Bridging the gap between physical activity evidence and practice for older adults with osteoporosis and frailty

by

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The following served on the examining committee for this thesis. The decision of the examining committee is by majority vote.

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This thesis consists of material all of which I authored or co-authored.

This is a true copy of the thesis, including any required final revisions, as accepted by my examiners.

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Statement of Contribution

Isabel Rodrigues was the sole author for Chapters 1 and 6, which were written under the supervision of Dr. Lora Giangregorio and were not written for publication.

This thesis consists in part of five manuscripts written for publication. Exceptions to sole authorship of material are as follows:

Research presented in Chapter 2:

Dr. Lora Giangregorio was the primary investigator on the Osteoporosis Canada grant, which supported the work in Chapter 1. Mr. Matteo Ponzano, Dr. Zeinab Hosseini, Dr. Lehana Thabane, Dr. Philip D. Chilibeck, Dr. Debra A. Butt, Dr. Maureen C. Ashe, Ms Jackie Stapleton, Dr. John Wark, Ms Joan Bartley, and Dr. Zahra Bardai are coauthors on the publications relating to this work.

This research was conducted at the University of Waterloo by Isabel Rodrigues under the supervision of Dr. Lora Giangregorio. Isabel Rodrigues contributed to the study design, protocol development, data collection, and writing the initial manuscript. Mr. Matteo Ponzano, Dr. Zeinab Hosseini, Dr. Lehana Thabane, Dr. Philip D. Chilibeck, Dr. Debra A. Butt, Dr. Maureen C. Ashe, Ms Jackie Stapleton, Dr. John Wark, Ms Joan Bartley, Dr. Zahra Bardai, and Dr. Giangregorio were involved in developing the protocol, reviewing the final analysis, and editing the final manuscript. Isabel Rodrigues wrote the draft manuscripts, which all co-authors contributed intellectual input on.

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This research was conducted at the University of Waterloo by Isabel Rodrigues under the supervision of Dr. Lora Giangregorio. Isabel designed the study protocol, recruited participants, collected the data, and completed the data analysis with assistance from Dr. Lora Giangregorio. Justin Wagler assisted in collecting some data related to the study. Ellen Wang assisted in implementing the exercise protocol at one location. Dr. Heather Keller, Dr. Lehana Thabane, Mr. Zach Weston, Dr. Sharon Straus, Dr. Alexandra Papaioannou, Dr. Marina Mourtzakis, Dr. James Milligan, Dr. Wanrudee Isaranuwatchai, Ms Desmond Loong, Mr Raini Jain, Mr Larry Funnell, Dr. Angela

Cheung, Ms Sheila Brien, and Dr. Maureen Ashe contributed to development of the MoveSrong program. Isabel Rodrigues drafted the manuscript and each author provided intellectual input on manuscript drafts.

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As lead author of these six chapters, I was responsible for contributing to conceptualizing study design, carrying out data collection and analysis, and drafting, and submitting manuscripts. My coauthors provided guidance during each step of the research and provided feedback on draft manuscripts.

Abstract

Exercise prescriptions that include moderate or high intensity progressive, resistance training, and functional and balance training may improve physical functioning and disability outcomes and prevent falls in older adults with chronic conditions. For certain individuals, moderate or high impact exercises may also have benefits for bone health. While exercise recommendations may be well recognized by the scientific community, the translation of exercise guidelines in practice may receive little to no attention. This thesis includes three studies (five manuscripts) with an overarching objective to improve exercise participation among people with osteoporosis and frailty in practice. To accomplish this goal, we sought a knowledge translation strategy to bridge the gap between current knowledge in exercise science and practice, specifically focusing on people with osteoporosis and frailty. The Knowledge-to-Action Cycle was used to guide the development and to implement meaningful and effective interventions.

The objectives of the thesis were: 1) to summarize the evidence on the effects of impact exercises on falls, fractures, health-related quality of life, mortality, and physical functioning and disability in individuals 50 years and older at risk of fractures; 2) to understand perspectives on starting or continuing moderate or high impact exercises and resistance training in people with osteoporosis; and 3) to determine the feasibility of implementing a model to teach pre-frail and frail older adults balance and functional strength training in combination with consuming enough protein (MoveStrong).

The **first study** resulted in two systematic reviews: one on impact exercises and the other on walking and Nordic walking. The first systematic review revealed that there is limited evidence on the benefits of impact exercises on several health-related outcomes, although there is low certainty evidence that impact exercises alone or combined with resistance training may improve mobility and bone mineral density at

the lumbar spine and femoral neck. The second review found a very limited number of studies on walking and Nordic walking in people with osteoporosis. Although most studies had a high risk of bias and of very low certainty, the evidence suggests that Nordic walking may improve mobility in older adults. There is insufficient data on the benefits of low, moderate, or high impact exercises on falls, fractures, and mortality in people with osteoporosis.

The **second study** was a qualitative study to understand perspectives on starting or continuing impact exercise and strength training. We used a qualitative description method and conducted semi-structured, one-on-one interviews with people living with osteoporosis. We generated three salient themes related to perspective on starting or continuing moderate or high impact exercise and strength training. Theme one identified that exercise terminology should be carefully selected since exercise terms may be interpreted literally and induce positive or negative perspectives about the activity or exercise. For example, impact exercises were perceived to be jolting, bursting, or jarring, whereas strength training was described as an activity that "strengthens". As a result, participant's literal interpretation of the exercise terminology may induce positive or negative attitudes that influence uptake of the activity. Theme two suggests that exercise programs should be delivered in a similar approach to other treatments and procedures in our medical system. There was a clear parallel in how participants would like exercise programs to be delivered versus how healthcare providers currently prescribe and monitor treatments and procedures in healthcare. Lastly, participants are strongly influenced by discussions with their healthcare provider or by conversations regarding management of osteoporosis with strangers over social media. Certain individuals had strong anti-medication views, which they read about over social media. As a result, to avoid pharmaceutical drugs, participants said they were willing to participate in moderate or high impact exercise or strength training.

In the **third study**, we conducted a pilot and feasibility randomized controlled trial to evaluate the MoveStrong program in areas that typically represent real-world practice. We determined feasibility by evaluating recruitment, retention, and adherence rates to the program. We also explored the effect of MoveStrong on secondary outcomes including body weight, gait speed, grip strength, fatigue levels, lower limb muscle strength, dynamic balance, health-related quality of life, and protein intake. We found the MoveStrong program was feasible in terms of recruitment and adherence but not retention. MoveStrong may improve some frailty outcomes including grip strength, lower limb muscle strength, and dynamic balance. Exploratory analyses of secondary outcomes found the program may improve gait speed, lower limb muscle strength, dynamic balance, and health-related quality of life index scores in older adults who are pre-frail or frail. We provide some suggestions to improve the implementation of MoveStrong for a larger trial including modifying some of the exercises, considering volunteer assistance, and employing recruitment strategies to target men and diverse groups.

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Dedication

I dedicate this thesis to all the people who have supported me during this journey. First, I dedicate this thesis to my family. Your patience and kindness have no boundaries. You have always been there to support me, while asking for nothing in return. I cannot imagine where I would be without your love, guidance, patience, and care.

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Thirdly, I want to dedicate this thesis to all adults and older adults who have osteoporosis and frailty especially those who are Black, Indigenous, Persons of Colour, and other under severed communities here in Canada and worldwide. I hope that in the future I will be able to improve management and care, so you get the best healthcare you deserve. Your voices matter.

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List of Abbreviations

AMDR Acceptable Macronutrient Distribution Range

ASA24[®] Automated Self-Administered 24-Hour Dietary Assessment Tool

BMD Bone Mineral Density

BW Body Weight

CAD Canadian Dollar

CI Confidence Intervals

CINAHL Cumulative Index to Nursing and Allied Health Literature

COM-B Capability, Opportunity, Motivation-Behaviour change model

DXA Dual-energy X-ray Absorptiometry

EQ-5D-5L EuroQol Group 5 Dimension 5 Level

EWGSOP2 European Working Group on Sarcopenia in Older People

FaME Falls Management Exercise Programme

FRAIL Fatigue, Resistance, Ambulation, Illnesses, and Loss of weight

GEE Generalized Estimating Equation

GRADE Grading of Recommendations Assessment, Development and

Evaluation

KT Knowledge Translation

KTA Knowledge-to-Action Framework

LiFE Lifestyle-integrated Functional Exercise program

LIFTMOR Lifting Intervention for Training Muscle and Osteoporosis

Rehabilitation

MCID Minimum Clinically Importance Difference

MD Mean Difference

PROGRESS Plus Place of Residence, Race/ethnicity, Occupation, Gender,

Religion/culture, Education, Socio-economic status, Social capital/networks, Plus other factors like disability, sexual

orientation

OR Odds Ratio

OEP Otago Exercise Program

RaR Rate Ratio

RDA Recommended Dietary Allowance

RR Risk Ratio

MCID Minimum Clinically Important Difference

MoveSToNg Model for delivering Strength Training and Nutrition education

for older adults

RCT Randomized Controlled Trial

SD Standard Deviation

SMD Standard Mean Difference

SPSS Statistical Package for the Social Sciences

TIDieR Template for Intervention Description and Replication

TUG Timed-Up and Go Test

Chapter 1: General Introduction

1.1 Introduction

Aging is a heterogeneous process where some individuals of the same age vary widely in their health and functional status (Heckman & Braceland, 2016; Mitnitski et al., 2002). Certain conditions such as being frail are not a natural consequence of aging and can affect a person's health and functional status. Although there is no consensus for an operational definition of frailty, (Cesari et al., 2014; De Vries et al., 2011; Rodríguez-Mañas et al., 2013), this condition is used to denote a multidimensional syndrome characterized by a loss of reserves, resulting in an increased vulnerability to developing negative health-related outcomes when exposed to endogenous and to exogenous stressors (Cesari et al., 2017; Rockwood et al., 2005). Recently, the concept of frailty in relation to osteoporosis is being studied with emerging studies measuring frailty as a predictor of osteoporotic fractures. Osteoporosis can increase a person's risk of a fracture, and, depending on the location of the fracture and the level of frailty, the individual may suffer from impaired physical function that accumulates over time and is worsened by complex psychosocial factors and pain (Kerr et al., 2017). In several studies of both men and women, frailty was identified as an important risk factor for falls and fractures (Chen et al., 2010; Ensrud et al., 2008; Ensrud et al., 2007). A fundamental relationship exists between frailty and osteoporosis where the frailer an individual, the more likely they are to sustain a fracture and be unable to return to baseline function (Van Den Bergh et al., 2012). It is important to develop and implement strategies to manage and prevent osteoporosis and frailty that can contribute to the adverse events that may lead to the heterogenous aging process.

