to rate the importance of functional training and their confidence on execution.

13.5 Identity associated with behaviour change	Persuasion	1:1 – Instructor, Group session #3	Participant were taught to identify as an individual committed to being physically active.
15. Self-belief			
15.1. Verbal persuasion about capability	Persuasion	1:1 – Instructor, Nutrition Q&A – Dietitian	Dietitian provided positive reinforcement when participants shared that they tried a high protein product or recipe.
15.3 Focus on past success	Persuasion	1:1 – Instructor, Nutrition Q&A – Dietitian	Exercise instructor advised participants to reflect on a time when they completed an exercise with proper form.
15.4 Self-talk	Training	1:1 – Instructor, Nutrition Q&A – Dietitian	Exercise instructor reminded participants to encourage themselves when training independently.

1.3.8 Outcomes (Primary, Secondary, Process and Qualitative Measures)

The primary research questions pertained to the feasibility of implementation as defined by recruitment (number of participants recruited in 12 weeks), retention (number retained at study end), adherence (percentage of exercise and nutrition sessions completed out of the total number of sessions prescribed per participant - 36 exercise and 3 nutrition). During structured exercise and nutrition sessions, adherence was taken by the exercise physiologist or the research assistant. For independent sessions, adherence was self-reported through Physitrack® or recorded using the sheets provided.

A modified version of PROGRESS-Plus was used to identify participant characteristics and describe the study population¹² (Table 10). Health status, previous falls, fractures/injuries, and medications were thoroughly detailed over telephone at baseline to ensure safety and guide the tailoring of exercises (Table 11). We measured secondary outcomes by telephone, an online survey platform (Qualtrics®) or web conference (Teams®) at baseline, post-intervention, and follow-up (Table 3):

a) Physical Function: The 30s chair stand test was used to assess lower extremity muscle function^{174,175}. Subjects were instructed to find a sturdy chair, place it against a wall and rise from the chair without the use of their arms. Static balance was measured using the 3-point balance test from the Short Performance Physical Battery (SPPB)¹⁷⁶. Participants were asked to hold three progressively challenging postures (side-by-side, semi-tandem and full tandem) for 10 seconds with a support object within arms reach. The instructions for both tests were adapted using materials from Later Life Training and self-administered under the

remote supervision of the exercise physiologist¹⁷⁷ [Appendix 2]. The baseline assessment was video, or audio recorded over Teams®.

- b) Physical Activity:** The Physical Activity Screen (PAS) was used to capture self-reported minutes of moderate to vigorous physical activity per week¹⁷⁸. This tool was created based on questions used in the Physical Activity Vital Sign questionnaire¹⁷⁹. The results were compared to Canadian 24-hour movement guidelines for adults 65+ which recommend ≥150 minutes of moderate to vigorous aerobic activity, ≥2 sessions of muscle strengthening and balance exercises each week¹⁸⁰.
- c) Exercise Self-Efficacy:** A modified version of the Exercise Self-Efficacy Scale (ESES) was used to capture variables related to the planning and execution of physical activity⁹⁷. Both research evidence and behaviour change theories suggest that exercise self-efficacy is associated with the adoption and maintenance of exercise behaviours^{181,182}.
- d) Fatigue:** The Physical Frailty Phenotype utilizes the Center for Epidemiologic Studies Depression Scale (CES-D) to captures levels of self-reported exhaustion^{17,183}. The two questions that pertain to fatigue were used for our study.
- e) Mental Wellbeing:** The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) was used to assess positive aspects of mental health. The short and robust 14-item scale has demonstrated high correlations with other mental health and well-being scales¹⁸⁴.
- f) Quality of life:** The EuroQol Group 5 Dimension 5 Level questionnaire is a multi-attribute health related quality of life tool¹⁸⁵. The system is comprised of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) and a visual analogue scale (VAS) of self-perceived health rating (0–100).
- g) Nutritional Risk:** The SCREEN-14 tool is a valid and reliable nutrition questionnaire designed specifically to capture nutrition risk in older adults¹⁸⁶. This tool was used to assess appetite, eating habits, changes in weight and promote viable self-management.
- h) Food Recall:** Dietary intake (24-hour recall) was collected and analyzed using the Automated Self-Administered 24-hour Dietary Assessment Tool (ASA24), version Canada-

2018, developed by the National Cancer Institute. All food and drinks consumed over two weekdays and one weekend (three days total) were reported online or collected by telephone and analyzed to determine average daily energy and protein intake¹⁸⁷.

- i) **Adverse Events:** Participants were asked to report all adverse events such as falls, fractures, and injuries by calling the study phone. In addition, the exercise physiologist inquired about changes to health at the start of every one-on-one session (weekly basis) and monitor safety throughout each session. Adverse events reported by participants or the exercise physiologist (on behalf of the participant) were evaluated by the research assistant using the Health Canada definition¹⁸⁸ to determine:

Severity

- **Non-serious adverse events:** Adverse events that are not considered serious as per definition below. This refers to adverse events that meet the Health Canada definition above but are not considered serious (see below).
 - **Serious adverse events:** "... (experience or reaction) is any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity" (Health Canada definition). NOTE: The term "life-threatening" in the definition of "serious" refers to an event which hypothetically might have caused death if it were more severe.
1. **Expected or Unexpected:** Expected adverse events include muscle soreness during or after exercise, shortness of breath that resolves on cessation of exercise, minor skin irritation, musculoskeletal pain.
 2. **Relatedness to the intervention:** Whether an adverse event could possibly be linked to study participation (due to any study-related activities), adjudicated by clinical investigators at each site. All falls and fractures should be considered adverse events.
 3. **Whether the adverse event leads to cessation of intervention activities**
 4. **Whether the adverse event leads to withdrawal from the study**

All adverse events were reported to the principal investigator (PI). The PI made the decision about the relatedness to the intervention using the Attribution of Adverse Events to Exercise Interventions Sheet [Appendix 2] and decided whether the incident was to be reported to the Office of Research Ethics.

Process Outcomes

- j) **Mode of delivery, device used, technical difficulties:** The following values for one-on-one exercise sessions and nutrition Q&A sessions were recorded:
- Mode of delivery (participants attending by web conference vs telephone)
 - Device used (tablet, laptop or desktop)
 - Technical difficulties
- k) **Video Analytics:** Nutrition videos were posted on a private YouTube® page that was only viewable by participants. The research team used YouTube® video analytics to track the total number of views and the average view duration.

Qualitative Measures:

- l) **Participant experience, suggestions, facilitators of and barriers to sustainability:** Semi-structured interview guides were designed for exit and follow-up [Appendix 2]. The questions from the exit interview were aimed at capturing reasons for participation, benefits, and satisfaction with each component of the program. The follow-up interview captured success and challenges to sustainability and plans to sustain exercise and nutrition behaviours. Interviews were completed over the phone or Teams®, audio-recorded and transcribed verbatim for qualitative analysis.

1.3.9 Data Collection and Management

Screening, Questionnaires and Assessments

Screening tools were completed over the phone with potential participants. Enrolled participants were de-identified and assigned a participant ID that was used in all electronic data collection. The linking document was password protected. Identifiable information (i.e., full name, age, and contact details) was kept on a separate password protected document. All data recorded electronically was stored on a secure lab drive. Only members of the research team, the exercise physiologist and colleagues had access to the lab drive. Questionnaires were hosted by Qualtrics® (Qualtrics, Provo, UT) and responses were stored in the Qualtrics® data centre [<https://www.qualtrics.com/privacy-statement/>]. Similarly, food recall data was stored in the ASA24 (National Cancer Institute, Bethesda, MD) data centre [<https://epi.grants.cancer.gov/asa24/respondent/confidentiality.html>]. At the end of the study, questionnaire and food recall data was downloaded onto Microsoft Excel® (Microsoft Corporation, Redmond, WA) spreadsheets which were then stored on the secure lab drive.

Participants without internet access received study-related forms by mail and completed them over the phone with a research assistant.

Program delivery and Interviews

The exercise physiologist used a standardized log in a Microsoft Excel® spreadsheet to record one-on-one attendance. All files accessed by the exercise physiologist were password protected and stored on the same secure lab drive. One-on-one exercise sessions were delivered via Physitrack® telehealth application which abides by the safety and access standards set forth by the Information and Privacy Commissioner of Ontario. Electronic data was stored in the Canadian database in Montreal [<https://www.physitrack.com/privacy>]. Teams® was used to deliver nutrition Q&As and groups sessions, video record the physical function assessment at baseline and audio record the qualitative interviews at post-intervention and follow-up. The voice and video recordings were immediately transferred from Microsoft Stream® (Microsoft Corporation, Redmond, WA) to the same secure lab drive and deleted from the server. The Canadian data centres are located in Quebec City and Toronto [<https://docs.microsoft.com/en-us/microsoftteams/location-of-data-in-teams>].

1.3.10 Privacy and Confidentiality

Participant privacy and confidentiality was protected throughout the study. Data was secured in accordance with University of Waterloo policies [<http://ist.uwaterloo.ca/security/policy/>]. Electronic records were to be retained for a period of 7 years. The results of this research project were published and presented in such a way that participants could not be identified.

1.3.11 Statistical Analysis

Primary outcomes of recruitment, retention and adherence were reported using descriptive statistics and compared to *a priori* criteria for success to determine feasibility. Sociodemographic and health information was reported using descriptive statistics including mean (standard deviation - SD) for continuous or frequency (percent - %) for categorical variables. Secondary outcome data was cleaned, organized, and inputted into SPSS 27 (IBM Corp., Armonk, NY). The quality of life index value was calculated according to Model 4 as recommended by the EQ5D5L Canadian value set¹⁸⁹. We conducted exploratory analyses of baseline to end of study and baseline to follow up differences using paired (dependant) samples t-tests. Complete case analysis was applied. Effect estimates and standard deviations ($p < 0.05$)

were presented. Adverse events were reported at a patient level (# of events and # of people who had events) and process outcomes were reported using descriptive statistics (sums).

Transcribed exit and follow-up interviews were analyzed using NVivo version 12 Pro (QSR International Pty Ltd, 2020). Qualitative description was used to code participant experience and suggestions for future studies^{190,191}. The inductive process began with open coding where units of meaning were organized into fluid code categories. The first nine transcripts were used to create a basic framework which was then applied to the remaining transcripts (EW). The codes were analyzed and reviewed by two research assistants for consistency (EW & AS). In conjunction, content analysis was used to identify facilitators of and barriers to behaviour maintenance which were mapped to TDF¹⁹⁰⁻¹⁹². The deductive process involved identifying and grouping similar codes (facilitators and barriers) together into meaningful sub-categories to reduce the amount of text while staying close to the data. These sub-categories (constructs) were collapsed into major categories (domains) and their constituent information was mapped to the TDF^{10,131} (Table 12). In a similar manner, BCTs were identified through deductive content analysis and organized according to the BCTTV1 (Table 13).