As the older adult population continues to grow, the progressive loss of muscle mass, strength, and function are also a concern. Sarcopenia is a condition characterized by the gradual loss in skeletal muscle mass, strength, and function which may theoretically contribute to the development of frailty and mobility disability in older adults (Cruz-Jentoft et al., 2014). Although the definition of sarcopenia is still a work in progress, current definitions confirm that the concept of sarcopenia is relevant, frequent, and linked with

adverse outcomes (Cruz-Jentoft et al., 2014). Several systematic reviews of prospective studies in individuals 60 years and older show that sarcopenia increases the odds of mortality between 1.6 to 3.6 (Beaudart et al., 2017; Kelley & Kelley, 2017; Liu et al., 2017). Sarcopenia is also associated with declines in physical function (pooled odds ratio 3.03, 95% CI 1.80 to 5.12, 6 studies) and higher incidence of hospitalization (Beaudart et al., 2017). Thus, it is essential to identify interventions to promote muscle mass, strength, and function in older adults.

There is evidence to suggest regular physical activity is key to managing frailty, sarcopenia, and osteoporosis in older adults. While there are no specific exercise guidelines for individuals that are frail or that have sarcopenia, the 24-hour movement guidelines for older adults (65 years and older) suggest accumulating at least 150 minutes of moderate-to-vigorous aerobic physical activity per week, with at least two days of progressive resistance training for major muscle groups and activities that challenge balance (El-Kotob et al., 2020; McLaughlin et al., 2020). Similarly, exercise recommendations for people with osteoporosis emphasize functional and balance training, moderate-to-high intensity progressive resistance training, and weight-bearing or impact exercise (Beck et al., 2017; Giangregorio et al., 2014). In addition, nutrition interventions that include protein supplementation represent an important option to preserve muscle mass and function. Indeed, low protein intake may lead to poor physical function. Several prospective studies found that short-term protein supplementation improved lean body mass, muscle strength, and physical performance (i.e., gait speed) and there is evidence that protein supplementation augments the anabolic effect of exercise (Børsheim et al., 2007; Gregorio et al., 2014; Morton et al., 2018). The 2018 Canadian Dietary Guidelines recommend Canadians of all age groups consume enough protein, although the recommendations are set as a "one-size-fits-all" for both young and older adults. Consuming enough protein, especially when one is physically active, is important for muscle anabolism. Thus, regular physical activity in addition to consuming

enough protein can be an important strategy to help manage osteoporosis and frailty in older adults.

The literature review that follows will outline research on the benefits of physical activity among older adults. In addition, it is important to recognize the ageing experiences of older adults may differ between individuals that are healthy versus those with osteoporosis and frailty. Often, large clinical trials on exercise recruit healthy older adults that may not be representative of clinical populations (e.g., exclude individuals with prior fractures). However, the benefits of exercise are probably more evident in those with underlying conditions. Studying the dimensions of age and disease status and how these dimensions intersect can have a large impact on the health and the quality of people's lives as they age. This literature review will report the finding from an aging and clinical disease perspective, specifically focusing on frailty and osteoporosis.

1.2 The effects of physical activity on outcomes for older adults

1.2.1 Falls

The highest quality and level of evidence on the effects of exercise on falls is from a 2019 Cochrane review that found exercise (all types) reduced the rate of falls by 23% in community-dwelling older adults (Rate Ratio [RaR] 0.77, 95% confidence interval (CI) 0.71 to 0.83, 12,981 participants, 59 studies, high certainty evidence). This review also reported exercise in general decreased the number of people experiencing one or more falls by 15% (Risk Ratio [RR] 0.85, 95% CI 0.81 to 0.89, 13,518 participants, 63 studies, high certainty evidence) (Sherrington et al., 2019). Subgroup analysis of the different types of exercise revealed balance and functional exercises reduced the rate of falls by 24% (RaR 0.76, 95% CI 0.70 to 0.81; 7920 participants, 39 studies, high certainty evidence) while balance and functional exercises combined with resistance training reduced the rate of falls by 34% (RaR 0.66, 95% CI 0.50 to 0.88; 1374 participants, 11 studies, moderate-certainty evidence) (Sherrington et al., 2019). Although there was no

subgroup analysis in individuals that were frail or that had osteoporosis, there is some evidence that exercise can prevent falls in individuals with Parkinson's disease (Odds Ratio (OR) 0.47, 95% CI 0.30 to 0.73) and cognitive impairments (OR 0.55, 95% CI 0.37 to 0.83) (Sherrington et al., 2017). There is less certainty about the efficacy of exercise in individuals who have experienced a stroke (95% CI 0.42 to 1.32, 3 studies) (Sherrington et al., 2017), who live in long-term care, who have been recently discharged from the hospital (OR 1.74, 95% CI 1.17–2.60, 2 studies) (Naseri et al., 2018), or who have visual impairments (RR 1.05, 95% CI 0.73 to 1.50, 3 studies) (Sherrington et al., 2017); but there is some evidence that multifactorial programs may be useful. Multifactorial programs may also be beneficial to individuals that are frail since some markers of frailty include low gait speed decreased mobility and poorer visual function, which are characteristics of people with Parkinson's disease and cognitive impairments. When possible, community dwelling older adults and people with Parkinson's disease or cognitive impairments should be encouraged to perform balance, functional exercises, and resistance training to reduce the risk of a fall.

1.2.2 Fall-Related Injuries

Fall-related injuries among adults aged 65 years and older are a major health concern. More than one third of older adults fall each year (Stel et al., 2004) and fall-related injuries are one of the leading cause of hospitalizations in Canada (Canadian Institute for Health Information, 2006). A network meta-analysis examined the efficacy of fall prevention interventions in community-dwelling older adults; this study found exercise (all types) decreased injurious falls by 49% (OR 0.51, 95% CI 0.33 to 0.79) (Tricco et al., 2017). Another meta-analysis reported exercise interventions for older adults reduced injurious falls (i.e., bruising) by 37%, severe injurious falls (i.e., head injuries) by 43%, and falls resulting in fractures by 61% (El-khoury et al., 2013). The most recent Cochrane review also suggests exercise may reduce the number of people experiencing one or more fall-related fractures, but the certainty of evidence is low (RR 0.73, 95% CI 0.56 to 0.95; 4047

participants, 10 studies) (Sherrington et al., 2019). The effect of exercise on the number of people who experience one or more falls requiring hospital admission is still unclear (RR 0.78, 95% CI 0.51 to 1.18, 1705 participants, 2 studies, very low-certainty evidence). Similarly, the effect of exercise on the number of people experiencing one or more falls requiring medical attention is of low certainty (RR 0.61, 95% CI 0.47 to 0.79, 1019 participants, 5 studies; low-certainty evidence) (Sherrington et al., 2019). There is some evidence to suggest exercise (all types) may have some effect on fall-related injuries in community dwelling older adults; however, high quality research on the effects of exercise on fall-related injuries is still needed in older adults that are frail or have multiple chronic conditions.

1.2.3 Fractures

The highest level of evidence on the effects of exercise on the rate of fractures in older adults comes from four meta-analyses of randomized controlled trials (RCTs); two of these studies report on incident fractures (Gillespie et al., 2012; Howe et al., 2011) while the other two studies describe the number of fractures as a result of a fall (El-khoury et al., 2013; Sherrington et al., 2019). Howe et al., (2011) reported, with a high level of certainty, that exercise had no effect on the number of fractures in postmenopausal women (OR 0.61, 95% CI 0.23 to 1.64, 539 participants, 4 studies); however, our confidence and certainty in this estimate should be hampered by the wide confidence intervals and by the point estimate crossing the line of no difference. El-Khoury et al., (2013) reported exercise may reduce the rate of severe injurious falls (i.e., fractures) by 39% (95% CI 0.22 to 0.66, 6 trials) and, similarly, a Cochrane review reported multicomponent exercise interventions could reduce the risk of fractures resulting from a fall (RR 0.36, 95% CI 0.19 to 0.70, 719 participants, 5 studies) (Gillespie et al., 2012). The most recent Cochrane review reported exercise in general reduced the risk of one or more fall-related fractures in community dwelling older adults (RR 0.73, 95% CI 0.56 to 0.95, 4,047 participants, 10 studies) (Sherrington et al., 2019). Sherrington et al., (2019) also performed a subgroup analysis in individuals at high risk of falling and the authors' reported exercise was not significant at reducing fall-related fractures in this group (RR 0.80, 95% CI 0.60 to 1.07, 5 studies). There is some justification that exercise probably reduces the risk of fractures in healthier community-dwelling older adults; however, based on Sherrington's (2019) subgroup analysis, the effects of exercise on fractures in older, clinical populations, such as those with osteoporosis or that are frail, are still unclear.

1.2.4 Health-related quality of life

A 2019 Cochrane review reported exercise (all types) may have little difference on health-related quality of life in older adults living in the community (Standard Mean Difference [SMD] -0.03, 95% CI -0.10 to 0.04; 3172 participants, 15 studies, low certainty evidence) (Sherrington et al., 2019). However, it may be possible that different types of exercise may affect health-related quality of life or that exercise in general may influence specific domains in health-related quality of life questionnaires. For example, there is emerging data for significant psychological and cognitive benefits accrued from regular exercise (Wojtek et al., 2009); some psychological components may be subdomains on health-related quality of life questionnaires. In addition, it may also be possible that studies reporting the effects of exercise on health-related quality of life are observing ceiling effects if most participants enrolled are already reporting decent scores at baseline such that there is little room for improvement. The effects of exercise on health-related quality of life should not be discounted.

1.2.5 Physical functioning and disability

The American 2018 Physical Activity Guidelines Advisory Committee Scientific Report cited strong evidence that aerobic exercises, resistance training, balance training, or a combination of these activities improved physical function and reduced the risk of age-related loss of physical function in community dwelling older adults (Physical Activity Guidelines Advisory Committee, 2018). Similarly, a meta-analysis reported resistance

training alone or in combination with aerobic training were effective at improving performance-based, composite measures of physical function in community dwelling older adults (SMD 0.62, 95% CI 0.40 to 0.84, 2,608 participants, 40 studies) (Chase et al., 2017). Another meta-analysis reported multicomponent exercise interventions significantly improved some, but not all, aspects of muscle strength and physical functional outcomes in older adults with sarcopenia (Vlietstra et al., 2018). Resistance training alone, performed for 3 to 18 months, improved muscle mass and strength, and physical performance variables, such as chair rise, stair climb, and the 12-minute-walktest in older adults with sarcopenia (Cruz-Jentoft et al., 2014). Progressive resistance training performed two to three times per week at a high intensity result in moderate to large significant improvements in gait speed, getting out of a chair, and muscle strength (Liu & Latham, 2009). There is also some evidence to support the efficacy of resistance training in older, clinical populations. For example, the 2018 American report found limited evidence that resistance training alone or as part of a multicomponent intervention improved physical function among older adults with cardiovascular disease, chronic obstructive pulmonary disease, cognitive impairments, osteoporosis, and hip fractures (Physical Activity Guidelines Advisory Committee, 2018). There is also some evidence on the effects of resistance training in people that are frail and that have experienced a stroke; the 2018 report cited 15 systematic reviews and meta-analysis that resistance training exercises improved a number of physical function outcomes in frail individuals including gait speed, time needed to walk 10 meters, and the timed up-and-go test (Physical Activity Guidelines Advisory Committee, 2018). There is evidence to suggest the benefits of resistance training alone or as part of a multicomponent intervention in community dwelling older adults and in older adults with multiple chronic conditions.