1.3.12 Ethics and Dissemination

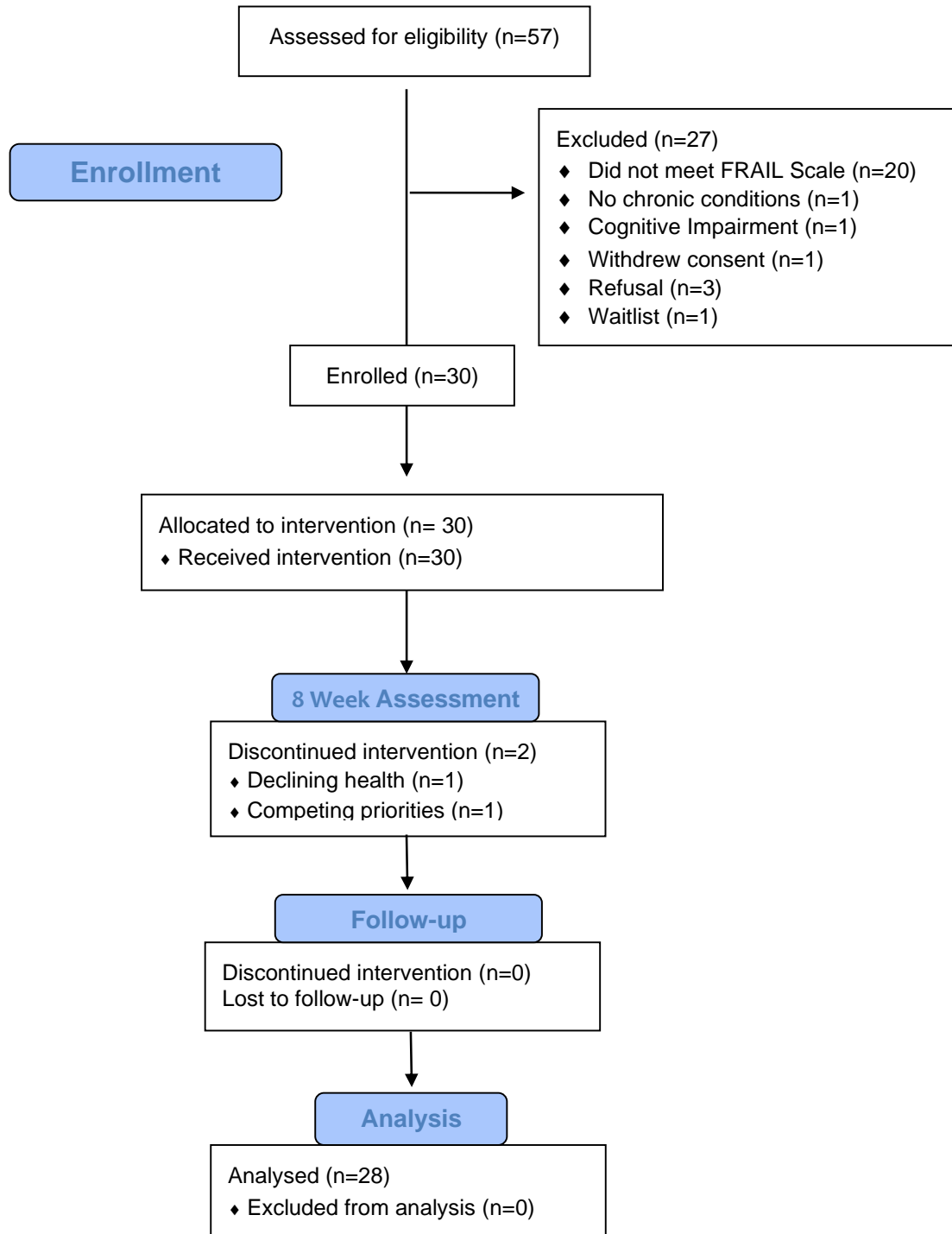
This study was conducted according to the 2014 Tri-Council Policy Statement, [<http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/default/>]. MoveStrong at Home received approval from the University of Waterloo Integrated Research Ethics Board (#42206) and the protocol was registered on ClinicalTrials.gov (#04663685) [<https://www.clinicaltrials.gov/ct2/show/NCT04663685?term=NCT04663685&draw=2&rank=1>]. All amendments were submitted to the University of Waterloo ethics board and to ClinicalTrials.gov. Important protocol modifications such as intervention design and outcome measures were supported with a letter to explain the reason for these changes.

1.4 Results

57 individuals were screened for eligibility over 12 weeks. 22 individuals did not meet the screening criteria; 20 did not meet any FRAIL Scale criteria, one individual did not have any chronic conditions and one individual was living with cognitive impairment. In total, 35 individuals met eligibility criteria (61%); three refused, one withdrew prior to the start of the study, and one was waitlisted. Reasons for refusal included the delay in starting the intervention

and loss of interest. One individual withdrew consent upon receiving multiple diagnoses (acute ear infection, melanoma) from their care provider, which made it unsafe to participate.

Figure 2: Consort Flow Chart



1.4.1 Sociodemographic and Medical Information

22 (73%) individuals were pre-frail, 8 (27%) were frail with an average FRAIL Scale score (SD) of 1.93 (0.89). Participants had anywhere from 1-6 chronic conditions (SD) with an average of 2.97 (1.47). 10 (33.3%) individuals had fallen, and two (6.7%) individuals experienced fractures within 12 months of recruitment (Table 11).

Table 10: Sociodemographic Information

Average Age (SD) years		74 (7.29)
Gender	Female	n (%) 26 (86.7%)
	Male	4 (13.3%)
Ethnicity	Caucasian	29 (96.7)
	South Asian	1 (3.3)
Marital Status	Single	3 (10.0%)
	Married	12 (40.0%)
	Common-law	4 (13.3%)
	Widowed	6 (20%)
	Divorced	5 (16.7%)
Education	Grade school	1 (3.3%)
	High school	2 (6.7%)
	College	1 (3.3%)
	University	16 (53.3%)
	Graduate school	7 (23.3%)
	Professional school	3 (10.0%)
Employment	Retired	26 (86.7%)
	Medical leave	1 (3.3%)
	Full-time	1 (3.3%)
	Part-time	2 (6.7%)
Income (in Canadian Dollars)	<20,000	2 (6.7%)
	20,000 to 40,000	16 (53.3%)
	40,000 to 60,000	10 (33.3%)
	80,000 to 100,000	1 (3.3%)
	Prefer not to say	1 (3.3%)
Area of residence	Urban	21 (70.0%)
	Suburban	5 (16.7%)
	Rural	4 (13.3%)
Place of residence	Lives in the community	24 (80.0%)
	Lives in a retirement home	6 (20.0%)
Co-habitation	Lives alone	14 (46.7%)
	Lives with spouse	15 (50.0%)
	Lives with family	1 (3.3%)

Social interaction	Daily	8 (26.7%)
	Weekly	20 (66.7%)
	Monthly	2 (6.7%)
Assistive Devices (type)	None	14 (46.7%)
	Cane	7 (23.3%)
	Walker	1 (3.3%)
	Cane and Walker	1 (3.3%)
	Walking poles	7 (23.3%)
Assistive Devices (frequency)	Never	14 (46.7%)
	Always	5 (16.7%)
	Occasionally	7 (23.3%)
	Rarely, as needed	4 (13.3%)

Table 11: Frailty Indicators and Health information

FRAIL Scale		n (%)
	Fatigue	11 (36.7%)
	Resistance	17 (56.7%)
	Ambulation	18 (60%)
	Illness	5 (16.7%)
	Loss of weight	6 (20.0%)
Average FRAIL Scale score (SD)		1.93 (0.89)
	#Individuals who were Frail or $\geq 3/5$ indicators	8 (26.7%)
	#Individuals who were Pre-frail or $\leq 2/5$ indicators	22 (73.3%)
Chronic Conditions		
	Cardiovascular (CAD, Congenital Heart Disease, MI)	5 (16.7%)
	Hypertension	9 (30.0%)
	Arthritis	21 (70.0%)
	Obesity	4 (13.3%)
	Diabetes	5 (16.7%)
	Osteoporosis	21 (70.0%)
	Stroke	1 (3.33%)
	Kidney/Liver/Thyroid (Fatty Liver, Hypothyroid)	5 (16.7%)
	Pulmonary Conditions (Asthma, COPD, Bronchitis, Sleep Apnea)	11 (36.7%)
	Autoimmune (Fibromyalgia, Celiac, Hashimoto's)	4 (13.3%)
	Depression	3 (10.0%)
	Average Chronic Conditions (SD)	2.97 (1.47)
Falls and Fractures		
	#Individuals who had a fall in the last 12 months	10 (33.3%)
	#Individuals who had a fracture in the last 12 months	2 (6.7%)

1.4.2 Primary Outcomes

1.4.2.1 Recruitment

In total, 30 participants were enrolled in the study. Half of the participants were recruited from advertising the study via email to a distribution list (n=15). Additional participants were recruited by word of mouth from Registered Kinesiologists at retirement homes (n=6). The remainder were recruited through our network and team members (n=4), social media (n=3) and physician referral (n=2).

1.4.2.2 Retention

28 participants (93%) completed program end and follow-up assessments. Reasons for dropout included declining health and competing priorities/no longer had the time to participate.

1.4.2.3 Adherence

Over 12 weeks, average participant adherence (SD) to one-on-one and independent sessions was 30.2/36 sessions (6.5) or 84%. 28 one-on-one sessions were rescheduled, and 16 absences were recorded. Two participants reported that they did not complete the MoveStrong at Home exercises during the follow-up period, citing poor health and lack of motivation. Participant adherence to nutrition Q&As (SD) sessions was 2.5/3 sessions (0.8) or 82%. 15 absences were recorded. Common reasons for absences for both exercise and nutrition sessions included: forgetfulness (9), poor health/illness/injury (6), medical related appointments (6), adverse events or surgeries (3), conflicts with work (3), lack of interest in nutrition Q&As (3), caretaking (1).

1.4.3 Secondary Outcomes

Table 14: Secondary Outcomes (complete case analysis, n=28 unless specified)

	Baseline	Post		Follow-up		
	Score	Score	Mean Difference	Score	Mean Difference	
3-point Balance Test (SPPB)	3.54 (1.00)	3.64 (1.00)	0.11 (1.20)	3.82 (0.67)	0.29 (0.98)	
30-second Chair Stand Test	8.00 (6.22)	11.50 (7.02)	3.50 (6.11)*	12.54 (7.23)	4.54 (6.69)*	
Physical Activity (PAS)	186 (213) ¹	318 (219) ¹	132 (167)*	269 (183) ¹	82 (150)*	
Exercise Self-Efficacy (ESES)	25.8 (13.7) ¹	34.2 (13.7)	8.4 (11.1)*	35.5 (14.5) ¹	9.7(12.1)*	
Fatigue (CES-D)	1.78 (1.31) ¹	1.07 (1.07) ¹	0.70 (1.17)*	1.07 (1.14) ¹	0.70 (1.27)*	
Mental Well-being (WEMWBS)	53.2 (8.9) ¹	54.5 (7.8) ¹	1.3 (6.5)	53.4 (9.2) ¹	0.2 (6.9)	
Quality of Life (EQ5D5L)	Index Value	0.837 (0.058) ¹	0.806 (0.088) ¹	-0.031 (0.080)	0.808 (0.098) ¹	-0.028 (0.091)
	VAS Self-Perceived Health Rating	70.9 (14.8) ¹	75.8 (12.7) ¹	4.85 (10.8)*	80.1 (13.8) ¹	9.15 (11.9)*
Nutritional Risk (SCREEN II)	30.3 (5.7) ¹	40.3 (6.9) ¹	10.0 (5.4)*	38.6 (8.4) ¹	8.3 (6.4)*	
Food Recall (ASA24)	Total Caloric Intake	1860 (421)	1997 (545)	137 (494)	1885 (493)	25 (538)
	Dietary Protein	79.8 (24.7)	92.7 (29.9)	12.9 (18.4)*	89.0 (29.5)	9.2 (22.7)*

* p<0.05

1.4.3.1 Physical Function (Balance Test and Chair Stand Test)

No statistically significant change in SPPB 3-point balance tests was measured throughout the study ($p>0.05$). However, scores for the 30-second chair stand test were greatly improved post-intervention and maintained through follow-up. On average, participants completed 3.5 (6.1) more chair stands post-intervention and 4.5 (6.7) more chair stands at follow-up.

1.4.3.2 Physical Activity (PAS) and Exercise Self-Efficacy (ESES)

A statistically significant change was seen in self-report moderate to vigorous physical activity (minutes/week). Compared to baseline, participants completed 132 (167) additional minutes of physical activity (per week) at the end of the study and over 82 (150) additional minutes at follow-up. Likewise, exercise self-efficacy had increased by 33% [8.4 (11.1) points] at the end of the intervention and 38% [9.7 (12.1) points] at follow-up.

¹ n=27, Baseline questionnaires (PAS, ESES, CES-D, WEMWBS, EQ5D5L, SCREEN) were not recorded for one participant.

1.4.3.3 Fatigue (CES-D), Mental Well-being (WEMWBS), Quality of Life (EQ5D5L)

A reduction in fatigue of 40% [0.70 (1.17) points] was measure post-intervention and at follow-up. No statistically significant change in EQ5D5L health-related index value was detected ($p>0.05$). However, EQ5D5L self-perceived health status was significantly improved post-intervention [4.85 (10.8)] and at follow-up [9.15 (11.9)].

1.4.3.4 Nutritional Risk (SCREEN) and Food Recall (ASA24)

Nutritional risk was significantly improved, while dietary protein intake was significantly increased from baseline to the end of the study and baseline to follow-up (Table 14). On average, participants consumed 9.2 (18.4) -12.9 (22.7) g more protein each day. No significant change in total caloric intake was measured ($p>0.05$).

1.4.3.5 Adverse Events

Six non-serious adverse events, not attributable to intervention, were reported by 5 participants. One participant reported a fragility fracture of the anterior 5th rib while attempting to lie down on a treatment bed during their osteopathic appointment. After a week of recovery and physician's clearance, the participant returned to a modified program with exclusively lower body movements. The same participant reported to the emergency room due to low oxygen levels that self-resolved on the day of the incident. A second participant experienced an episode of chest discomfort after attending an exercise class in their retirement home. After two days of rest, they resumed their exercise program at reduced volume and gradually worked back up to completing two sets of each exercise. A third participant experienced increased pain as a side effect of a cortisone injection. All weight bearing components were removed for the remainder of the intervention. A fourth participant reported a trip and fall over a street curb during the follow-up period. The participant suffered minor scrapes and bruises. Lastly, one individual developed knee bursitis during the follow-up period and modified their own program.

1.4.4 Process Outcomes

1.4.4.1 Mode of Delivery and Device Used

27 participants attended one-on-one exercise sessions via web conference. 14 participants used tablets, seven used laptops, and six used desktop computers. Three participants connected with the exercise physiologist by telephone. One participant chose to attend via telephone due the constrained space surrounding their desktop computer. Another had trouble operating Physiapp and Teams on their device, while a third participant lacked internet access.

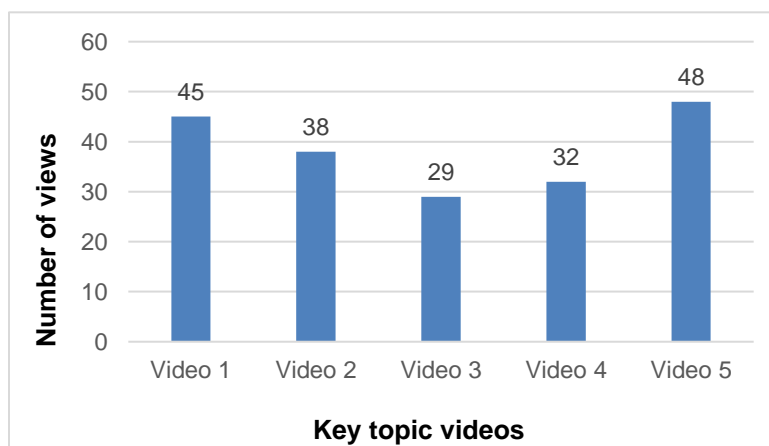
1.4.4.2 Technical Difficulties

52 technological issues occurred across 290 one-on-one sessions delivered by the exercise physiologist (18%). A total of 465 minutes was spent troubleshooting technical issues (5% of total one-on-one delivery time). Common problems included poor internet connection (e.g., lag, frozen screen, dropped calls) and glitches with Physitrack and Teams (audio or visual input, feedback, difficulty sharing screen). Hard-ware incompatibility and operating system software updates forced a handful of participants to switch to WebEx. In addition, participants reported continued difficulties with login for Physiapp and Teams; citing that they could not find the meeting link, forgot personal login credentials or the application was malfunctioning.

1.4.4.3 Video Analytics

The five nutrition videos were viewed a total of 189 times, average view duration per video was 2 minutes and 43 seconds (49%).

Figure 3: Video Analytics



1.4.5 Participant Experience Interviews

We interviewed 28 participants at the end of the study and again at follow-up.

1.4.5.1 Exit Interview

Reasons for joining and perceived benefits

The main reasons participants enrolled in the study were to improve mobility, physical function, overall health and live an active lifestyle despite the presence of chronic conditions.

“Cause I kind of feel that just because I have osteoporosis doesn't mean I can't live a full active life. I'm a very active person, I have tons of energy and I don't want the osteoporosis to slow me down.”

Additional reasons included the inability to access in-person exercise programming due to lockdown restrictions, an interest in research, and environmental factors such as winter weather that disrupted participation in outdoor activities. Participants reported several physical benefits including improvements in strength, balance, mobility, and posture. Levels of energy and the ability to complete daily tasks (e.g., cleaning, gardening) were also improved. Psychological benefits included establishing a sensible exercise routine, as well as increased accountability and motivation to exercise. As one participant noted,

“...it reinforced the importance of exercise in my life.”

One-on-one exercise training

One-on-one training allowed the exercise physiologist to tailor functional movements to meet the specific needs of each participant. Immediate and precise feedback, as well as physical demonstration and verbal cues further enhanced learning.

“The critiquing of my movements was the most important thing. Certainly [exercise physiologist] tweaked the exercises to ones that worked for me and I could do without any discomfort.”

Several participants touched on how accessible and realistic the program was to complete.

“I really like that aspect of it. Like it's not too ambitious, it is doable, and you realized that very quickly.”

Nutrition Q&As

In terms of nutrition, a handful of individuals were surprised to learn that they were not meeting target protein intake (1.0g/kg of BW/day) at baseline.

“I definitely had no idea about the protein. And I don't know why I didn't realize how important that was and that I really wasn't getting nearly enough.”

Individuals looked forward to having their specific questions answered by the registered dietitian. In addition, participants enjoyed the suggestions and recipes that were circulated, including vegetarian and vegan options. The nutrition education booklet was generally well received, the only comment being that the information provided was relatively basic.

“You know, some of some of the materials, like I say, you know, without sounding too full of myself, I think I'm fairly knowledgeable about nutrition already.”

Physiapp

Physiapp was positively reviewed. The word *“helpful”* was often used to describe the audio, visual and written exercise instructions that reminded participants to execute the functional movements with proper form.

“I really like the PhysiApp. To be able to see someone doing the exercises again, and [exercise physiologist] could put in their own comments. I could mark it complete and go on.”

However, several individuals commented on the fact that the exercises described in the app were not always aligned with the variation they were prescribed which caused confusion.

1.4.5.2 Follow-up Interview

Capability

Within the capability system, three TDF domains (Knowledge, Skills, Behavioural Regulation) were described and corresponded to both psychological and physical capability. Many participants mentioned an increase in exercise and nutrition related knowledge.

“I certainly have a greater awareness of sources of protein and that intake over the day has to be somewhat distributed.”

It was important to participants to develop the skills needed to execute functional movements with good form or modify exercises to be more suitable to their needs.

“I can look at an exercise and kind of analyze it better and say oh yeah, that that would be a good one.”

However, physical restrictions such as poor health and pain/discomfort acted as barriers which limited the capacity to sustain change. The use of behavioural regulation strategies such as self-monitoring (i.e., tracking exercise adherence and keeping a food journal) were consistently mentioned. In addition, participants emphasized the importance of forming a schedule and integrating functional movements into their day whenever possible.

“I can do my balance while I'm waiting for the kettle to boil, I mean those are functional things that that I can do anyplace”.

For nutrition, participants engaged in meal planning and made a point to consciously incorporate protein at each meal.

Opportunity

Two TDF domains (Environmental Context and Resources, Social influences) were related to the opportunity component of the COM-B model. Participants articulated numerous situational hinderances such as COVID related anxiety and the holidays (Christmas and Easter long weekend) which derailed regular physical activity and dietary patterns. Facilitators include rearranging furniture or dedicating a specific space to exercise, as well as utilizing prompts, cues, and reminders. A lack of accountability and social support were reported as barriers to exercise maintenance during follow-up.

“I’m a person who likes to have accountability, homework, somebody who’s supporting me, all those things are helpful, so I definitely found it much more difficult this month to do the program.”

Motivation

In terms of Motivation, six domains were covered during participant interviews (Beliefs about capabilities, Beliefs about consequences, Reinforcement, Emotion, Intentions and Goals) that touched on both automatic and reflexive motivation. Participants developed self-efficacy and learned to enjoy the challenge of a progressive training program. One individual noted, *“I’m able to have a little bit more confidence now when I move around the house or go out, and not think about falling”*. A few participants felt that a lack of appetite and food intolerances made it more difficult to meet target protein recommendations. Luckily, participants agreed that the physical and psychological improvements they experienced were strong motivators for sustainability. Unfortunately, a couple of participants reported a lack of non-specific motivation.

“I haven’t been able to make myself do this regularly. I’ve been able to schedule it and I’ve been able to have a good attitude toward doing it, and then I have not done it most of the time.”

Reinforcement was provided through meaningful commitments to oneself and support from Physiapp. Several individuals reported emotions such as *“feeling good”* after they exercise. Overall, participants intended to continue with their prescribed program beyond the follow-up period. Participant goals were related to being healthy and active, as well as maintaining independence and fending off chronic conditions.

“I don’t want to get to the point where I can’t be mobile. Where I live, I’m in an apartment building. I see folks that have gotten to that point, and you know they’re down to walkers and next to a wheelchair type of thing. And I want to avoid that as long as I can.”

Table 12: Behavioural Constructs mapped to the Transtheoretical Domains Framework

COMB-B systems	TDF domains
<p>Capability (the individual's capacity to engage in behaviour modifications)</p>	<p>(1) Knowledge</p> <ul style="list-style-type: none"> ✓ Exercise-related knowledge and proper form (exercise) ✓ Awareness and recognition of the importance of protein (nutrition) <p>(2) Skills</p> <ul style="list-style-type: none"> ✓ Ability to assess, modify and complete exercises independently (exercise) ☒ Poor health, injury, or pain/discomfort (exercise) <p>(14) Behavioural regulation</p> <ul style="list-style-type: none"> ✓ Forming an exercise routine or schedule (exercise) ✓ Tracking, recording, or journaling (exercise and nutrition) ✓ Meal planning (nutrition) ✓ Incorporating high protein options at each meal (nutrition)
<p>Opportunity (factors in the environment that influence individual behaviours)</p>	<p>(11) Environmental context and resources</p> <ul style="list-style-type: none"> ✓ Rearranging space, prompts/cues, and reminders (exercises) ☒ Lack of time or schedule conflicts (exercise) ☒ Holidays (exercise & nutrition) ☒ COVID-related anxiety (exercise & nutrition) <p>(12) Social influences</p> <ul style="list-style-type: none"> ☒ Lack of accountability or social connection (exercise)
<p>Motivation (the individual's willingness to change)</p>	<p>(4) Beliefs about capabilities</p> <ul style="list-style-type: none"> ✓ Enjoys a challenging and progressive exercise program (exercise) ✓ Improved exercise self-efficacy or confidence (exercise) ✓ Enjoys high protein foods (nutrition) ✓ Protein sufficient diet (nutrition) ☒ Lack of non-specific motivation (exercise) ☒ Lack of appetite and food intolerances (nutrition) <p>(6) Beliefs about consequences</p> <ul style="list-style-type: none"> ✓ Ability to complete ADLs (exercise) ✓ Gait and mobility (exercise) ✓ Strength and balance (exercise) ✓ Psychological benefits (exercise) ✓ Tailored functional movements (exercise) ☒ Fear of gaining weight (nutrition) <p>(7) Reinforcement</p> <ul style="list-style-type: none"> ✓ Physiapp - visual, audio and written instructions (exercise) ✓ Commitment (exercise and nutrition) <p>(8) Intentions</p> <ul style="list-style-type: none"> ✓ Consciously think about incorporating protein into their diet (nutrition) ✓ Continue exercising at the same frequency each week (exercise) <p>(9) Goals</p> <ul style="list-style-type: none"> ✓ Be healthy, active, mobile, and strong (exercise and nutrition) <p>(13) Emotion</p> <ul style="list-style-type: none"> ✓ "Feel good/better" or improvements in mood

- ✓ Facilitator
- ☒ Barrier

Behavior Change Techniques (BCTs)

The most frequently mentioned BCTs [≥ 8 mentions] that contribute to the sustainability of exercise and nutrition behaviours include Goal setting (outcome), Action planning, Commitment, Self-monitoring of behaviour and Monitoring of emotional consequences. Somewhat frequently used BCTs [3-7 mentions] include Goal setting (behaviour), Anticipated regret, Prompts/cues, Restructuring the physical environment, Behavioural practice/rehearsal, Behaviour substitution, Habit formation, Generalisation of target behavior and Graded tasks. None of the BCTs mentioned by participants targeted the IFs of Education, Incentivization, Coercion, Restriction and Modelling.