1.3 Knowledge-to-Practice Gap: Translating evidence-based physical activity in practice

There is strong evidence on the benefits of certain types of exercise to prevent falls and improve mobility among older adults. There is limited evidence on the benefits of exercise on falls, fall-related injuries, fractures, and health-related quality of life, especially among those with osteoporosis and frailty. There are several barriers to participating in exercise such as having low exercise self-efficacy, accessing exercise programs that meet needs and preferences, and lacking exercise-related knowledge (Ziebart et al., 2018). In addition, most individuals fall short of achieving the recommended levels of physical activity, with 88% of adults over 65 not reaching the intended level and intensity of physical activity (Public Health Agency of Canada, 2016). The successful translation of evidence-based recommendations into practice are still in its infancy. There is a need to move beyond generating a list of barriers to understanding how barriers can be overcome by theory-informed knowledge translation interventions.

Evidence relating to the efficacy and safety of exercise is scarce for individuals at high risk of fractures and prior fragility fractures. Exercise classes in community centers may not always target goals relevant to people with frailty or osteoporosis such as preventing weight loss or building muscular strength with sufficient intensity. The lack of safe and effective exercise classes in the community poses barriers to patients seeking safe and effective exercises as a means to improve mobility and reduce fracture risk. We still require exercise models targeted specifically for individuals with osteoporosis and frailty. Since the Too Fit to Fracture initiative in 2014 (Giangregorio et al., 2014) and the 2010 osteoporosis guidelines (Papaioannou et al., 2010), new research has been published related to moderate and high-intensity resistance training and impact exercises in individuals with osteoporosis, which may alter recommendations. There is also a need to implement evidence-based models to help older adults with frailty meet the physical activity guidelines, particularly focusing on balance and strength training. In addition to

exercise, many older adults do not eat enough protein and consume less than the Estimated Average Requirement of 0.66 grams/kg of body weight/day (Berner et al., 2013). Food intake in older adults is extremely complex and there are several barriers to consuming enough protein including poor health, poor appetite, changes in food preference, and chewing difficulties (Keller, 2007). A population-based study (2,066 community-dwelling adults 70 to 79 years) showed that those consuming at least 1.2 grams of protein/kg of body weight/day lost lean mass over the three-year follow-up period, but this loss was 40% lower compared to those consuming 0.8 grams of protein/kg of body weight/day (Houston et al., 2008). Initiating exercise when protein intake is inadequate may cause weight loss, or limit capacity or strength gains. It is important to consider nutrition as part of an exercise intervention, especially among frail individuals.

1.4 Thesis objectives

The purpose of this thesis was to develop and implement a strategy to better manage osteoporosis and frailty among older adults guided by the Knowledge-to-Action (KTA) framework (Figure 1). The KTA framework is comprised of two components: Knowledge Creation (the funnel) surrounded by the Action Cycle (Graham et al., 2013). The Action Cycle is the process by which knowledge is implemented, while the Action cycle represents phases of activities that are needed for knowledge applications to achieve a deliberate change in groups that vary in size and setting.

1.4.1 Knowledge Creation

The Knowledge Creation component refers to the production of knowledge and is composed of three phases: 1) knowledge inquiry (first generation knowledge); 2) knowledge synthesis (second generation knowledge); and 3) creation of knowledge tools (third generation knowledge). The Knowledge Creation component is shaped as a funnel to represent "research knowledge being filtered through the funnel"; as the research

enters each stage in the Knowledge Creation process, the resulting work becomes more synthesized and potentially relevant for the end users (Graham et al., 2013).

1.4.2 The Action Cycle

There are seven phases in the Action Cycle and each phase can occur sequentially or simultaneously with other phases. There are multiple theories based on different disciplines that can be used to help guide each phase. The seven phases of the cycle include: 1) identifying the problem and determining the knowledge gap; 2) adapting or customizing the knowledge to local context; 3) assessing the determinants of knowledge use (barriers and facilitators); 4) selecting, tailoring and implementing an intervention; 5) monitoring knowledge use; 6) evaluating outcomes or the impact of using the knowledge; and 7) determining strategies for ensuring sustained knowledge use (Graham et al., 2013).

1.5 Thesis objectives

This thesis is composed of three studies. Each study was guided by a phase or several phases on the KTA cycle. The objectives of this thesis were to:

- Conduct a systematic review and meta-analysis on the effects of impact exercises
 on a number of health outcomes including falls, fractures, and health-related
 quality of life in individuals at risk of fracture (Chapter two);
- Understand the perspectives on starting or continuing moderate or high impact exercise and resistance training among individuals living with osteoporosis (Chapter three);
- Assess the feasibility of a model to deliver functional strength and balance training and promote adequate protein intake in older adults that are pre-frail or frail (Chapter four and five).

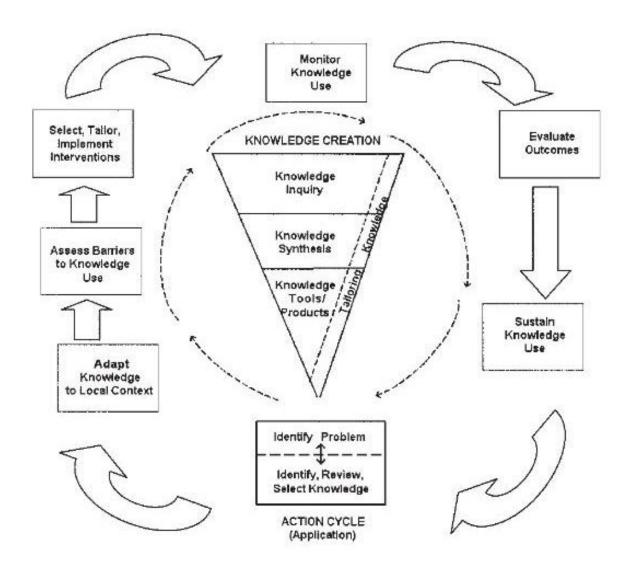


Figure 1: Knowledge-to-Action (KTA) Framework. Reproduced with permission from Graham et al., 2006 in Appendix E.

The first study was guided by the "knowledge synthesis" and "knowledge tools/products" components of the Knowledge Creation section of the KTA framework. First, we synthesized primary studies (randomized controlled trials) to form secondary knowledge (systematic reviews and meta-analyses). Chapter two is composed of two

systematic reviews and meta-analyses: one on impact exercises and the other on walking and Nordic walking. The results of these reviews were used to inform the 2021/2022 Clinical Practice Guidelines for the Management of Osteoporosis. The guidelines are not part of this thesis.

Some recommendations suggest moderate or high impact exercises and resistance training may have an osteogenic benefit on bone health. Before designing additional interventions to determine the efficacy of such exercises, we should explore patient's perspectives and attitudes to starting or continuing moderate or high impact exercise and resistance training. The second study was guided by the Action Cycle, which suggests "Identify, review, and select knowledge". The results of study two can be used to design and tailor interventions for people with osteoporosis.

The third study focused on pilot testing the implementation of a model (MoveStrong) to teach pre-frail and frail older adults how to safely perform functional strength and balance training. To maximize the benefits of resistance training, this model includes an education component on consuming enough protein. This study was guided by the Action Cycle and focused specifically on "selecting, tailoring and implementing the intervention" and "assessing barriers and facilitators to knowledge use". MoveStrong is a multifaceted intervention and includes educational material, educational meetings, and educational outreach to promote uptake of balance and functional strength training, and dietary protein levels.

Chapter 2: The effects of impact exercises on health-related outcomes in people at risk of fracture: A protocol of a systematic review and meta-analysis

This chapter was published as two manuscripts:

1. Study One: https://link.springer.com/article/10.1007/s40279-021-01432-x

Rodrigues IB, Ponzano M, Hosseini Z, et al. (2021). The Effect of Impact Exercise (Alone or Multicomponent Intervention) on Health-Related Outcomes in Individuals at Risk of Fractures: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Sports Med*, 51, 1273–1292.

2. Study Two: https://doi.org/10.1123/japa.2020-0262

Rodrigues IB, Ponzano M, Butt DA, et al. (2021). The Effects of Walking or Nordic Walking in Adults 50 Years and Older at Elevated Risk of Fractures: A Systematic Review and Meta-Analysis. *Journal of aging and physical activity*, 1–14. Advance online publication.

2.1 Introduction

Maintaining an active lifestyle by participating in regular physical activity is an important strategy to optimize health and reduce the risk of osteoporosis and related fractures (Giangregorio et al., 2014; Sievänen & Kannus, 2007). Some types of exercise or physical activity may not be appropriate or may require modifications in individuals at elevated risk of fracture (Giangregorio et al., 2014). There is evidence that regular weightbearing or resistance training can slow the age-related decline in bone mineral density (BMD) at clinically relevant sites such as the proximal femur and the lumbar spine (Martyn -St James & Carroll, 2010; Welsh & Rutherford, 1996). Bone tissue is thought to respond to mechanical stimuli (Turner & Robling, 2005; Turner & Robling, 2003) applied either through impact with a surface (i.e., weight-bearing) or through muscle contractions (i.e., muscle loading) (Kohrt et al., 2011). Weight-bearing or impact exercises (e.g., walking, stepping-up, dancing, jumping) can be used to generate a mechanical load on the bone through ground reaction forces (GRF) to stimulate osteogenesis in pre-menopausal and post-menopausal women (Martyn -St James & Carroll, 2010; Welsh & Rutherford, 1996). The term "weight-bearing" is often used in clinical studies to categorize physical activities with respect to their bone-loading potential (Kelley et al., 2013).

There is less evidence about the benefits versus the harms of prescribing impact exercises to people at moderate or high risk of fractures. The long-term effects of impact exercise on preventing fragility fractures has not been characterized (Nikander et al., 2011). While BMD and fracture risk are important health outcomes, it is also relevant to consider the opinions of people living with osteoporosis and to understand what outcomes are important to them when developing recommendations. We distributed surveys to over 1000 participants with osteoporosis (Morin et al., 2019) and to over 100 exercise professionals (Rodrigues et al., 2019) to identify outcomes important to individuals with osteoporosis. From these surveys we learned people living with osteoporosis and exercise professionals place the highest value on physical functioning and disability, health-related quality of life, fracture prevention, and mortality (Morin et al., 2019). From our patient survey, we also learned that patients had questions specifically on walking as a standalone intervention (Morin et al., 2020). In addition, we included Nordic walking in the walking systematic review since this activity is becoming popular among our target

population. For this reason, we reported the effects of walking and Nordic walking as a separate systematic review.

The proposed systematic review protocols were part of a series of systematic reviews investigating the effects of different types of exercise on health-related outcomes in people at elevated risk of fractures. The final reviews informed the 2021/2022 Clinical Practice Guidelines for Management of Osteoporosis and Fracture Prevention in Canada. The primary objectives of this study were to:

- 1. summarize the evidence on the effects of impact exercises on falls, fractures, health-related quality of life, mortality, and physical functioning and disability in individuals 50 years and older at risk of fractures; and
- 2. review the evidence on the effects of walking or Nordic walking on falls, fractures, health-related quality of life, mortality, and physical functioning and disability in individuals 50 years and older at risk of fractures.

Each objective was published as separate systematic review (see page 34).