Table 13: Behaviour Change Techniques reported in Exercise and Nutrition Maintenance¹¹

Intervention Functions	Behaviour Change Techniques
Education	
Persuasion	5.4 Monitoring of emotional consequences*
	5.5 Anticipated regret
	9.3 Comparative imaging of the future
	10.8 Incentive (outcome)
	13.2 Framing/reframing
	15.3 Focus on past success
	15.4 Self-talk
Incentivization	
Coercion	
Training	2.3 Self-monitoring of behaviour*
	8.1 Behavioural practice/rehearsal
	8.2 Behaviour substitution
	8.3 Habit formation
	8.6 Generalisation of target behavior
	8.7 Graded tasks
Restriction	
Environmental restructuring	7.1. Prompts/cues
	12.1 Restructuring the physical environment
	12.5 Adding objects to the environment
Modelling	
Enablement	1.1 Goal setting (behavior)
	1.2 Problem solving
	1.3 Goal setting (outcome)*
	1.4 Action planning*
	1.9 Commitment*
	11.3 Conserving mental resources

Most frequently mentioned*

Somewhat frequently mentioned

In-person vs home-based

When asked if they preferred an in-person or home-based program, many individuals expressed that they greatly valued the social component of in-person exercise.

“I like social interaction. Seeing the person and being able to ask questions or make comments, I like that format and the encouragement.”

On the other hand, individuals recognized the accessibility and practicality of a home-based program. As one individual noted,

“The advantages of being at home is you can do whatever you want. You can kind of wear what you want. No one's going to see you. You could do it early in the morning or late at night. Or you can split it up into two sessions.”

The main determinant for participants when choosing to take part in an exercise program is *“Location, location”*. Other important factors included time of day, road conditions, level of expertise of the instructor, and costs (program and parking).

Staying connected using social media

Participants expressed interest in staying connected after the study. Most individuals were open to the idea of connecting over a Facebook group to receive information and share ideas, even if they had no previous experience with social media. Others were concerned about privacy and confidentiality online.

“My concern with Facebook is that there's so little security. I don't know it, when you put something on, it goes everywhere, and I'm just not comfortable with that.”

A few individuals cited *“feeling overwhelmed”* or *“getting lost”* when using online platforms.

Suggestions for future studies

Participants recommended a thorough description of the benefits of functional strength and balance training and the importance of sufficient protein intake to help *“establish context”* at the start of the intervention. For written and mailed instructions, a few participants asked for more information regarding proper training techniques; noting that breathing, timing for each

part of the movement, and rest periods became especially important as their exercises progressed. Others requested details related to the theory of exercise overload and program design to help inform future progressions that they would have to make on their own. In addition, several individuals requested measurements that would allow them to track physical changes.

“...because you're not really measuring tangible things like your weight or doing some real physical measurements pre and post, you have to rely on how you feel.”

It was noted that greater structure during the nutrition Q&A sessions would allow for a more productive use of time. Specific suggestions included, asking the registered dietitian to present a few ideas at the beginning of each session to prime appropriate and focused discussion.

“...my recollection is that we always started with okay, well what questions do you have today? And maybe to have it a little more focused and with something that provided a catalyst focus to take off. Maybe it's a 10-minute presentation or something like that...”

In terms of study design, participants recommended a longer study duration with at least a 12-week follow-up period to support maintenance. The importance of reminders and check-ups was especially emphasized. Participants proposed a formal wrap-up session to review the purpose of the study and plan exercise progressions.

1.5 Discussion

From our study we determined that remotely delivered one-on-one functional strength and balance training, combined with nutrition education was feasible and acceptable according to *a priori* criteria. We recruited 30 participants (≥ 25) within 12 weeks, achieved an adherence rate of 84% for exercise and 82% for nutrition ($\geq 70\%$) and retained 93% ($\geq 80\%$) of participants through follow-up. Overall individuals were extremely satisfied with the remotely delivered program and many reported physical and psychological benefits including improvements in strength, balance, mobility, and mood. In addition, significant changes were measured in exploratory outcomes including the 30s chair stand test, levels of physical activity and dietary protein. From the qualitative interviews, we identified barriers to sustainability and mapped them to the TDF domains of environmental context and resources, and social influences (opportunity). No adverse events related to intervention occurred. Although results are

encouraging, a larger pragmatic trial is needed to confirm our findings and determine preliminary effectiveness.

Remote delivery has the potential to extend the reach of health-related services and improve feasibility. A growing body of research suggests that the use of non-traditional recruitment strategies such as email lists and social media can be cost-effective alternatives, especially during the COVID-19 pandemic^{138,193}. Half of the MoveStrong at Home participants were recruited by email distribution list within the first few weeks of the screening period. In addition, participants agreed that the timing and logistics of the feasibility trial made it appealing, especially during winter months when travel became an issue. Secondly, telerehabilitation has been found to positively affect levels of adherence in clinical populations¹⁴⁹. As mentioned previously, remote delivery has the potential to increase accessibility and practicality. In the future, a hybrid model that encourages participants to attend in-person or from the comfort of their own home may better support long-term engagement. Lastly, e-health interventions are hampered by substantial participant attrition¹⁹⁴. Druce et al. (2019) were successful at retaining participants in their study by prioritizing the usability of technology, motivating factors and personal contact¹⁹⁵. MoveStrong at Home used similar strategies including a technology session to familiarize participants with communication platforms, a personalized training program that was more tolerable for frail individuals and weekly one-on-one sessions with the exercise physiologist.

Significant improvements were measured in secondary outcomes including the 30s chair stand test, levels of physical activity, exercise self-efficacy, fatigue, self-perceived health status, nutritional risk, and protein intake. At baseline, three participants (10%) reported joint pain/discomfort and declined to participate in the 30s chair stand test. Another five participants (17%) were unable to complete the test without the use of their hands, which resulted in a score of zero. Two participants post-intervention (7%) and three participants (11%) at follow-up declined to participate due joint pain/discomfort. At baseline, 13 participants (43%) achieved ≥ 150 minutes of moderate to vigorous physical activity each week, while only seven (23%) participants completed muscle strengthening ≥ 2 times per week. At the end of the study and follow-up, 20 participants (71%) met physical activity recommendations, while 26 participants (93%) performed strength training ≥ 2 times per week. At baseline, 14 participants consumed < 1.0 g of protein/kg of BW/day. At the end of the 8-week intervention and follow-up this number had decreased to six and eight participants, respectively.

No significant change in SPPB 3-point balance test was measured. Overall, our sample had fairly strong scores at baseline [3.54 (1.00)], which were comparable to normative population values for adults 70-79 years of age [3.5 (1.0)]¹⁹⁶. A ceiling effect was detected in 23/30 tests (77%) at baseline which has been observed previously in studies involving community-dwelling older adults in Canada¹⁹⁷. Perera et al. (2006) estimated that meaningful change for the SPPB test is 1.00 points¹⁹⁸, however we only utilized a single component of the assessment. Secondly, it is important to note that several balance tests were completed by telephone, therefore we were unable to visually verify foot positioning or proper use of support objects. Thirdly, we did not assess dynamic balance (e.g., Four Square Step test) due to safety concerns. It has been suggested that balance tests which are too easy can mask the underlying deficits and fail to capture significant improvements¹⁹⁹. There is a need to develop tools that are appropriate for measuring physical function in community-dwelling older adults, especially ones that can be administered and monitored in person, virtually or by telephone.

Mental well-being and quality of life remained consistent throughout the intervention; no significant changes were detected. However, it is possible that participation in MoveStrong at Home acted to offset situational and environmental stressors. As Reardon (2015) previously noted, the number of individuals whose mental health is affected during pandemics tends to exceed the number affected by the disease²⁰⁰. It is well reported that COVID-19 triggered a rise in self-report loneliness and levels of anxiety around the world^{201,202}. Furthermore, there is uncertainty regarding the effects on home-based physical activity interventions on quality of life in frail older adults^{70,203}. A recent review by Campbell and colleagues suggests that improvements in quality of life and physical function are coupled due to the multi-factorial nature of frailty²⁰⁴. Since several participants experienced adverse events and underwent surgery (i.e., excision biopsy and knee replacement), a temporary reduction in physical function may have affected quality of life. An isolated examination of the influences of the global pandemic and confounding factors may help to better explain our results.

The importance of social support in the delivery of remote lifestyle interventions for older adults has been observed previously^{205,206}. A cross-sectional analysis of a sample of 586 community-dwelling individuals over the age of 65 found that social support is the strongest predictor of a reduction in depressive symptomology, particularly when combined with positive exercise-induced mood states²⁰⁷. For older adults living with frailty, physically active makes

social interaction possible and facilitates participation⁹⁵. Furthermore, there is emerging evidence to suggest that mobile technology can create opportunities for social connectedness and reduce feelings of loneliness among older adults^{208,209}. However, individuals who are not already socially connected seem to benefit less from online communication than those who are²¹⁰. To add on, balancing social interaction and the need for privacy and confidentiality in a virtual environment proved to be a challenge. More research is required to determine how best to create secure opportunities for dialogue among older adults, especially those who are not already socially connected.

Overall, the uptake of technology was acceptable. Participants demonstrated willingness to learn how to operate Physiapp and Teams for the intervention. However, Physiapp required non-mobile users to login and Teams required preregistration for an account. Additional steps to getting online created a barrier to entry and participants lacked the skills to troubleshoot minor technical issues that arose. Maki et al. have previously observed low usability of e-health tools among older adults living with frailty^{211,212}. Literature suggests that ease-of-use is necessary in promoting practicality, smooth operation, and adherence to therapy²¹³. Our findings suggest that proper training and on-going technical support are also vital. The true impact of technology on the uptake and effectiveness of behaviour change interventions has yet to be demined.

1.5.1 Limitations

We acknowledge several design limitations of our feasibility study. First, the likelihood of self-selection bias was high as individuals volunteered to be in an exercise and nutrition education program. Half of the participants were recruited by email distribution list and thus represent a convenience sample. Our intention was to determine feasibility, and not the effectiveness of the protocol. Secondly, a within-subject design allowed us to provide the intervention to all participants. However, results are subject to extraneous variables such as lockdown restrictions that could have masked the true effect of the intervention on outcomes. Furthermore, the generalizability of the results is limited to independent, community-dwelling pre-frail and frail older adults. Only four (13.3%) participants in our sample were male. Individuals living with cognitive impairment were excluded from the study. In addition, a large proportion of participants identified as Caucasian, socioeconomically advantaged, and lived in an urban area with internet access. During follow-up interviews, participants expressed concerns over the lack of continued guidance and resources on how to progress exercises. In future studies, considerations for sustainability should be made during the design process.

1.5.2 Implications for practice

Future studies should consider the possible merits of individualized, multicomponent, and progressive exercise programs, delivered one-on-one, either in-person or remotely. The act of tailoring movements is necessary to meet the specific needs of an individual and the functional limitations of a particular illness/injury. The creation of a scalable framework to guide exercise prescription may be a viable option. In addition, exercise physiologists and kinesiologists are an underutilized human resource capacity that can translate knowledge, possibly improve cost-effectiveness, and scale implementation. Researchers would do well to provide standardized training and resources for exercise professionals and monitor program fidelity.

For the health care system to reach underserved populations, it must first involve underrepresented groups in the research process. It is well established that race, income and area of residence are strong predictors of physical activity and health outcomes across age groups^{214–216}. Previous findings suggest that minority groups are equally willing to participate in health care research²¹⁷. However, meaningful participation among marginalised communities may require translated materials, interpreters and the recognition of different ethical values; all of which increase costs and resource use²¹⁸. To add on, more recent findings suggest that modest financial incentives can support research participation and long-term exercise adherence²¹⁹. Funding agencies have a role to play in terms of the requirements and budgeting for grants. Lastly, buy-in from policy makers is required to expand communication infrastructure to those living in rural or remote areas to lay the groundwork for successful service delivery.