2.2 Methods

2.2.1 Protocol and Registration

This protocol was designed based on the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines. The protocol was informed by the Cochrane Handbook for Systematic Review of Interventions and both the walking/Nordic walking and the impact exercise review were registered via the International Prospective Register of Systematic Reviews at https://www.crd.york.ac.uk/prospero/.

2.2.2 Search Strategy

A librarian with experience conducting systematic reviews developed a literature search in the following databases: MEDLINE (Ovid), EMBASE (Ovid), Cochrane CENTRAL (clinical trial), Cochrane Database of Systematic Reviews, CINAHL (allied health journal content), Epistemonikos, and Web of Science. The search strategy was developed using a combination of subject headings (i.e., Medical Subject Headings) and author keywords for the following concepts: "osteoporosis", "exercise", and "older adults" (see Table 12). There were no restrictions on gender, ethnicity, or exercise setting. We

restricted the search to randomized controlled trials (RCTs) and quasi-RCTs conducted in humans written in English, Portuguese, Spanish, Italian, or Farsi. Duplicates were removed, and titles and abstracts were imported into Covidence (Veritas Health Innovation, Melbourne, Australia).

2.2.3 Study Selection

Two independent reviewers assessed the eligibility criteria at each phase: level 1 screening (title and abstract; Table 10), level 2 screening (full-text review; Table 11), and level 3 data extraction. Conflicts were discussed between reviewers and if an agreement could not be reached, a third independent evaluator was used.

2.2.4 Eligibility criteria

2.2.4.1 Population

We included studies with men and postmenopausal women aged 50 years or older with either: 1) a diagnosis of low bone mass or osteoporosis at the femoral neck or the lumbar spine (T-score < -1) measured with dual-energy X-ray absorptiometry (DXA); 2) a history of a fragility fracture (i.e., spine, hip, wrist, humerus); or 3) a score of moderate or high-risk of a fracture based on a 10-year risk using either the CAROC, FRAX, or GARVAN calculators. We excluded studies of individuals diagnosed with secondary osteoporosis, glucocorticoid-induced osteoporosis, or traumatic fractures.

2.2.4.2 Intervention

The systematic review on impact exercises included exercise interventions with a $GRF \ge 1 \times \text{body}$ weight (BW) on the lower extremities. GRFs are a non-invasive surrogate measure of bone strain during impact activities. Examples of impact interventions include jumping, stair climbing, and dancing. If GRF was not provided in a study, we selected a peak vertical GRF from a table of common impact exercises to determine if the exercise has a GRF greater than or equal to one BW (Weeks & Beck, 2008). We included walking interventions as the focus of a separate review because in our patient survey, patients had questions focused specifically on walking as a standalone intervention (Morin et al., 2019). For the walking systematic review, we included studies that evaluated walking or

Nordic walking as part of the main intervention offered at least two or more times per week for bouts of ten minutes or more. For both systematic reviews, the intervention could be home-delivered or performed in a center outside the home, group-based or individual, and supervised or non-supervised. We included trials that combine impact or walking/Nordic walking interventions with other types of exercise. Studies were excluded if a pharmacological therapy was used as a co-intervention but not administered to both groups or if trials combined impact exercises or walking/Nordic walking programs with whole-body vibration.

2.2.4.3 Comparator

Studies were included if at least one group received a placebo, a non-exercise, or a non-physical therapy intervention (e.g., educational intervention or stretching). Active controls were included if the control group was not hypothesized to influence one or more of the outcomes of interest.

2.2.4.4 Outcomes

We established a list of outcomes deemed critical or important to individuals living with osteoporosis and to exercise professionals (Morin et al., 2019). The outcomes of interest included: 1) *mortality*, due to any cause such as natural, disease, or injury-related circumstances that result in a fatal injury or in death (19); 2) *fracture-related mortality*, defined as deaths attributed to a fragility fracture (20); 3) *fragility fractures*, fracture of the spine, wrist, humerus, or pelvis caused by minimal trauma (21); 4) *hip fractures*, fracture at the femoral neck or trochanter (22); 5) *number of falls*, defined by the number of people who experienced one or more falls during the study (23) or *fall-related injuries*, any injury (e.g., head injury or fracture) from a fall (24); 6) *physical functioning and disability*, any validated performance-based measure of physical function (e.g., gait speed, 5x sit-to-stand, Timed Up and Go (TUG)) but not including isolated measures of muscle strength (e.g., knees extensor strength); 7) *health-related quality of life*, determined using any validated generic quality of life questionnaire or osteoporosis-specific quality of life questionnaire (25–27); and 8) *serious adverse events*, defined as any untoward medical occurrence, that at any dose, results in death, life-threatening, inpatient hospitalization,

or prolongation of existing hospitalization, or in persistent or significant disability/incapacity (28) or *non-serious adverse events*, defined as any reaction related to the intervention such as musculoskeletal injuries (e.g., sprains, strains, joint pain, overuse injuries) that do not require immediate medical attention.

Pain and BMD were not voted as critical outcomes for the guidelines but will be included in this review. We collected *BMD* measures of the lumbar spine, total hip, femoral neck, and distal radius reported with DXA. *Pain* outcomes were assessed using any validated questionnaire such as a pain intensity scale (e.g., Visual Analog Scale), a global measurement scale (e.g., overall improvement, proportion of participants recovered), or a generic functional status (e.g., SF-36, Nottingham Health Profile) (29). Falls and BMD were considered indirect outcomes for fall-related injuries and fracture risk, respectively.

2.2.4.5 Time Frame

Studies were included if the planned duration of the intervention was four weeks or longer or if at least ten sessions are offered over a shorter time frame. Studies measuring BMD were included in the meta-analysis if the intervention was at least eight months or longer to allow at least one to two bone remodelling cycles (Kimmel, 1982; Marotti, 1975).

2.2.4.6 Study Design

RCTs and quasi-RCTs were considered for inclusion. We planned on including both RCTs and quasi-RCTs because we anticipated that for some outcomes there would be few RCTs.

2.2.5 Data synthesis and statistical analysis

In Covidence, the following information was extracted by two independent reviewers: year of publication, study setting, participants' characteristics based on PROGRESS-Plus (Place of Residence, Race/ethnicity, Occupation, Gender, Religion/culture, Education, Socio-economic status, Social capital/networks, Plus other factors like disability, sexual orientation, and age (Neill et al., 2014)), exercise frequency, intensity, and duration, the control group's intervention, the number of recruited

participants at baseline, adherence rates in intervention group(s), retention rates, outcomes of interest, and adverse effects. If data was missing, authors were contacted. If authors did not respond, but the data was presented in a figure, we used the WebPlotDigitizer (https://automeris.io/WebPlotDigitizer/) to estimate values. Two reviewers selected values based on the darkest pixelated point in the middle of each estimate and if the values differ between reviewers by more than 2%, the data were considered missing. Categorical data were reported as a range or as a mean and standard deviation (SD). Studies using the same endpoint measurements were reported as post-intervention mean and SD or as the overall mean difference (MD) and SD. If standard error was reported, a SD was calculated using Review Manager version 5.3. For each outcome category we reported the most used tool(s). For health-related quality of life we used standardized mean difference (SMD) to pool data for tools other than QUALEFFO-41 (Lips et al., 1999), which was pooled separately. For other outcomes, we considered pooling the data if there were two or more studies measuring the same outcome. For the meta-analysis, the effect size was estimated using a fixed-effect model. Heterogeneity between trials was calculated using the I² statistic. If there were two or more available studies reporting on the same outcome in people with vertebral fractures, we conducted a subgroup analysis in individuals with vertebral fractures. If there are two or more available studies, we performed a sensitivity analysis using impact exercise, walking, and Nordic walking studies only exercises. To describe the type of impact exercise used in each study, we used the estimated peak vertical GRF for that activity (Weeks & Beck, 2008). For exercise protocols using various types of impact activities, we provided multiple peak vertical GRFs. Exercises with a GRF ≤ 1.50 were designated as low impact exercises, between 1.51 to 3.10 as moderate impact, and ≥ 3.11 as high impact. If there are two or more studies with similar levels of impact, we performed a sensitivity analysis. The meta-analysis was performed in Review Manager version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014).

2.2.6 Risk of Bias

Two reviewers independently assessed risk of bias using the Cochrane Risk of Bias tool (Higgins et al., 2011). Any conflicts were first discussed between reviewers and

if an agreement could not be reached, the decision was resolved by a third independent evaluator.

2.2.7 Certainty of Evidence

We used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to rate the certainty of evidence for each outcome as high, moderate, low, or very low (Atkins et al., 2004).

2.2.8 Ethics and Dissemination

The results were presented in two manuscripts. The first systematic review examined the effects of impact exercise on several health-related outcomes important to people with osteoporosis while the second systematic review reported on the effects of walking and Nordic walking on the same outcomes. Both reviews identified gaps in the literature regarding the characteristics of impact exercise and walking/Nordic walking interventions and health-related outcomes that still require further investigation. The results of the systematic reviews were disseminated via publications in health service journals and presented at conferences specific to people with osteoporosis and physical activity. Both reviews informed the 2021/2022 clinical practice guidelines on exercise for people with osteoporosis.

Chapter 3: A reflexive thematic analysis on perspectives on impact exercise and strength training among people with osteoporosis

Submitted to Osteoporosis International

Title

A reflexive thematic analysis on perceptions on impact exercise and strength training among people with osteoporosis

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Previous presentations and Disclaimers None

Chapter 3 (i.e., study 2) was conducted between April to June 2021, while the results of Chapters 4 and 5 (i.e., study 3) were collected between September 2019 to March 2020. The findings from study 2 were not used in the design of study 3.

3.1 Overview

Purpose: The aim of this study was to understand perspectives on starting or continuing moderate or high impact exercise or strength training among people with osteoporosis. Methods: We conducted semi-structured, one-on-one interviews with people 50 years and older with osteoporosis or low bone mass (T-score<-1). We recruited individuals through our email distribution list, social media, and snowball sampling. Transcripts were transcribed verbatim, uploaded to NVivo, and analyzed using reflexive thematic analysis. **Results:** We interviewed 43 individuals (68 ± 6.9 years). We generated three salient themes related to perspectives on starting or continuing moderate or high impact exercise and strength training. In theme one, participants literal interpretation of the exercise may induce positive or negative perceptions about the activity. For example, impact exercises were literally and negatively perceived as "jolting", "bursting", or "jarring", while strength training were literally and positively described as activities that "strengthen". Theme two suggests that exercise should be delivered in a similar format as other healthcare treatments or procedures; there was a clear parallel in the way participants described how an exercise program should be delivered and how medical treatments or procedures are prescribed and monitored by healthcare professionals. Lastly, participants are strongly influenced by discussions with their healthcare provider or by conversations with other individuals with osteoporosis over social media regarding management of osteoporosis. Certain individuals developed strong anti-medication views from advice over social media. As a result, to avoid pharmaceutical drugs, participants said they were willing to

Conclusion: We generated three salient themes related to perspective on starting or continuing moderate or high impact exercise and strength training: exercise interpretation is literal and may induce positive or negative perceptions toward the activity, exercise is medicine and should be delivered in a similar format as other treatments and procedures in our healthcare system, and when it comes to advice on managing osteoporosis, people with osteoporosis trust healthcare professionals or social media. These three themes may be useful when developing or implementing exercise programs for people with osteoporosis.

participate in moderate or high impact exercise or strength training.