Participatory research and co-design of innovations with older adults living with chronic conditions and mobility impairments is imperative. The importance of providing education and training for older individuals has been emphasized in the literature^{213,220}. During intake, it is worth noting levels of comfort with technology and which device/model the participant owns, as well as any previous experience with technology. To improve the usability of applications, researchers can create step-by-step instructional videos and printed manuals that include visual and written guidance. Despite interest in specific technologies for everyday use²²¹, older adults in particular, are concerned about privacy and unfamiliarity with technology²²². It is critical to first establish if participants are comfortable with sharing their name, audio, and visual data. A brief reminder of the data policy and a quick review of basic operating functions at the beginning of group sessions may help to alleviate concerns. Lastly, it is worth exploring the use of

determinants (social support) and behaviour change techniques (self-monitoring and feedback) in the design of lifestyle technology to further support the adoption and maintenance of healthy behaviours.

1.6 Conclusion

Our study demonstrated the feasibility and acceptability of a model for remote delivery of functional strength and balance training combined with nutrition education. MoveStrong at home exceeded *a priori* criteria for community and network recruitment, 12-week retention, and adequate adherence. Furthermore, participants expressed positive feedback and their intention to continue exercising and consuming more protein beyond short-term follow-up. The success of our feasibility study can be attributed to the theory-guided implementation process. Contributions from stakeholders helped to ensure that the intervention was both relevant and appropriate for the target population and context. The use of behaviour change frameworks allowed us to identify and target determinants of change while accounting for barriers to participation. Several amendments must be made to the study design and protocol to address opportunity barriers and support sustainability in future pragmatic trials. Our finding will be disseminated through online resources and public webinars on exercise and nutrition hosted by the Osteoporosis Canada and the Research Institute for Aging.

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Appendices

Appendix 1

Table 1: Study Timeline

	Week -4 &-3	Week -2 &-1	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9	Week 12 Follow Up
Questionnaires	X										X	X
Physical Function Assessments	X Video/Audio recording										X	X
3 Day Dietary Recall		X	X								X	X
Exit interview	as necessary										X	
Follow up interview												X
1-on-1 session		X Meet & Greet	X 2 sessions	X 2 sessions	X	X	X	X	X	X Planning for Sustainability		
Nutrition session				X		X		X				
(Optional) Group Session					X		X		X			

Table 2: Study Schedule

	PHASE I (9 participants)	PHASE II (Remaining participants, 21)
Recruitment & Screening	October 5th - December 25th (12 weeks)	
Technology Consultation & Baseline Assessment	October 13 th - 16 th (2 weeks prior)	Nov 23 rd - Dec 29 th
Meet & Greet	October 19 th - 23 rd (1 week prior)	January 4 th - 15 th (2 weeks prior)
Intervention (Weeks 1-8)	October 26 th - December 18 th	January 18 th - March 12 th
Post Assessment (Week 9)	December 19 th & 21 st (2 days)	March 15 th - 19 th (1 week)
Follow-Up Assessment (Week 12)	January 11 th - 15 th (1 week)	April 5 th - 9 th (1 week)

Table 3: Outcomes & Assessments

	BASELINE 5 hours	POST 3 hours	FOLLOW-UP 3 hours	MODE OF DELIVERY
Screening & Recruitment Survey (30min)				Telephone
Consent Process (10min)				Telephone
Sociodemographic Info and Medical History (30min)				Telephone
Questionnaires (30min) <ul style="list-style-type: none"> • Physical Activity Screen (PAS) • Exercise Self-Efficacy Scale (ESES) • Center for Epidemiologic Studies Depression Scale (CES-D) • Warwick-Edinburgh Mental Well-being Scale (WEMWBS) • EuroQol Group 5 Dimension 5 Level questionnaires (EQ5D5L) • SCREEN tool 				Qualtrics (online) or Telephone <i>*Completed independently or with the help of the research assistant</i>
Technology Consultation (30min)				Physiapp, Teams or Telephone
Physical Function Assessment (30min)	Video recorded			Teams
ASA 24 (3X30min)				ASA 24 Website (online) or Telephone <i>*Completed independently or with the help of the research assistant</i>
Meet & Greet (50min)				Physiapp, Telephone
Interviews (30min)		Audio recorded	Audio recorded	Teams

Table 4: MoveStrong Logic Model (Intervention Map)

Project: MoveStrong at Home					
Goal: Evaluate the feasibility of remotely delivered exercise and nutrition education among pre-frail and frail community dwelling older adults (60+).					
INPUTS		ACTIVITIES		OUTCOMES	
What we invest	What we do	Who we reach	Why this project: short-term results	Why this project: intermediate results	Why this project: long-term results
<p>Funding: Network of Aging Research</p> <p>Personnel: Graduate Student, Research Coordinator, Registered Dietitian</p> <p>Partners: RIA, CCCARE, OP Canada, CSC, YMCA</p> <p>Equipment: Computer, Internet</p> <p>Materials: Exercise band, printed nutrition education booklet and program instructions</p> <p>Technology: Physitrack/Physiapp, Microsoft Teams and WebEx</p>	<p>Deliver weekly 30min 1-on-1 training session by web conference or telephone.</p> <p>Host threeX60min Nutrition Q&A sessions during weeks 2,4,6.</p> <p>Support behaviour change over threeX60min group sessions during weeks 3,5,7.</p>	<p>≥25 pre-frail/frail older adults (60+) in Ontario.</p>	<p>Establish feasibility:</p> <ol style="list-style-type: none"> 1. Recruitment – ≥25+ participant/3 months 2. Adherence – ≥70% 3. Retention – ≥80% <p>Improve outcomes:</p> <ul style="list-style-type: none"> • Physical functional (strength and balance) • Levels of physical activity and exercise self-efficacy • Fatigue, mental wellbeing, quality of life • Nutritional risk and protein intake 	<p>Developpe exercise nutrition behaviors:</p> <ul style="list-style-type: none"> • Functional strength and balance training 3X/week for 30min • Protein intake of 1.0-1.5g/kg of body weight each day • Use the finding to inform the development of a sustainable and scalable model for large scale implementation 	<p>In pre-frail/frail older adults (60+) in Ontario:</p> <ul style="list-style-type: none"> • Prevent and manage frailty. • Improve health outcomes. • Maintain independence.

<p>Assumptions</p> <ul style="list-style-type: none"> • Pre-frail and frail older adults in Ontario are interested in taking part, can be motivated to exercise consistently (3 days/week), and remain engaged throughout (attrition rate <20%). • Participants are English speaking and have web conferencing or telephone capabilities. 	<p>External Factors</p> <ul style="list-style-type: none"> • (+) Accessibility and practicality of a tailored home-based exercise program may encourage adoption and maintenance. • (-) Dependent on external funding. • (-) Unforeseen technical difficulties can hinder communication and delivery. • (-) Data privacy and security issues with the virtual environment.
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Table 5: CONSORT 2010 Checklist: Information to include when reporting a pilot or feasibility trial

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a pilot or feasibility randomised trial in the title	iii
	1b	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	iii
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	11
	2b	Specific objectives or research questions for pilot trial	12
Methods			
Trial design	3a	Description of pilot trial design (such as parallel, factorial) including allocation ratio	13
	3b	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	14
	4b	Settings and locations where the data were collected	13
	4c	How participants were identified and consented	14
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	14-19
Outcomes	6a	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	20-23
	6b	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
	6c	If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	12
Sample size	7a	Rationale for numbers in the pilot trial	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation			
Sequence generation	8a	Method used to generate the random allocation sequence	NA
	8b	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12	Methods used to address each pilot trial objective whether qualitative or quantitative	25
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	26
	13b	For each group, losses, and exclusions after randomisation, together with reasons	26

	14a	Dates defining the periods of recruitment and follow-up	Appendix 1 - Table 2
Recruitment	14b	Why the pilot trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	27,28
Numbers analysed	16	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	29,30
Outcomes and estimation	17	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	26-38
Ancillary analyses	18	Results of any other analyses performed that could be used to inform the future definitive trial	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	31
	19a	If relevant, other important unintended consequences	NA
Discussion			
Limitations	20	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	42
Generalisability	21	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	39, 42
Interpretation	22	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	39-43
	22a	Implications for progression from pilot to future definitive trial, including any proposed amendments	44
Other information			
Registration	23	Registration number for pilot trial and name of trial registry	26
Protocol	24	Where the pilot trial protocol can be accessed, if available	26
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13
	26	Ethical approval or approval by research review committee, confirmed with reference number	26

Citation: Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010, extension to randomised pilot and feasibility trials, Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Table 6: TIDieR Checklist: Template for Intervention Description and Replication for the MoveStrong Program

Item Category	Description
Brief name	MoveSTroNg at Home: A model for remote delivery of functional strength and balance training with nutrition education for older frail adults in Ontario. A Feasibility Study.
Why	The purpose of this study is to evaluate the feasibility of a remotely delivered exercise program that focuses on functional movement patterns, high protein intake and behaviour change strategies to help older adults improve levels of physical activity.
What: Materials	<p>1) <u>Participant's program instructions package</u> will be used during and after the intervention. The package contains a description of the functional movements, goal setting and action planning resources, RPE scale, Decision aid and other exercise materials.</p> <p>2) <u>Participant's nutrition booklets</u> will be used during and after the intervention. The booklets contain tips and recipes complimented by pictures and visual cues to encourage greater protein intake throughout the day.</p> <p>3) <u>Instructor's manual</u> will be provided to the exercise instructor prior to the start of the program and contains information on how to run the exercise programs (e.g., equipment and set-up, how to select and teach each exercise, safety, warm-up and cool down, etc.), as well as cueing tips.</p> <p>4) <u>Study manual</u> will be provided to the exercise physiologist and the dietitian, and other individuals involved in implementing the MoveStrong program. The manual contains information about the program timeline, informed consent, and adverse event reporting.</p> <p>5) <u>Equipment</u> will be mailed to participants (exercise band).</p>
What: Procedures	The exercise physiologist will review each participant's medical history and meet with them prior to the start of the program. The participant and the exercise physiologist will select one of four starting levels for each movement. There are 7 functional movements (see Table 7) which will be progressed, as necessary.
Who: Provided	Weekly one-on-one sessions and virtual group sessions will be delivered by an exercise physiologist. The nutrition sessions will be offered by an experienced dietitian.
How	The intervention is provided remotely by web conference or telephone (Physiapp and Teams). All materials will be mailed to the participants
Where	Participants will complete the exercise in their own homes, twice weekly.
When and how much	<p>Frequency/Duration: 2x/week for weeks 1-2, 1x/week for week 3-8, 30 minutes/private session</p> <p>Intensity: 2-3 sets of 8-10 repetitions of each exercise with time under tension per repetition of 4:0:2 seconds for eccentric: isometric:concentric phases.</p>
Tailoring	Individual tailoring of repetitions, sets, and exercise variation will be provided during a weekly 30min one-on-one session with the exercise physiologist. The dietitian will be available to answer participant questions during the three 60min nutrition Q&As.
Modifications	No modifications at this time.
How well	<p>Planned: No fidelity assessment planned.</p> <p>Actual: No fidelity assessment planned.</p>

Table 9: MoveStrong Movements with Progressions

Exercise physiologist selects 1 version per movement for each participant (intensity 3-8RM, volume 2-3 sets, 3 to 8 repetitions, time under tension per rep of 4:0:2 seconds, eccentric:isometric:concentric). Progression: increase resistance, weight, or volume (e.g., sets, reps), or select a harder exercise. Seated exercises are for participants who cannot perform level 1, even with a support object.

Functional movement	Seated Version ³	Level 1	Level 2	Level 3
1. Balance	Dance Step, add arms March	Standing march Weight shifting	Tandem walk Grape vine	Tandem walk, add leg lift/head turn Single leg stance
2. Pull	Resisted ¹ row	Resisted ¹ row Resisted ¹ pull apart	Resisted ¹ pull down or pull apart, ↑ resistance	Single arm resisted ¹ pull down or row
3. Squat	Press ups (use arms) Resisted ¹ leg press	Sit to stand (may use arms)	Low unassisted sit to stand Half squat	Body weight squat
4. Push	Resisted ¹ chest press	Resisted ¹ chest press Wall push up	Narrow Wall push up	Counter/table push up
5. Hinge	Hip hinge	Standing wall tap	Supine glute bridge ²	Single leg supine glute bridge ²
6. Lift and carry	Perched posture with pressure through feet	Stand tall walk	Stand tall & carry	Lift & Carry
7. Calf Raise	Weighted ¹ calf raises	Calf raise	Elevated calf raise	Single leg calf raise
8. Step ups		Low step up	Step up, add hip extension	Weighted ¹ step up

¹Resisted: use elastic tubing or bands. Weighted: weights or household objects, held close to body e.g., water bottles, laundry detergent, weighted grocery bags or backpack. Priority is form over intensity. ²Include transitions of getting on and off floor if that is participant's goal, with or without chair or support object.

Table 15: Variables, Hypotheses, Primary Outcomes and Methods of Analysis

Variable	Hypothesis	Outcome Measures	Methods of Analysis
Primary			
Recruitment	We will recruit 25 participants over 3 months (8 participants per month).	Number of participants recruited	Descriptive statistics
Retention	We will retain ≥80% of our sample.	Number of participants that we can gather data from at follow-up.	
Adherence	The average proportion of exercise and nutrition Q&A sessions completed will be ≥70%.	% of completed sessions (one-on-one and nutrition seminars)	
Participant Experience	Answers to questions and suggestions for future trials (Inductive) Facilitators of and barriers to maintenance (Deductive – Mapped to the TDF and BCW)	Semi-structure Exit & Follow-up interviews	Qualitative Description

Table 16: Variables, Hypotheses, Secondary Outcomes and Methods of Analysis

Variable	Hypothesis	Outcome Measures	Methods of Analysis
Secondary			
Sociodemographic and medical information		<ul style="list-style-type: none"> • PROGRESS-PLUS 	Descriptive statistics
Physical Activity	Increased Physical Activity	<ul style="list-style-type: none"> • Physical Activity Screen 	Paired T-test (for exploratory analyses)
Frailty indicators	Reduced Fatigue	<ul style="list-style-type: none"> • CES-D (Fatigue questions) 	
Quality of Life	Increase Quality of Life	<ul style="list-style-type: none"> • EQ5D5L 	
Well-being	Increased Well-being	<ul style="list-style-type: none"> • WEMWBS 	
Exercise Self-Efficacy	Increased Exercise Self-Efficacy	<ul style="list-style-type: none"> • Modified ESES 	
Nutrition	Reduce Nutritional Risk	<ul style="list-style-type: none"> • SCREEN Tool 	
Food Recall	Increased Protein Consumption	<ul style="list-style-type: none"> • ASA24 	
Adverse Events	Participants will most likely experience minor musculoskeletal changes due to the intervention	<ul style="list-style-type: none"> • Self-report adverse events 	Descriptive statistics
Process Outcomes		<ul style="list-style-type: none"> • Mode of delivery • Physitrack & Teams tech issues • YouTube video analytics • Technological devices <ul style="list-style-type: none"> • Activity trackers • Cubii or other devices 	Descriptive statistics
Exercise Compliance	The average proportion of functional movements completed per session at post intervention (9 weeks) and at follow-up (12 weeks) will be $\geq 70\%$.	<ul style="list-style-type: none"> • % of completed functional movements 	Descriptive statistics

Appendix 2

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 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: <input type="text"/>
SCREENING & RECRUITMENT	
Date of Screening & Recruitment interview: <input type="text"/> <small style="text-align: center;">dd-mmm-yyyy</small>	
Was VERBAL consent received to conduct the Screening & Recruitment interview? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Completed by Research Team Member: <input type="text"/>	
INFORMED CONSENT	
When was the consent form first given to the participant?	
Date: <input type="text"/> <small style="text-align: center;">dd-mmm-yyyy</small>	Time: <input type="text"/>
When was VERBAL consent given by the participant?	
Date: <input type="text"/> <small style="text-align: center;">dd-mmm-yyyy</small>	Time: <input type="text"/>
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	<input type="text"/>
The procedures of the trial were explained to the participant	<input type="text"/>
The possible risks and benefits of participation were explained to the participant	<input type="text"/>
The scope of privacy and confidentiality was explained to the participant	<input type="text"/>
The voluntary nature of the trial and its components were explained to the participant	<input type="text"/>
QUESTIONS (list all questions asked, and the responses given)	
COMMENTS	
Signature of Research Team Member: <input type="text"/>	Date: <input type="text"/> <small style="text-align: center;">dd-mmm-yyyy</small>

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.

Sociodemographic Information & Health History

1. SOCIODEMOGRAPHIC INFORMATION

<p>1.1 What is your age?</p> <p><input type="text"/><input type="text"/> years old</p>	<p>1.2 What sex were you assigned at birth (e.g., what sex is on your birth certificate)?</p> <p><input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> I prefer not to say</p>	<p>1.3 Which option best describes your current gender identity?</p> <p><input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Non-binary/fluid/two-spirit <input type="checkbox"/> I prefer not to say</p>
<p>1.4 What is your marital status?</p> <p><input type="checkbox"/> Single <input type="checkbox"/> Married <input type="checkbox"/> Common-law <input type="checkbox"/> Divorced <input type="checkbox"/> Widow/widower <input type="checkbox"/> Other: _____</p>	<p>1.5 What is your highest level of education?</p> <p><input type="checkbox"/> Grade school <input type="checkbox"/> High school <input type="checkbox"/> College <input type="checkbox"/> University <input type="checkbox"/> Graduate school (e.g., PhD, master's) <input type="checkbox"/> Professional school (e.g., MD, DMD)</p>	
<p>1.6 What kind of area do you live in?</p> <p><input type="checkbox"/> Rural area <input type="checkbox"/> Suburban area <input type="checkbox"/> Urban area <input type="checkbox"/> Other: _____</p>	<p>1.7 What is your employment status?</p> <p><input type="checkbox"/> Full-time (40+ hours/week) <input type="checkbox"/> Part-time (less than 40 hours/week) <input type="checkbox"/> Unemployed (seeking work) <input type="checkbox"/> Unemployed (not seeking work) <input type="checkbox"/> Retired <input type="checkbox"/> On medical leave/disability</p>	
<p>1.8 What ethnicity do you identify as?</p> <p><input type="checkbox"/> African American <input type="checkbox"/> Middle Eastern <input type="checkbox"/> Caucasian <input type="checkbox"/> Native Hawaiian or another Pacific Island <input type="checkbox"/> East Asian <input type="checkbox"/> South Asian <input type="checkbox"/> Hispanic <input type="checkbox"/> Prefer not to say <input type="checkbox"/> Indigenous <input type="checkbox"/> Other: _____</p>		
<p>1.9 Do you use any mobility aids?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>1.10 If yes, which one(s)?</p> <p><input type="checkbox"/> Cane <input type="checkbox"/> Walker <input type="checkbox"/> Other</p>	<p>1.13 If yes, how frequently?</p> <p><input type="checkbox"/> Always <input type="checkbox"/> Occasionally <input type="checkbox"/> Rarely, as needed</p>
<p>1.12 Which category best fits your personal income last year?</p> <p><input type="checkbox"/> Less than \$20,000 <input type="checkbox"/> \$20,000–\$40,000 <input type="checkbox"/> \$40,001–\$60,000 <input type="checkbox"/> \$60,001–\$80,000 <input type="checkbox"/> \$80,001–\$100,000 <input type="checkbox"/> Greater than \$100,000 <input type="checkbox"/> I prefer not to answer</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>We ask about income because sometimes access to health services and exercise is affected by income or socioeconomic status.</p> </div>		

1.13 How often do you see your family/friends?

- Daily
- Weekly
- Monthly

1.14 What is your living situation?

- I live at home
- I live in a retirement community

with other adults (18+)

1.15 Do you live alone or with others?

- Alone
- With spouse
- With family
- Other: _____

2. FALLS, FRACTURE & INJURY HISTORY

We define a fall as unintentionally coming to rest on the ground, floor, or other lower level with or without injury. This means that if you fell, but you landed on a couch, or stair rather than the floor, it is still a fall.

2.1 Have you experienced any falls in the past 12 months? Yes No

If so, how many falls did you have in the past 12 months? _____

How many of your falls resulted in injuries? _____

2.3 Please describe these injuries below

What was the type of injury or injuries? (e.g., bruise, scrape, torn muscle, broken bone)	
What parts of the body were affected?	
Did you need to be admitted to hospital?	
How did the injury or injuries occur?	

3. FRACTURE RISK FACTORS

3.1 Do you currently smoke cigarettes, cigars, or other tobacco products? Yes No

3.2 Have you ever been a smoker of cigarettes, cigars, or other tobacco products? Yes
 No

3.3 Do you currently drink alcohol? Yes No

How many per week?

Beer (bottles/week): _____ **Wine (glasses/week):** _____ **Liquor: (oz./week):** _____

3.4 Have you ever been prescribed any steroid medication, taken by mouth, in the last 12 months?

Name of Medication: _____	<input type="checkbox"/> Yes – current use <input type="checkbox"/> Yes – past use <input type="checkbox"/> No <input type="checkbox"/> Unknown	If “Yes”, for how long in total? □□ months
Name of Medication: _____	<input type="checkbox"/> Yes – current use <input type="checkbox"/> Yes – past use <input type="checkbox"/> No <input type="checkbox"/> Unknown	If “Yes”, for how long in total? □□ months

3.5 Do you have arthritis?

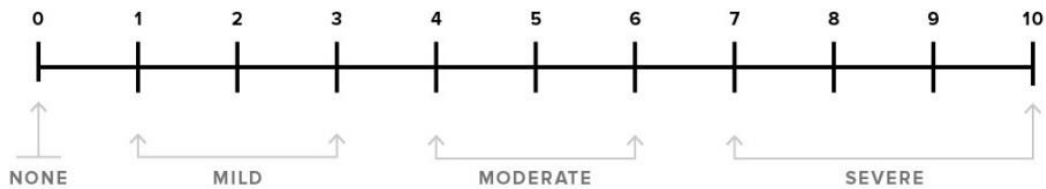
If so, what type?

- Osteoarthritis
- Rheumatoid arthritis
- Other: _____
- I do not know

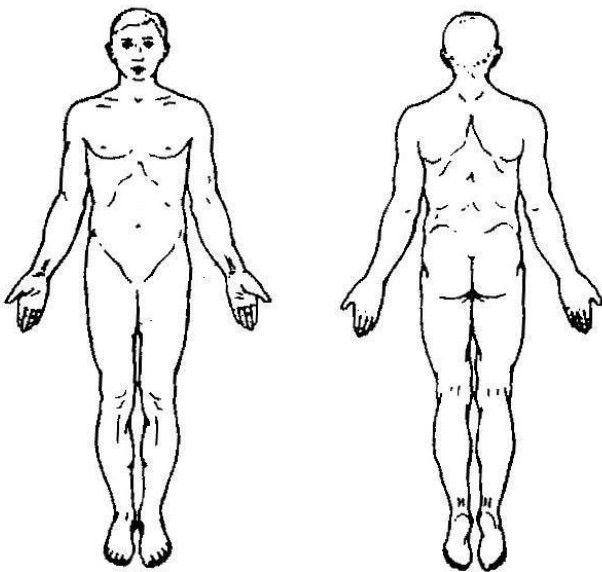
If you have arthritis, what joints are affected?