3.2 Introduction

Fragility fractures are often the first indication of osteoporosis, a skeletal disorder that compromises bone strength (Public Health Agency of Canada, 2020). As osteoporosis is a chronic condition, patient self-management is important to prevent fractures (Holman & Lorig, 2004) with exercise being a key strategy (Giangregorio et al., 2014). The efficacy of exercise may vary by exercise type and outcome of interest. While outcomes such as bone mineral density and fracture are important to consider, other outcomes relevant to people with osteoporosis include physical performance, falls, and health-related quality of life (Morin et al., 2020). In community dwelling older adults, balance and functional exercises reduce the rate of falls by 24% (rate ratio 0.76, 95%) confidence intervals [CI] 0.70 to 0.81; 7920 participants, 39 studies; high-certainty evidence) and the number of people experiencing one or more falls by 13% (risk ratio 0.87, 95% CI 0.82 to 0.91; 8288 participants, 37 studies; high-certainty evidence) (Sherrington et al., 2019). In people at high risk of fractures, progressive resistance training alone may improve Timed-Up-and-Go values by 1.24 seconds (95% CI -1.67 to -0.82 seconds, 5 studies, very low certainty evidence) (Ponzano et al., 2021) while impact exercises alone may increase femoral neck (95% Cl 0.02 to 0.07 g/cm², 2 studies, 136 participants, low certainty evidence) and lumbar spine (95% CI 0.02 to 0.06 g/cm², 2 studies, 117 participants, low certainty evidence) bone mineral density by 0.04 g/cm² (Rodrigues et al., 2021). There may be benefits to engaging in a multicomponent exercise program to target several outcomes of interest.

Some studies suggest that moderate or high weightbearing exercises such as impact exercises and strength training may have an osteogenic benefit for bone health in older adults with osteoporosis (Benedetti et al., 2018; Gomez-Cabello et al., 2012; Watson et al., 2018). Position statements such as the Exercise and Sports Science Australia position statement for the management of osteoporosis recommend "moderate to high impact weightbearing activities" and "moderate to high intensity strength training" for people with osteoporosis (Beck et al., 2017). There may be a benefit to participating in moderate or high impact exercise. Walking, a low impact exercise, is often touted as an excellent activity for bone health (McArthur et al., 2018); however, walking alone may not increase bone mineral density in people at risk of fracture, although the certainty of

this evidence is low (Rodrigues et al., 2021). Programs that incorporate moderate or high weightbearing impact loads (e.g., > 2 times body weight) that are progressive and multidirectional may be osteogenic for pre-menopausal women and older adults (Bassey et al., 1998; Beck et al., 2017; Watson et al., 2018). Moreover, some exercise programs that combine both high intensity progressive strength training and moderate or high impact activities improved multiple musculoskeletal outcomes for older women and men including bone mineral density, and muscle mass, strength, and function (Engelke et al., 2006; Kukuljan et al., 2009). There may be some benefits to participating in moderate or high impact exercises and/or strength training for certain individuals with osteoporosis (Beck et al., 2017).

With the release of the updated osteoporosis exercise guidelines, it is important to understand peoples' perspectives to the specific recommendations and suggestions in the guidelines. Understanding and incorporating an individual's exercise perspectives into a program can help increase motivation to exercise. Previous work provides insight on preferences to exercise in general in people with osteoporosis (Ziebart et al., 2018). Commonly reported barriers to engaging in multicomponent physical activity include fear of injury or experience of pain from disease-related symptoms (Ziebart et al., 2018). But it is unclear if these barriers would translate to specific suggestions related to moderate or high impact exercise or moderate or high intensity strength training. The aim of this study was to understand and describe patients' perspectives on starting or continuing moderate or high intensity strength training or moderate or high impact exercises, with a sub-objective to identify facilitators and barriers as described by persons living with osteoporosis. The goal of this study was to understand perspectives to ultimately apply the results to develop patient education tools and to design exercise interventions.

3.3 Methods

3.3.1 Study design

We utilized a qualitative description method for this study, as it is a naturalistic approach to qualitative inquiry in which a phenomena may be understood through the perspectives and meanings derived by those who experience them (Kim et al., 2017; Neergaard et al., 2009; Sandelwski, 2000). Qualitative description is consistent with the

ontological position of relativism such that reality is subjective and the epistemological position of subjectivism where meaning exists within the participants (Bradshaw et al., 2017). In terms of positionality, the main researcher (IBR) is primarily a quantitative researcher yet values the qualitative approach. IBR identifies as a female researcher and has a background in rehabilitation science and knowledge translation. Although the main researcher is not an exercise physiologist, having knowledge in rehabilitation science facilitated the approach to understand perspectives on moderate or high impact exercise and strength training among people living with osteoporosis. Our approach to the research design was based on the "Big Q" approach to qualitative data (Braun & Clarke, 2013), which is set in contrast to the "small q" approach; the "small q" approach is concerned with reliability, avoiding bias, inter-rater reliability, and generalizability that stem from a scientific positivist-empiricist quantitative orientation. Ethics approval was obtained from the University of Waterloo Office of Research Ethics (approval number: 42322).

3.3.2 Participants

We used convenience sampling to recruit participants through purposive and snowball recruitment techniques. We identified participants from local community centers, national organizations (e.g., Osteoporosis Canada), and online forums (Twitter, Facebook, and Inspire). Eligible participants (both males and females) were at least 50 years or older with a self-confirmed or physician-confirmed diagnosis of osteoporosis or low bone mass (T-score ≤ -1). We included individuals regardless of their current physical activity levels to ensure we had a diverse sample of perspectives. We collected information on participants' demographics based on PROGRESS-Plus (Place of Residence, Race/ethnicity, Occupation, Gender, Religion, Education, Socio-economic status, Social capital/networks, Plus other factors like disability and age) (O'Neill et al., 2014). We also asked each participant about their physical activity levels in the last week using the Physical Activity Screen (Clark et al., 2020). Data on fall history in the last six months was collected using a questionnaire previously used in other studies (Gibbs et al., 2015; Rodrigues et al., 2021). Participant's characteristics, physical activity levels,

and fall history were reported as a mean and standard deviation (SD), or as a count and percentage (%).

3.3.3 Sample Size

Sample size for qualitative research can vary (LoBiondo-Wood & Haber, 2014) and a common practice among researchers is to recruit participants until "saturation" is achieved. Saturation is achieved when the research question is sufficiently answered with the goal of obtaining rich in information (Fawcett & Garity, 2009).

3.3.4 Data collection

We used a semi-structured interview guide to prompt discussion on perspectives on starting or continuing moderate or high impact exercise and strength training while living with osteoporosis. We used the COM-B (Capability, Opportunity, Motivation-Behaviour) model to help guide our initial questions (see Table 7) (Michie et al., 2014). COM-B is a commonly used model to identify components to change in order for a behaviour change intervention to be effective (Michie et al., 2011). Given the iterative nature of qualitative research, the interview guide was modified whenever new information emerged from successive interviews. We conducted all interviews online using Microsoft Teams or over the telephone between April 2021 to June 2021. A member of the research team (IBR) conducted all interviews and made notes during the interview as a back-up for the audio file. Each interview was audio-recorded and transcribed verbatim in MS word by IBR and three trained student volunteers at the University of Waterloo (KHP, AS, KWG). IBR reviewed transcription conventions with each volunteer to ensure accurate transcription. Due to limited resources, transcripts were not listened to for cleaning. Immediately after each interview, IBR created field notes to record the conduct of the interview, such as if the interview was done face-to-face, tone of language, and impressions of the encounter.

3.3.5 Analysis

We analyzed our results in accordance with the Braun and Clark 2006 method for reflexive thematic analysis because it offers the most theoretical independence and flexibility for a wide variety of qualitative data, especially when dealing with a large qualitative dataset. Our analysis focused on both semantic and latent features of the data, and we took a relativism perspective. We used an inductive approach to thematic analysis, where codes and themes were developed from the data content. In practice, this meant familiarisation of the transcribed interviews through reading and re-reading, then a recursive coding of the data, where codes were returned to, improved upon, and revised as the coding process proceeded. Codes were then clustered together into categories and themes were developed based on patterns described across the entire data set (Braun & Clarke, 2006). All coding and initial theme development was performed by IBR. We transcribed 42 audio recordings; one audio file was corrupt and could not be transcribed so we used notes taken during that interview. NVivo, version 12 (QSR International Pty Ltd, Doncaster, VIC, Australia) was used to manage the data and support our analysis. Data analysis began after five interviews were completed.

3.4 Results

We enrolled 43 participants (Table 1); 41 individuals identified as female while the other two participants identified as male and were recruited via snowball sampling. We generated three salient themes related to perspectives on starting or continuing moderate or high impact exercise and strength training: exercise interpretation is literal and may induce positive or negative perceptions about the activity, exercise is medicine and should be delivered in a similar format to other treatments and procedures in our healthcare system, and when it comes to advice on managing osteoporosis, people with osteoporosis trust healthcare professionals or social media.

Table 1: Demographic characteristics of participants (n = 43)

Demographics	n (%)
Age (years; mean [SD])	68.14 (6.97)
Sex (Female)	41 (95)
Ethnicity:	
White	35 (82)
South Asian	2 (5)
Asian	3 (7)
Hispanic	1 (2)
Jewish	2 (5)
Highest level of education:	

Demographics	n (%)
High School	4 (10)
College	10 (23)
University (Bachelor's degree)	16 (37)
Postgraduate	13 (30)
Employment:	, ,
Retired	29 (67)
Medical leave	1 (2)
Part-time (<40 hours/week)	7 (16)
Full-time (>40 hours/week)	6 (14)
Annual family income (in 2021 CAD):	,
≤40,000	4 (9)
40,001 to 60,000	7 (16)
60,001 to 80,000	14 (33)
≥80,001	15 (35)
Prefer not to answer	3 (7)
Place of residence:	, , , , , , , , , , , , , , , , , , ,
Lives in the community alone	11 (26)
Lives in the community with others	32 (74)
Visits from friends and family:	,
Daily	26 (61)
Weekly	16 (37)
Monthly	1 (2)
Country:	, ,
Canada	30 (70)
Living in a metropolitan area	20 (67)
Living outside population centres	10 (33)
USA	11 (26)
United Kingdom	1 (2)
Australia	1 (2)
Medical History	n (%)
Osteoporosis/low bone mass	35 (81)/ 8 (19)
Cardiovascular diseases	5 (12)
Hypertension	11 (26)
Respiratory illnesses (Asthma or COPD)	6 (14)
Osteoarthritis	21 (49)
Type II Diabetes	1 (2)
Falls and Fractures	n (%)
Individuals who had a fall in the last 6 months	10 (23)
Individuals with at least one fragility fracture	19* (44)
Distal radius	7 (16)
Ulna	1 (2)
Humerus	2 (5)
Rib	1 (2)
TAIN	' (<i>L)</i>

Demographics	n (%)
Spine (thoracic and lumbar vertebrae)	6 (14)
Pelvis	1 (2)
Tibia	3 (7)
Fibula	2 (5)
Self-Reported Physical Activity Levels	n (%)
Number of participants who achieved at least 150 minutes per week of moderate to vigorous aerobic activity	9 (21)
Number of participants who achieved at least 2 days of strength training for major muscle groups	10 (23)

^{*}Nine individuals sustained multiple fragility fractures

Theme 1: Exercise terminology should be carefully selected since exercise terms may be interpreted literally and induce positive or negative perceptions about the activity

The first theme captured the way participants interpreted impact exercises and strength training. Participants associated the term impact exercise with moderate or high impact activities such as "boxing", "running", and "jumping". Participants' description of impact activities were literal synonyms of the term 'impact' such as "jarring", "bursting", or "jolting". Many participants made statements like the following:

"For me it would be things like running... or jumping... umm. Yeah Bursts of something." – Participant 3, female, 67 years.

Participants' description of impact exercise was logical as common synonyms of the term "impact" include nouns such as collision, smash, and bump. Similarly, strength training was described using the literal term "strengthen":

"I think of strength training using weights, using a machine in order to strengthen. Weight machines or weights like lifting weights, doing I guess barbells So there's a lot of different resistance exercises I guess in order to help strengthen a person." –

Participant 40, female, 60 years.

Several participants stated they were involved in or understood the benefits of strength training programs for bone health. They participated in several types of strength training activities that involved body weight, free weights, or resistance bands:

"When you say strength training, I immediately thought of.... I think of having a few little weights in my hands. Or... I think of being down on my knees doing some kind of a push-up for strength. Or I think of something like a wall push as some strength training."

— Participant 18, female, 66 years.

"Well, the first... the first thing that comes to my mind is like training the muscles or something that that provides strength." – Participant 42, male, 64 years.

Participants literal interpretation of the exercise terminology may affect their perception about the safety, benefits, and uptake of the exercise or activity. The term strength training was preferred over resistance training. We learned that all participants felt comfortable engaging in strength training and several participants made statements where they used positive language to describe the exercise:

"I think strength training is a controlled movement, whereas impact... uh.... impact activity.... ummm, you know, you just don't know whether you're going to be hurting yourself. Yeah. Whereas with strength training.... when you're.... when you're lifting weights or doing... umm yeah you're doing it slowly and in control, I don't feel.... I don't get fearful." – Participant 26, female, 70 years.

They also associated several benefits to participating in strength training; however, participants raised concerns about the safety and benefit of participating in impact exercise programs. They often used positive language when referring to strength training and negative language when discussing impact exercises. Participants were unanimous in their perception that strength training was a "safer" type of activity because they perceived that impact exercises could cause injuries or fractures. Perceptions that strength training is "a more controlled movement" than impact exercises is important to recognize since impact exercises were associated with disorderly movements such as bursting and jolting. When describing impact exercises, participants referred to impact exercises using negative language like the following:

"I guess because during strength training, I am not jarring anything. But with high impact I don't like the idea of jarring my bones." – Participant 22, female, 77 years.

Other participants believed participating in impact exercise could jeopardize their medical health (i.e., cause injury), which could be dangerous especially during the COVID-19 pandemic where access to medical care and hospital beds may be limited:

"I just wouldn't do it [moderate or high impact exercises]. I wouldn't do that with my knees right now. They're quite painful as it is, even after they've been replaced because I still have the osteoarthritis surrounding them. No, I wouldn't. I wouldn't do anything to jeopardize myself medically right now, if possible to deal with getting an appointment." – Participant 21, female, 77 years.

Theme 2: Exercise is perceived as medicine and should be delivered in a similar structure as other treatments and procedures in our healthcare system

Participants described their preferences for delivery of an exercise program in a manner akin to other treatments and procedures in healthcare. Participants emphasized that the exercise program should be delivered by a qualified instructor (N.B., how a qualified healthcare provider prescribes a treatment) who closely monitors the participant's progress (N.B., how a healthcare provider monitors the patient's treatment or procedure). Several participants emphasized phrases such as "qualified instructor", "monitor", and "watch me":

"If someone could monitor and watch me, I need that. Some people don't need that. When I went to another gym a few years ago, the instructor there was phenomenal watching our posture and everything else." – Participant 6, female, 59 years.

In addition, participants highlighted the importance of the exercise program having a purpose/goal and be personalized to the individual (N.B., how a healthcare provider prepares a purposeful and individual treatment plan). Almost all participants reflected on the need to see a program that includes three or four levels of difficulty with modifications to the individual's ability. The resources should also cater to younger, middle-aged individuals with more positive messages.

"I would like to see a program put together for resistance training for people with osteopenia and osteoporosis for many different levels to work with people depending upon their capabilities and for them to progress or to see a progression through that to see that there is an outcome. A <u>positive</u> outcome. I know as I said it's different for everyone. I know that there's a lot of people that cannot lift weights or could on a very limited basis but maybe even a very simplified version of just helping them progress along and as I said different levels for different people with different capabilities and capabilities and abilities" – Participant 40, female, 60 years.

Participants stated they had a goal or purpose they wanted to accomplish with exercise such as maintaining their mobility and independence or preventing falls and fractures:

"I just want to stay healthy as long as I can. And I feel that as long as I can do them, without damaging it in any way, I'm gonna continue doing." – Participant 19, female, 72 years.

The benefits to mental and social health and the effect on body image were also raised. Participants with hyperkyphosis and vertebral fractures said they developed "osteobelly" and a major priority was losing fat in the lower abdomen.

Theme 3: Healthcare professionals or social media are considered trusted sources for medical advice

Participants trust healthcare professionals or social media for advice to manage and prevent osteoporosis. Some healthcare professionals may influence participants' perceptions about participating in certain types of activities or exercises:

"I've been told by my surgeon that I have to be careful. I have to keep to low to moderate impact on my hip. He said don't do running because it'll, um, the higher impact will deteriorate the hips or can cause joint issues so I <u>avoid</u> high impact for that reason. I avoid high impact" — Participant 34, female, 67 years.

While some individuals trust their healthcare provider, we learned that other participants had less faith in the healthcare system and often turned to social media for medical advice. Social media is an important tool for participants to social network and share medical advice with other individuals who are also living with osteoporosis. Through certain social media platforms, some individuals learned about the side effects of osteoporosis medications. As a result, some participants felt medications were unnecessary to treat osteoporosis and were willing to engage in an exercise program as an alternative to prescribed osteoporosis medications:

"Because I am not taking any drugs, and I don't want to. My physician wants me to and I don't want to. <laughs> So, I just keep telling her when I see her, I say just give me another year so I can increase my bone density. If I was told moderate to high impact exercises, I would start doing it immediately. As long as it is not determinantal or causing me harm I would try it." – Participant 6, female, 59 years.

3.5 Discussion

We learned there are several factors that may influence participant's perspectives on starting or continuing moderate or high impact exercise and strength training. Theme one identified that exercise terminology should be carefully selected since exercise terms may be interpreted literally and induce positive or negative perspectives about the activity or exercise. For example, impact exercises were negatively and literally perceived to be jolting, bursting, or jarring, while strength training was positively and literally described as an activity that strengthens; however, participant's literal interpretation may not always be accurate. Theme two suggests that exercise programs should be delivered in a similar approach to other treatments and procedures in our medical system. There was a clear parallel in how participants would like future exercise programs to be delivered versus how healthcare providers currently prescribe and monitor treatments in healthcare. Lastly, participants are influenced by discussions with their healthcare provider or by conversations with other individuals living with osteoporosis over social media regarding management of osteoporosis. Certain individuals had strong anti-medication views, which they read about over social media. As a result, to avoid pharmaceutical drugs, participants said they were willing to participate in moderate or high impact exercise or strength training.

It is possible that the terminology researchers and healthcare providers use plays an important role in how patients and the public perceive impact exercise and strength training. For example, a Google search of synonyms of the term "impact" include "collision", "crash", or "smash". An interesting finding in our study was the way participants perceived exercise terms as either positive or negative. Negative or positive perceptions of certain activities may influence participation or uptake of that activity. Participants in our study made logical assumptions about what they perceived to be impact exercise based on the term 'impact'. One study by Buckton and colleagues found that language is often the source of misunderstandings and terminology can have a great impact on public perceptions of health promotion messages (Buckton et al., 2015). In the study by Buckton and colleagues, the authors explored public perceptions of language commonly used to communicate the link between food and diet (Buckton et al., 2015). The authors demonstrated that the negative language used to communicate misperceptions linking food and diet reduced both the opportunity and motivation for behaviour change (Buckton et al., 2015). Furthermore, healthcare professionals are often perceived as having specific knowledge and skills to advise people on being physically active (Tomasone et al., 2016;

Williams et al., 2017). Some participants in our study were advised by their healthcare provider to avoid moderate or high impact exercises. It is possible that these healthcare providers may also be interpreting the literal meaning of the word 'impact' when advising patients about participating in impact exercises. However, there is not enough evidence on the harms versus the benefits of participating in moderate or high impact exercises for people at moderate or high risk of fracture. In fact, a recently meta-analyses by our group found the effect of impact exercises are uncertain for adverse events, falls, fractures, and mortality (Rodrigues et al., 2021). The terminology researchers and healthcare providers use with patients may be interpreted literally and influence positive or negative perceptions toward the activity, treatment, or procedure. The findings in our study suggest that researchers and healthcare professionals should be aware of the terminology they use when disseminating or implementing knowledge tools or interventions for older adults with osteoporosis.

An important finding in our study was the concept that exercise is medicine, and that exercise should be delivered in a similar manner to other treatments and procedures in our current healthcare system. The healthcare sector has the potential to offer a variety of resources and settings to counsel, refer, and deliver physical activity and exercise promotion programs for purposes of primordial, primary, secondary, or tertiary prevention or management of chronic diseases (Lobelo et al., 2014; Patrick et al., 2009). However, our healthcare system requires a "system level change" approach to spark the necessary personal, institutional, and political impetus to break barriers that currently prevents delivery of exercise as a medicine; it is likely that we will need a multimodal approach. Some common barriers that impede the integration of clinical-community linkages for exercise promotion are the lack of requisite skills and expertise to refer patients to a community-based exercise program (Clark et al., 2017), the limited staff time to deliver physical activity counselling (Clark et al., 2017), and the lack of viable financial sustainability and innovative payment models to support clinical-community integration (Lobelo et al., 2014). Additional challenges include recommendations not being acceptable to the local patient population or providers due to cultural or other factors (Graham et al., 2013). Over the years, researchers have developed and implemented several strategies to address such barriers (Clemson et al., 2010; Davis et al., 2010;

Gibbs et al., 2019; Grimshaw et al., 2004, 2012; Rodrigues et al., 2021). One strategy to bridge the clinical-community gap is through the utilization of exercise referral schemes, where a primary care provider refers a patient to a program to encourage increased physical activity or exercise (Din et al., 2015). The referrals are prepared by a primary care professional such as a nurse, physiotherapist, or physician (Din et al., 2015; Rowley et al., 2018). There is some evidence to suggest exercise referral schemes may increase physical activity levels in older adults (Pavey et al., 2011; Rowley et al., 2018); one metaanalysis found, when compared to the usual care group, 11% (95% confidence intervals 2% to 26%) more patients in the exercise referral scheme group achieved 90 to 150 minutes of moderate intensity aerobic physical activity per week at 6 to 12 months of follow-up (Pavey et al., 2011). However, it is unclear if exercise referral schemes promote long-term adherence to exercise, especially among adults and older adults with chronic conditions who require a more tailored exercise prescription. While the linkage between clinic and community-based exercise program is important to consider, we learned that participants want exercise-based programs to be delivered by a qualified professional who can monitor their progress similar to how a family doctor will refer a patient to a specialist physician who will deliver a specialized medical procedure or treatment with follow-up. Service provision models such as the Otago Exercise program includes a version where a physical therapist assesses and prescribes initial exercises to reduce falls in older adults (Davis et al., 2010); service provision models such as the Otago Exercise program were developed to specifically address barriers where a qualified exercise professional could deliver and monitor progress (Davis et al., 2010). However, the concept of continuous monitoring in our current healthcare system may not be feasible for all individuals, and so behaviour change techniques such as self-monitoring may be more realistic (Michie et al., 2009). While there is evidence to show such models are effective at improving exercise and physical activity levels, there is less information about how to scale and sustain such models in practice especially among different populations such as those with chronic diseases. Nevertheless, there is substantial evidence, with more continuing to emerge, in support of physical activity counselling, prescriptions, referral strategies, and service provision models that link healthcare and communitybased resources (Vuori et al., 2013).