3.6 In the last week, have you experienced pain during movement? Rate below.

0-10 NUMERIC PAIN RATING SCALE



Label location of the pain on diagram



<u>Type of pain</u>
<u>Aggravating factors</u>
<u>Easing factors</u>
<u>Daily pattern of pain (i.e. morning/day/night)</u>

Notes:

4. COMORBIDITIES & ALLERGIES

4.1 Have you ever had, or has a doctor ever told you that you have, or had:

Condition	Yes	No	Comments
Heart problems (ask about type)	<input type="checkbox"/>	<input type="checkbox"/>	
High blood pressure	<input type="checkbox"/>	<input type="checkbox"/>	
Heart attack or angina	<input type="checkbox"/>	<input type="checkbox"/>	
Asthma	<input type="checkbox"/>	<input type="checkbox"/>	
Bronchitis/emphysema	<input type="checkbox"/>	<input type="checkbox"/>	
Sleep apnea	<input type="checkbox"/>	<input type="checkbox"/>	
Diabetes (Type I or II)	<input type="checkbox"/>	<input type="checkbox"/>	
Liver or kidney disease	<input type="checkbox"/>	<input type="checkbox"/>	
Thyroid disease (hypo vs hyper)	<input type="checkbox"/>	<input type="checkbox"/>	
Osteoporosis/osteopenia	<input type="checkbox"/>	<input type="checkbox"/>	
Low back pain	<input type="checkbox"/>	<input type="checkbox"/>	
Unexplained weight loss/gain	<input type="checkbox"/>	<input type="checkbox"/>	
Prolapse repair surgery, or hernia repair, or hysterectomy	<input type="checkbox"/>	<input type="checkbox"/>	
Allergies (latex)	<input type="checkbox"/>	<input type="checkbox"/>	

4.2 In the last year, have you experienced:

Condition	Yes	No	Comments
Light-headedness, fainting, dizziness, falls	<input type="checkbox"/>	<input type="checkbox"/>	
Pain, discomfort in chest, neck, or jaw	<input type="checkbox"/>	<input type="checkbox"/>	
Heart palpitations or rapid heart rate	<input type="checkbox"/>	<input type="checkbox"/>	
Heart murmur	<input type="checkbox"/>	<input type="checkbox"/>	
Ankle/lower leg swelling	<input type="checkbox"/>	<input type="checkbox"/>	
Bilateral muscle cramps on exertion	<input type="checkbox"/>	<input type="checkbox"/>	
Excessive fatigue	<input type="checkbox"/>	<input type="checkbox"/>	
Shortness of breath with daily activities	<input type="checkbox"/>	<input type="checkbox"/>	
Feeling of dragging/heaviness at vagina, difficulty moving bowels	<input type="checkbox"/>	<input type="checkbox"/>	

4.3 Are there any other health conditions/diseases that you have experienced that you think we should know about?

	History of Disease	Current Disease	Details
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	
	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Yes <input type="checkbox"/> No	

5. MEDICATIONS AND CO-INTERVENTIONS

Please document a list of the participant's current medications and supplements. If there are any medications taken sometimes, but not always (like medication for pain or sleeping), document them with "As needed" under frequency.

Name of Medication	Dose and Units	How often is it taken?	Notes
1.			
2.			
3.			
4.			
5.			
6.			

Are you currently doing any other exercise programs? Yes No

If yes, please describe the program(s) you are involved in.

Exercise Type	Frequency	Intensity low/moderate/high	Is it progressive?	Time
			<input type="checkbox"/> Yes <input type="checkbox"/> No	
			<input type="checkbox"/> Yes <input type="checkbox"/> No	

Questionnaires Package

1. Baseline Assessment: Questionnaires will be conducted over the telephone during a 60-minute session following Informed Consent and Sociodemographic & Medical Information. If participants prefer to complete the forms independently, they will be mailed to the participant with a return envelope and stamp. The research assistant will offer to call the participant to facilitate and answer any questions.
2. Post Assessment: Questionnaires will be conducted over the telephone during a 60-minute session following the Exit Interview. If participants prefer to complete the forms independently, they will be mailed to the participant with a return envelope and stamp. The research assistant will offer to call the participant to facilitate and answer any questions.
3. Follow-up Assessment: Questionnaires will be conducted over the telephone during a 60-minute session following the Follow-up Interview. If participants prefer to complete the forms independently, they will be mailed to the participant with a return envelope and stamp. The research assistant will offer to call the participant to facilitate and answer any questions.

1. Physical Activity Screen (PAS)
2. Modified Exercise Self-Efficacy Scale (ESES)
3. EuroQol 5 Dimensions 5 Levels (EQ5D5L)
4. Center for Epidemiology Studies Depression Scale (CES-D)
5. The Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
6. Seniors in the Community: Risk Evaluation for Eating and Nutrition (SCREEN©)

**If the participant refuses to complete any of the questionnaires, please take note.*

Physical Activity Screen (PAS)

We want to know about the types of moderate or vigorous intensity physical activities you have done in the last week.

Light intensity activities will not cause you to sweat or breathe harder. It is easy to carry on a conversation. Examples: leisurely walk, gardening, yoga, flexibility exercises, static balance exercises, golf, or even keeping busy with shopping or chores throughout the day. Please note that we are not quantifying light intensity activities.

Moderate intensity activities may make you sweat and breathe a little harder. You may only be able to carry on a conversation in short sentences. It will feel a little like work to keep it up. Brisk walking (like when you are late!), an aerobics class, or raking are examples of moderate intensity activities.

Vigorous intensity activities will cause you to sweat and be out of breath. You will not be able to say more than a few words before stopping to catch your breath

What physical activities do you enjoy doing? Refer to the list below. For each moderate to vigorous intensity physical activity you identify, answer:

1. On average, how often did you do it in the last week?
2. On average, how long do you do it for each time? (In minutes)

Moderate or Vigorous Intensity Physical Activities	How many days in the last week?	How long did you do it for each time? (min)	Comments
Brisk Walking			
Cycling, Elliptical trainer			
Fitness Class (e.g., Yoga, Tai Chi)			
Swimming			
Running			
Sports (e.g., Golf, tennis, pickleball)			
Muscle strengthening (e.g., Using weights, elastic tubing)			
Heavy Yard Work			
Physically demanding job (e.g., Requires carrying objects over 25lb)			
Other:			

Modified Exercise Self-Efficacy Scale (ESES)

We want to understand any plans you have for exercise right now. Please indicate how true the sentence is for you using the boxes to the right. Select only one option per statement.

	Not at all true	Barely true	Unsure	Mostly true	Exactly true
I have made concrete plans about when to exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have made concrete plans about how to exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have made concrete plans about where to exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have made concrete plans regarding how often to exercise.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I have made a detailed plan for what to do if something interferes with my plans.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I intend to perform exercise for at least 30 minutes on most days of the week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

We want to understand how confident you are about participating in exercise right now. Please indicate how true the sentence is for you using the boxes to the right. Select only one option per statement.

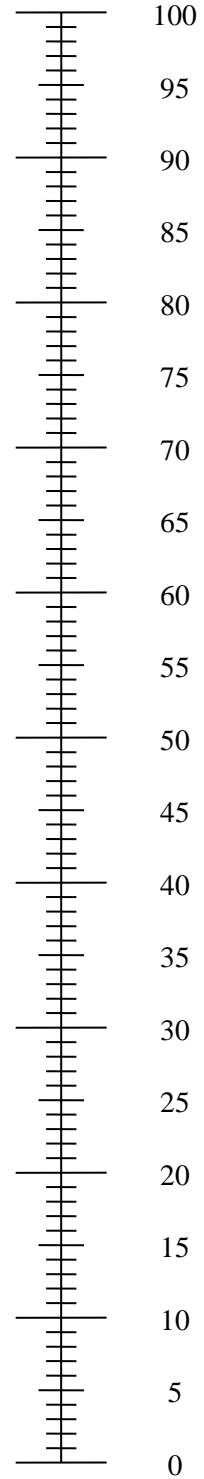
	Not at all true	Barely true	Unsure	Mostly true	Exactly true
I am sure that I can be physically active on a regular basis, even if it is difficult.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am sure that I can perform exercise on most days of the week.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am capable of exercising regularly, even if I don't see success at once.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am sure I can resume regular exercise even if I stop doing it for a while.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I am sure I can keep exercising regularly, even if it takes me a long time to make it a habit.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

EQ5D5L Health Questionnaire – English version for Canada

Under each heading, please tick the ONE box that best describes your health TODAY.	
MOBILITY	
I have no problems in walking about	<input type="checkbox"/>
I have slight problems in walking about	<input type="checkbox"/>
I have moderate problems in walking about	<input type="checkbox"/>
I have severe problems in walking about	<input type="checkbox"/>
I am unable to walk about	<input type="checkbox"/>
SELF-CARE	
I have no problems washing or dressing myself	<input type="checkbox"/>
I have slight problems washing or dressing myself	<input type="checkbox"/>
I have moderate problems washing or dressing myself	<input type="checkbox"/>
I have severe problems washing or dressing myself	<input type="checkbox"/>
I am unable to wash or dress myself	<input type="checkbox"/>
USUAL ACTIVITIES (e.g., work, study, housework, family, or leisure activities)	
I have no problems doing my usual activities	<input type="checkbox"/>
I have slight problems doing my usual activities	<input type="checkbox"/>
I have moderate problems doing my usual activities	<input type="checkbox"/>
I have severe problems doing my usual activities	<input type="checkbox"/>
I am unable to do my usual activities	<input type="checkbox"/>
PAIN / DISCOMFORT	
I have no pain or discomfort	<input type="checkbox"/>
I have slight pain or discomfort	<input type="checkbox"/>
I have moderate pain or discomfort	<input type="checkbox"/>
I have severe pain or discomfort	<input type="checkbox"/>
I have extreme pain or discomfort	<input type="checkbox"/>
ANXIETY / DEPRESSION	
I am not anxious or depressed	<input type="checkbox"/>
I am slightly anxious or depressed	<input type="checkbox"/>
I am moderately anxious or depressed	<input type="checkbox"/>
I am severely anxious or depressed	<input type="checkbox"/>
I am extremely anxious or depressed	<input type="checkbox"/>

We would like to know how good or bad your health is TODAY.
This scale is numbered from 0 to 100.
100 means the <u>best</u> health you can imagine. 0 means the <u>worst</u> health you can imagine.
Mark an X on the scale to indicate how your health is TODAY.
Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



Center for Epidemiology Studies Depression Scale (CES-D)

Instructions: Below is a list of some ways you may have felt or behaved. Please indicate how often you have felt this way during the last two weeks by placing an X in the appropriate space. Please only provide one answer to each question.

	Rarely (<1 day)	Sometimes (1-2 days)	Occasionally (3-4 days)	Most (5-7 days)	Nearly every day
I felt that everything I did was an effort					
I could not get going					

Warwick-Edinburgh Mental Well-being Scale (WEMWBS)

Below are some statements about feelings and thoughts.

Please circle the box that best describes your experience of each over the last 2 weeks.

	<i>None of the Time</i>	<i>Rarely</i>	<i>Some of the Time</i>	<i>Often</i>	<i>All of the Time</i>
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Seniors in the Community: Risk Evaluation for Eating and Nutrition (SCREEN©)

- For each question, check **only one** box
- Your response should reflect your **typical eating habits**.

1a. Has your weight changed in the past 6 months?

- 0 Yes, *I gained* more than 10 pounds.
1 Yes, *I gained* 6 to 10 pounds.
2 Yes, *I gained* about 5 pounds.
4 No, my weight stayed within a few pounds.
2 Yes, *I lost* about 5 pounds.
1 Yes, *I lost* 6 to 10 pounds.
0 Yes, *I lost* more than 10 pounds.
0 I don't know how much I weigh or if my weight has changed.

1b. Have you been trying to change your weight in the past 6 months?

- 4 Yes.
4 No.
0 No, *but it changed anyway*.

1c. Do you think your weight is ...?

- 0 More than it should be.
4 Just right.
0 Less than it should be.

2. Do you skip meals?

- 4 Never or rarely.
2 Sometimes.
1 Often.
0 Almost every day

3. Do you limit or avoid certain foods?

- 4 I eat most foods.
2 I limit some foods and I am managing fine.
0 I limit some foods and I am finding it difficult to manage.

4. How would you describe your appetite?

4 Very good.

3 Good.

2 Fair.

0 Poor.

5. How many pieces or servings of vegetables and fruit do you eat in a day?

Vegetables and fruit can be canned, fresh, or frozen.

4 Five or more.

3 Four.

2 Three.

1 Two.

0 Less than two.

6. How often do you eat meat, eggs, fish, poultry, tofu, dried peas, beans, lentils, nuts, or nut butters?

4 Two or more times a *day*.

3 One to two times a *day*.

1 Once a *day*.

0 Less than once a *day*.

7. How often do you have milk or soy beverages or milk products such as cheese, yogurt, or kefir?

4 Three or more times a *day*.

3 Two to three times a *day*.

2 One to two times a *day*.

1 Usually once a *day*.

0 Less than once a *day*.

8. How much fluid do you drink in a day?

Examples are water, tea, coffee, herbal drinks, juice, and soft drinks, but not alcohol.

4 Eight or more cups.

3 Five to seven cups.

2 Three to four cups.

1 About two cups.

0 Less than two cups

9. Do you cough, choke, or have pain when swallowing food OR fluids?

4 Never.

3 Rarely.

1 Sometimes.

0 Often or always.

10. Is biting or chewing food difficult for you?

4 Never.

3 Rarely.

2 Sometimes.

0 Often or always.

11. Do you use commercial meal replacements or supplements?

Shakes, puddings, or energy bars.

4 Never or rarely.

2 Sometimes.

0 Often or always.

12. Do you eat one or more meals a day with someone?

0 Never or rarely.

2 Sometimes.

3 Often or always.

4 Almost always.

13a. Who usually prepares your meals?

4 I do.

4 I share my cooking with someone else.

4 Someone else cooks most of my meals.

13b. Which statement best describes meal preparation for you?

- 4 I enjoy cooking most of my meals.
2 I *sometimes* find cooking a chore.
0 I *usually* find cooking a chore.
4 I'm *satisfied* with the quality of food prepared by others.
0 I'm *not satisfied* with the quality of food prepared by others.

14. Do you have any problems getting your groceries?

Problems can be poor health or disability, limited income, lack of transportation, weather conditions, or finding someone to shop.

- 4 Never or rarely.
2 Sometimes.
1 Often.
0 Always

Thank you for telling us about your eating habits.

Physical Function Assessment Package

Balance Test

Before We Start:

- Are you able to stand without having something to hold on to? YES NO
- Would you feel comfortable if we test your ability to stand with your feet in positions that challenge your balance? YES NO

If you answered “NO” to any of the above, please move onto the next page.

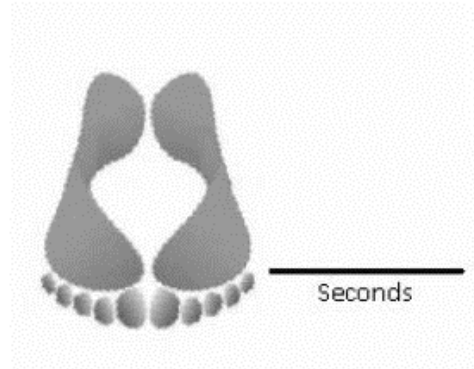
Test Instructions

- With your shoes on, move your feet into the positions shown below from left to right.
- Please record how long you hold each position for in the space provided. If you manage to hold a position for 10 seconds, you may stop and move on to the next position.

Camera View: frontal view/line of sight

A. Side-by-Side Stand

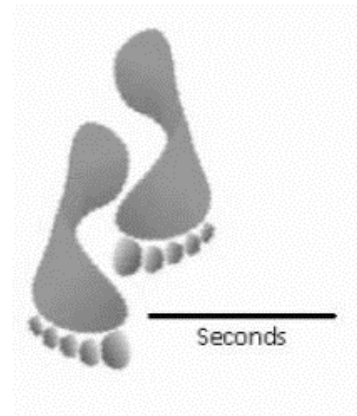
1. We will ask you to stand with your feet together, side-by-side, for as long as you can. We will start the timer once your feet are in position.
2. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position for a maximum of 10 seconds. We will stop the timer if you step out of position or once the 10 seconds have passed.
 - a. *If someone is assisting you, ask them to say “Go” and start the timer once they have confirmed you are ready.*
 - b. *If someone is assisting for you, ask them to stand nearby and say “Stop” once the 10 seconds are up.*



Do not attempt any exercise that you feel might be unsafe!

B. Semi-Tandem Stand

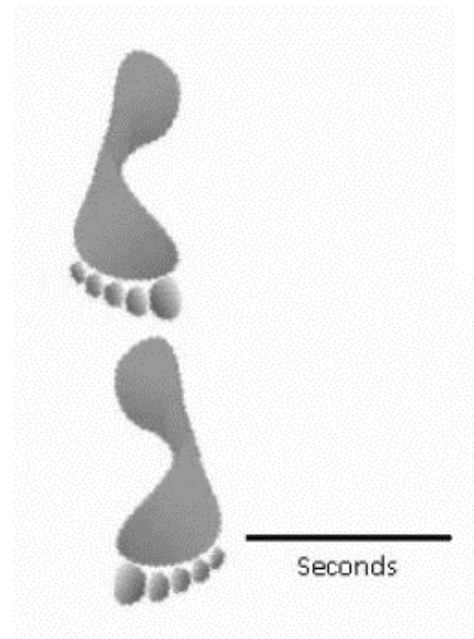
1. Stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds.
2. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position for a maximum of 10 seconds. We will stop the timer if you step out of position or once the 10 seconds have passed.



- *If someone is assisting you, ask them to say “Go” and start the timer once they have confirmed you are ready.*
- *If someone is assisting for you, ask them to stand nearby and say “Stop” once the 10 seconds are up.*

C. Tandem Stand

1. Stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.
2. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position for a maximum of 10 seconds. We will stop the timer if you step out of position or once the 10 seconds have passed.



- *If someone is assisting you, ask them to say “Go” and start the timer once they have confirmed you are ready.*
- *If someone is assisting for you, ask them to stand nearby and say “Stop” once the 10 seconds are up.*

Chair Stand Test

Before You Start

- Are you able to get out of a chair and sit back down? YES NO

If you answered “NO”, this is the end of the test.

Test Instructions

- With your shoes on, complete as many repetitions as you can safely and at your own pace.

Camera View: side angle/perpendicular to your line of sight

Single Chair Stand (Practice)

1. Sit in the middle of the chair.
2. Keep your feet flat on the floor, hip width apart.
3. Keep your back straight and hold your arms across the chest.
4. Rise to a full standing position, then sit back down again.
5. If you are able to complete one repetition safely, proceed with the full test on the next page. If not, this is the end of the test.



Do not attempt any exercise that you feel might be unsafe!

30 second Chair Stand

The purpose of this test is to see how many single chair stands you can complete in 30 seconds.

1. Sit in the middle of the chair.
2. Keep your feet flat on the floor, hip width apart.
3. Keep your back straight and hold your arms across your chest.
4. When we say go, rise to a full standing position, then sit back down again as many times as you can until we say stop.
 - If someone is assisting you, ask them to say “Go” and start the timer once they have confirmed you are ready.
 - If someone is assisting you, ask them to count the number of times you come into a full stand and say “Stop” once 30 seconds have passed.

Number of Chair Stands in 30 seconds: _____

Interview Guide to Conduct Exit Interviews

At the end of the study, all participants are asked **Part B**. If a person requests to be withdrawn, use the following script first then move to Part B if applicable:

Part A – To be completed if someone decides to leave the study early.

“I understand that you do not wish to (participate in the program/be in the study) anymore. Are there any parts of the study, like the follow-up visit, or questionnaires over the phone, which you might still be willing to do?”

If yes, make note of what they are and are not willing to do. Continue to next question.

If no, thank them for contributing their time to the study.

“Would you be willing to answer a few short questions now about your experience in the study?”

If yes, continue to Part B.

If no, thank them for contributing their time to the study.

Part B – To be completed at the end of the study. All sessions should be audio recorded.

“I will be asking a few questions about your experience with the study. If there are any questions that you do not want to answer, please let me know.”

1. Why did you decide to join this study? (Prompt: What made you interested in taking part?)
2. What, if any, benefit (are you getting/did you get) out of your involvement in the study? (Prompt: If nothing, what were you hoping to get out of your involvement?)
3. What did you think of the one-on-one exercise sessions? What parts did you enjoy? What could we have done better?
4. What did you think of the group sessions? What parts did you enjoy? What could we have done better?
5. What did you think about the nutrition workbook? What parts of it did you find useful? How can we improve the nutrition workbook?
6. What did you think about the nutrition seminars? What parts of it did you find useful? How can we improve the nutrition seminars?
7. What did you think about the nutrition videos? What parts of it did you find useful? How can we improve the nutrition videos?
8. What do you think about Physiapp? What parts of it did you find useful? How can we improve the user experience?

Interview Guide to Conduct Follow-up Interviews

4 weeks after the end of the stud, all participants are asked **Part C**.

Part C – To be completed at Follow-up. All sessions should be audio recorded.

“We want to understand your experience with the study. If there are any questions that you do not want to answer, please let me know and we will move on.”

1. Tell me about your experience continuing with the MoveStrong at Home program in the last month. (Prompt: What made it hard for you to continue? What encouraged you to stay motivated? Were there any parts of the program that helped keep you exercising?)
2. What, if any benefits are you getting out of you continues involvement in the study?
3. Tell me about your plan for exercise moving forward. (Prompt: How do you intend to stay active)
4. Tell me about your plan for making sure you eat enough protein moving forward. (Prompt: How do you intend to ensure you are eating well?)
5. Imagine the “stay at home” orders weren’t in place, and things were back to normal. What do you think about attending a program like MoveStrong at a gym or other centre in person? If you were to choose between in person or virtual deliver, what would influence your decision?
6. What social media platforms do you use, if any? (Prompt: YouTube, Facebook, Instagram, Snapchat, Twitter, Linked in. What do you use to get information about exercise or nutrition?)
7. We want to find ways to help people stay engaged in exercise or connect with a MoveStrong community of participants. Some people do this by connecting via social media, staying informed via newsletters, or attending a graduate program. What do you think about that?
8. What mode of communication was most helpful?
9. What really works for you?

Attribution of Adverse Events to Exercise Interventions

This information may help you evaluate the factors underlying the onset of an adverse event (AE), and help you with determine if the AE can be attributed to an intervention. This information was adapted from *Improving Attribution of Adverse Events in Oncology Clinical Trials* by George, GC *et al.*¹

Patient-Level Factors

1. The timing of the AE relative to the intervention
 - a. Is the timing of the AE possible given when the exercise intervention was administered?
 - b. Did the AE occur, or increase in severity during or after the exercise intervention?
2. Relationship to baseline symptoms
 - a. Is there evidence that the AE is an existing comorbidity or disease symptom based on baseline data?
 - b. Did the AE increase in severity during or after the exercise intervention?
3. The response to stopping the exercise intervention, and restarting the exercise intervention after recovery
 - a. Did the AE resolve after stopping the exercise intervention?
 - b. Did the AE recur when the exercise intervention was restarted?
4. Likelihood of other causes, such as disease and medication symptoms
 - a. Does the participant have comorbidities, or take concomitant medications that are likely to cause this AE?
 - b. Are AEs like this common in the patient population?

Agent-Level Factors

1. Clinical knowledge of the exercise intervention
 - a. Is the AE something that an exercise intervention may be expected to cause?
 - b. Is it biologically plausible that the AE is caused by the exercise intervention?

Trial or Program Level/Aggregate Data Level Factors

1. Incidence of the AE in the intervention group vs. placebo or active comparator groups
 - a. Is there a relevantly higher frequency in the experimental arm(s)?
2. Intensity-response patterns across participants that may indicate a causal relationship
 - a. Does the incidence increase with exercise intervention intensity?

¹ George GC, Barata PC, Campbell A, et al. Improving attribution of events in oncology clinical trials. *Cancer Treat Rev.* 2019;76:33–4

Appendix 3

MoveStrong at Home – Participant Program Instructions



MoveStrong at Home
- Participant Program

MoveStrong at Home – Instructor Manual



MoveStrong at Home
- Instructor Manual_v.

MoveStrong at Home – Nutrition Education Booklet



MoveStrong at Home
- Nutrition Education

MoveStrong at Home – Nutrition FAQ



Nutrition FAQ.pdf

MoveStrong at Home – Recipe Book



MoveStrong at Home
- Recipe Book.pdf