We identified factors that may motivate the uptake of moderate or high impact exercise and strength training. Participants in our study mentioned several benefits of exercise or physical activity as a countermeasure to the decline in health. We learned that participants enjoyed activities that include a social aspect, enthusiastic exercise instructors, and exposure to the natural environment (e.g., exercising outside). Also mentioned in our interviews was the social interaction achieved through exercise and the importance of independence and mobility, which are both important factor to adherence (Brown et al., 2008). Previous studies have reported that perceived social support through healthcare providers, peers, family, and friends is a critical factor in exercise engagement (Cohen et al., 2000). The concept of a safe and supervised training environment was also a motivating factor that has been supported by several other studies (Dodd et al., 2006; Rodrigues et al., 2017; Ziebart et al., 2018). An interesting perspective from our study that has not been reported in other studies was that some individuals with strong antimedication views were willing to engage in moderate or high impact exercise and strength training. There is good evidence to show that patients' trust their physician's advice to manage and treat a condition (Kao et al., 1998); however, with the rapid explosion of the Internet, one important theme identified in our paper involved the use of social media as a trusted source for medical advice. There are concerns related to the extent to which patients are learning and spreading misleading information from the Internet. Our study found that social media is an important tool in patient decision making and proper use of social media may be an important facilitator of or barrier to exercise. As with the factors that motivate people to exercise, we also identified barriers to moderate or high impact exercise and strength training. A common barrier to engaging in moderate or high impact exercises was fear of sustaining an injury. Several other studies have reported fear of injury is a common barrier to exercise among people with osteoporosis (Olsen & Bergland, 2014; Pozano et al., 2020; Rodrigues et al., 2017; Ziebart et al., 2018). The most common barriers to exercise are the individual's health/comorbidities, time, transportation, and knowledge (Brawley et al., 2003; I. B. Rodrigues et al., 2017; Schutzer & Graves, 2004; Ziebart et al., 2018). Interestingly, time was not mentioned as a barrier to impact exercise or strength training. We believe time is still an important barrier but considering the participants in our study were highly motivated to exercise, participants

selected for this study may have their own personal agendas that may not be reflective of other populations.

Although our study reflected the views of many individuals living with osteoporosis, it had some limitations. Our recruitment strategies resulted in more women expressing interest than men, so the themes reflected in our study may not be transferable to individuals that identify as male. In addition, it is known that individuals who volunteer for exercise-related studies are commonly more motivated and feel good about the time they donate (Greenfield & Marks, 2004). These participants often receive free or affordable quality guided training by enrolling in research programs and, as a result, their access to information and understanding of exercise programs may be different from other groups.

3.6 Conclusion

We generated three salient themes related to perspectives on starting or continuing moderate or high impact exercise and strength training: exercise interpretation is literal and may induce positive or negative perceptions toward the activity, exercise is medicine and should be delivered in a similar format as other treatments and procedures in our healthcare system, and when it comes to advice on managing osteoporosis, people with osteoporosis trust healthcare professionals or other individuals with osteoporosis on social media. These three themes may be useful when developing or implementing exercise programs for people with osteoporosis.

Chapters 4 and 5 are related to the MoveStrong study. Chapter 4 pertains to the primary outcome (i.e., feasibility), participants' and providers' experience with MoveStrong, adaptations to the model based on participants' and providers' experiences, and program fidelity. Chapter 5 describes the results from the secondary outcomes. Each chapter was published as a separate manuscript.

Chapter 4: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0257742

Rodrigues IB, Wang E, Keller H, Thabane L, Ashe MC, Brien S, et al. (2021) The MoveStrong program for promoting balance and functional strength training and adequate protein intake in pre-frail older adults: A pilot randomized controlled trial. PLOS ONE 16(9): e0257742. https://doi.org/10.1371/journal.pone.0257742

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Chapter 4: The MoveStrong program for promoting balance and functional strength training and adequate protein intake in pre-frail older adults: A pilot randomized controlled trial

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Title

The MoveStrong program for promoting balance and functional strength training and adequate protein intake in pre-frail older adults: A pilot randomized controlled trial

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DSMB Members

The DSMB chair was represented by Dr. Stephanie Kaiser from the Division of Endocrinology and Metabolism at Dalhousie University. The DSMB clinical investigator was Dr. Christine Friedenreich, a senior director of the Cancer Epidemiology and Prevention Research Alberta Health Services, and the DSMB biostatistician was Dr. Eleanor Pullenayegum from Dalla Lana School of Public Health at the University of Toronto.

Registration

This trial was registered in ClinicalTrials.gov under identifier NCT04037436.

Funding

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4.1 Overview

Background: Balance and functional strength training can improve muscle strength and physical functioning outcomes and decrease the risk of falls in older adults. To maximize the benefits of strength training, adequate protein intake is also important. However, the number of older individuals that consume enough protein or routinely engage in strength training remains low at less than 5% and even lower for activities that challenge balance. Our primary aim was to assess the feasibility of implementing a model (MoveStrong) of service delivery to teach older adults about balance and functional strength training and methods to increase protein intake.

Methods: This study was a closed cohort stepped wedge randomized controlled trial. We recruited individuals ≥60 years considered pre-frail or frail with at least one chronic condition who were not currently engaging in regular strength training from Northern (rural) and Southern (urban) Ontario sites in Canada. The primary outcome was feasibility of implementation, defined by recruitment, retention, and adherence, and safety (defined by monitoring adverse events). We also reported participants' and providers' experience with MoveStrong, adaptations to the model based on participant's and provider's experience, and program fidelity.

Results: We recruited 44 participants to the study and the average adherence rate was 72% with a retention of 71%. The program had a high-fidelity score. One person experienced a fall-related injury during exercise, while two other participants reported pain during certain activities. Five individuals experienced injuries or health problems that were not related to the program. Suggestions for future trials include modifying some exercises, exploring volunteer assistance, increasing the diversity of participants enrolled, and considering a different study design.

Conclusions: Our pilot trial demonstrates the feasibility of recruitment and adherence for a larger multisite RCT of balance and functional strength training with attention to protein intake in pre-frail and frail older adults.

4.2 Introduction

Balance and strength training can improve muscle strength and physical functioning and disability outcomes, and decrease the risk of falling in older adults with chronic conditions (Cruz-Jentoft et al., 2014; Peterson et al., 2011; Sherrington et al., 2019; Sherrington et al., 2017; Wojtek et al., 2009; Yoshimura & Wakabayashi, 2017). For example, for older adults with sarcopenia, strength training performed between 3 to 18 months, improved muscle mass and strength, and physical performance outcomes such as the chair rise, stair climb, and the 12-minute-walk-test (Cruz-Jentoft et al., 2014). Progressive strength training performed two to three times per week at a high intensity resulted in moderate to large improvements in gait speed, getting out of a chair, and muscle strength (Liu & Latham, 2009). Furthermore, a Cochrane review reported that balance and functional exercises reduced the rate of falls by 24% in community dwelling older adults (Sherrington et al., 2019), and balance and functional exercises in combination with strength training could potentially reduce the rate of falls by more than 30% (Sherrington et al., 2019).

The benefits accrued from exercise are evident, but less than 5% of adults 60 years of age and older regularly perform two days a week of balance and strength training (Public Health Agency of Canada, 2016). The biggest challenge is not a lack of evidence that balance and functional strength training is beneficial, but the absence of effective and sustainable real-world models for implementation of balance and functional strengthening exercises, especially for older adults with chronic conditions. There are a few, welldesigned home and facility-based exercise programs that reduce falls and increase shortterm physical activity levels in older adults (Campbell et al., 1999; Clemson et al., 2012; Shubert et al., 2017). However, there are few feasible, sustainable, and cost-effective models to deliver balance and functional strength training in a real-world setting (Gibbs et al., 2019; Katz et al., 2012). There is also limited evidence on how to effectively implement and sustain these types of exercise interventions in practice, especially for older adults with chronic conditions (Gibbs et al., 2019). To address these challenges, we collaborated with several stakeholders to create MoveStrong – a model of service delivery that provides education and training on performing balance and functional strength training aligned with movements performed during activities of daily living for pre-frail and frail older adults. To maximize the benefits of strength training, we provided nutrition education on consuming enough protein, to support muscle growth and function (Morton et al., 2018). Adequate protein intake is a prerequisite to allow net muscle protein accretion after strength training (Morton et al., 2018; Phillips et al., 2009). However, many older adults do not eat enough protein and consume less than 0.66 grams/kg of body weight/day (Berner et al., 2013). Food intake in older adults is extremely complex and there are several barriers to consuming enough protein including poor health, poor appetite, changes in food preference, and chewing difficulties (Keller, 2007). A population-based study (2,066 community-dwelling adults 70 to 79 years) showed that those consuming at least 1.2 grams of protein/kg of body weight/day lost lean mass over the three-year follow-up period, but this loss was 40% lower compared to those consuming 0.8 grams of protein/kg of body weight/day (Houston et al., 2008). Initiating exercise when protein intake is inadequate may cause weight loss, or limit capacity or strength gains.

The purpose of this study was to conduct a pilot of the MoveStrong program to assess the feasibility of implementation for a larger pragmatic trial. This pilot study assessed the feasibility, fidelity, and the adaptability of a stepped wedge trial evaluating the MoveStrong model in diverse settings across Ontario, Canada. The primary objective was feasibility determined by: 1) evaluating the number of participants recruited to participate; 2) determining retention rates at the end of the study; and 3) calculating adherence rates to the program. We also reported the participants' and providers' experience with MoveStrong, adaptations to the model based on participants' and providers' experiences, and program fidelity. The secondary outcomes (body weight, gait speed, grip strength, fatigue levels, lower limb muscle strength, dynamic balance, health-related quality of life, resource use, and protein intake) were reported in another manuscript.

4.3 Methods

We conducted this study in accordance with the extension of the CONSORT 2010 reporting guidelines for stepped-wedge cluster randomized trials (Hemming et al., 2019) and pilot and feasibility trials (Eldridge et al., 2016). We also used the TIDieR (Template

for Intervention Description and Replication) checklist to promote full and accurate description of the intervention (Hoffmann et al., 2014).

4.3.1 Trial design

The study design was an eight-week pilot, assessor-blinded, multisite, closed cohort stepped wedge randomized controlled trial (RCT). In a stepped wedge design each site was exposed to the intervention but not at the same point in time. Before the program begins, all sites were randomized to start at different time points, each three weeks apart. At regular three-week intervals (the "steps"), one site crosses from the control group to the intervention group (Figure 2) (Copas et al., 2015). This process continues until all sites have been exposed the MoveStrong program. We selected the stepped wedge design because it provides the advantage that all participants will eventually receive the intervention (Copas et al., 2015). This design also allowed us to determine the feasibility of using a stepped wedge design for a larger pragmatic trial.

4.3.2 Study setting

We evaluated the program in areas that typically represent real-world practice and we selected three distinct settings: retirement/assisted living homes, community centers, and a family health team in four cities across Ontario. One northern and three southern Ontario sites were chosen to ensure diversity in city population, structure, and health service. We hired exercise physiologists with at least one-year of experience delivering exercise to older adults so that we could assess the feasibility of real-world implementation rather than have it delivered in a research setting by researchers. We also hired two registered dietitians with the Dietitians of Canada: one dietitian at the northern Ontario site and the other at the southern Ontario sites. The MoveStrong program was implemented and delivered at a kinesiologist-led clinic partnered with Arbour Trails (retirement/assisted living home and independent living, Guelph, site 1), the City of Lakes Family Health Team (Sudbury, site 2), the Village of Winston Park (retirement/assisted living home and independent living, Kitchener, site 3), and two of the YMCA's of Cambridge and Kitchener-Waterloo (each YMCA is part of one site, site 4). The Sudbury site is located in northern Ontario, while the other three sites are in southern

Ontario. The Sudbury site is in rural Ontario, while the other three sites are in urban centers. There are differences between urban and rural populations in terms of health seeking behaviours, health status, and health service use, cost, and outcomes. In general, rural residents have access to a smaller number of health services and providers than urban residents (Sibley & Weiner, 2011).

	Study start-up, training	Pre- rollout period -					Rolle	out, E	Expo:	sure	and	Ma	inte	nano	ce					Data cleaning, analysis, dissemination
Time in weeks	1 to 8	9 to 16	17 to 18	19 20	21	22 2	23 2	24 25	5 26	27	28	29	30	31	32	33	34	35	36	37 to 52
Site 1			Х				7	Х					Х						Х	
Site 2			Х				7	Х					Х						Х	
Site 3			Х				7	X					Х						Х	
Site 4			Х					Х					Х						Х	
Site 4	J	of staff, o	rientatio		,		ateri	als											Х	
During the pre-rollout period, study sites will initiate advertisement and recruitment.																				
	Roll-out period: Intervention is rolled out every three weeks																			
	Exposur	e to Move	STroNg	worksh	op															
	Maintena	ance perio	d: Move	STroNo	y wo	rksho	p is	com	olete	. Pai	rticip	ant	s ar	e en	cou	rage	ed to	o su	stair	n behaviour char

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

Figure 2. Timeline for the MoveStrong Trial.

4.3.3 Participants

We included participants if they: 1) spoke English or attended with a translator; 2) were ≥ 60 years of age; 3) had a FRAIL Scale score ≥1 (i.e., a score of 0 is robust, a score 1 or 2, pre-frail, and a score of 3 to 5, frail) (van Kan et al., 2008); and 4) had at least one of the following chronic conditions diagnosed by a physician: diabetes, obesity, cancer (other than minor skin cancer), chronic lung disease, cardiovascular disease, congestive heart failure, hypertension, osteoporosis, arthritis, stroke, or kidney disease. We encouraged participants to attend with a caregiver/friend for social or physical support, and the caregiver/friend was given the opportunity to complete the screening and assessment process to determine if they were eligible to enroll in the study. We excluded individuals who: 1) were currently doing a similar resistance exercise ≥2x/week; 2) were receiving palliative care; 3) could not perform basic activities of daily living; 4) had severe cognitive impairment (e.g., unable to follow two-step commands or could not explain the research study to the research assistant); 5) were travelling >1 week during

the MoveStrong program; or 6) had absolute exercise contraindications. We determined absolute exercise contraindications to exercise using the American College of Sports Medicine guidelines (American College of Sports Medicine position stand, 1998).

4.3.4 Recruitment and randomization

We recruited participants from local primary care practices, retirement//assisted living homes, and via advertisement in the local community (e.g., physiotherapy clinics, libraries, and churches) using face-to-face techniques, traditional and social media (Facebook and Twitter), posters, flyers, and brochures. We set up recruitment booths at the two retirement/assisted living home sites. Due to the delay between recruitment and randomization, we decided a priori that participants that dropped out prior to randomization could be replaced up until the intervention started. A biostatistician, independent of the study, created a computer-generated randomization sequence at St. Joseph's Healthcare in Hamilton to randomize sites to start the program at one of four start times, each three weeks apart. A co-investigator at the University of British Columbia kept the randomization sequence concealed and communicated the sequence to all sites after randomization. Each site was assigned to receive the intervention at either week 19, 22, 25, or 28 (see Figure 2); participants that received the intervention at weeks 22, 25, and 28 were asked to continue their usual activities until the start of the program. Sites 3 and 4 acted as our "control" group.

4.3.5 Intervention

4.3.5.1 Exercise program

The MoveStrong exercise program includes functional strength training movements for older adults of varying abilities, using minimal equipment. Each exercise was informed by the GLA:D program for arthritis (Skou & Roos, 2017), BoneFit[™] (Giangregorio et al., 2014), and meta-analyses on resistance exercise and fall prevention for older adults (Borde et al., 2015; Liu & Latham, 2009; Peterson et al., 2011; Sherrington et al., 2017; Tricco et al., 2017) (Table 8). We sought input from representatives from the YMCAs of Cambridge and Kitchener-Waterloo, Community Support Connections, and

Osteoporosis Canada, as well as patient advocates. The exercises are aligned with functional movements to promote personal relevance such as lunging/stepping, reaching, squatting, pulling, lifting and carrying, and pushing (see Table 2 for the TIDieR checklist). Each participant received a one-to-one session with an exercise physiologist (not blinded to site allocation) who selected a starting level and variations for each functional movement, intensity, and the number of repetitions and sets. Then, participants attended an exercise physiologist-led group exercise workshop (1 exercise physiologist to ≤ 6 participants ratio) twice a week for 8-weeks. The exercise program started with a warmup (5 minutes), followed by the exercise program (50 minutes) and a cool-down (5 minutes). During the first two weeks, the focus was on form rather than on intensity. Exercise difficulty, resistance used, or volume (up to 3 sets, up to 8 reps) was progressed over time, with a target intensity of < 8 repetitions maximum. During the cool-down, the exercise physiologist led a 5-minute group discussion where participants discussed when and where to practice the exercise(s) at home or in a setting of choice. Each site received a standardized toolkit with materials for participant workbooks and a trainer manual. The manual provided guidance on how to deliver the workshop, select and progress exercises, adapt exercises for common impairments, cueing tips, and discussion topics. The research team met with each site for one to two-hours to demonstrate how to deliver the MoveStrong program and to review the manual. Participant workbooks were assembled to include pictures and instructions of each exercise so the participants could practice and exercise at home or at another location. Participants received their workbooks during the one-on-one session with the exercise physiologist.

Table 2. Template for Intervention Description and Replication (TIDieR) Checklist

Item Category	Description
Brief name	MoveSTroNg: A Model for delivering Strength Training and Nutrition education for older adults in Canadian communities.
Why	The benefits accrued from balance and functional strength training in older adults is evident. However, the number of older individuals that routinely engage in strength training remains low at less than 5% and even lower for activities that challenge balance. Novel concepts and models with the potential for large scale implementation and long-term adherence to balance and function strength training are urgently needed for frail older adults.

What: Materials	The MoveStrong program includes an exercise and a nutrition component. The exercise component is an exercise physiologist led balance and functional strength training program aligned with functional movements to promote personal relevance. Participants are provided an exercise booklet to track their goals and exercises. The nutrition component includes two dietitian-led interactive group seminars to promote strategies to increase protein intake supported by a nutrition booklet. 1) Participant's exercise booklet: A guide containing a series of pictures and written instructions on how to perform each movement with proper form and technique. There is also a goal setting and planning worksheet. 2) Participant's nutrition booklets: A guide with tips and recipes complimented by pictures and visual cues on methods to increase protein intake throughout the day. 3) Instructor's manual: A manual containing 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.), cueing tips, and motivational interviewing strategies. 4) Study manual: A manual containing information about the program timeline, research forms, physical assessment forms, and adverse event reporting forms. 5) Equipment: All sites received the following equipment: Therabands (3 levels), two sets of Kettlebells (5, 10 and 15 lbs), and step-ups with modifiable levels.
What: Procedures	The exercise physiologist reviewed each participant's medical history and met with each participant one-on-one prior to the start of the group sessions. The participant and the Kinesiologist selected one of four starting levels for each movement. There were seven functional movements (lunging/stepping,
	impacting, reaching, squatting, pulling, lifting and carrying, and pushing), and each movement was progressed as necessary.
Who: Provided	Exercise sessions were delivered by an exercise physiologist with at least one-year of experience working with older adults. The nutrition sessions were offered by an experienced dietitian.
How	The exercise program was delivered face-to-face for eight-week in a group setting with one exercise physiologist to five or six participants. Two nutrition sessions were delivered in a group setting with one dietitian to ten participants.
Where	We selected sites that represent real-world practice. There were four locations where the program was implemented: 1) Kinnect to Wellness (Sudbury, rural Northern Ontario site); 2) Arbour Trails (retirement/assisted living home and independent living, Guelph, Southern Ontario site); 3) Village of Winston Park (retirement/assisted living home and independent living, Kitchener, Southern Ontario site); and 4) YMCAs of Cambridge and Kitchener (Southern Ontario site).
When and how much	Frequency/Duration: 2x/week for 8 weeks, 60 to 90 minutes/session. Intensity: 2-3 sets of 3-8 repetitions of each exercise with time under tension per repetition of 4:0:2 seconds for eccentric:isometric:concentric phases.

Tailoring	Participants began exercising at lower intensity; the focus was on form and technique rather than on effort for the first few weeks. The exercise physiologists increased participants intensity over the first five weeks until participants were at 3 sets of 8 repetitions of each exercise.
Modifications	We recruited volunteers to assist the exercise physiologists at the Northern Ontario site and at the retirement/assisted living homes located in the Southern Ontario sites.
How well: Planned	A third party, who is not involved in collecting outcome data, assessed if the intervention was delivered and performed as it was intended using a Fidelity Checklist. The average fidelity score was 1.74 out of two. Most exercise physiologists arrived on time, delivered the program the way it was intended, prescribed the correct frequency for each movement, and provided positive reinforcement to encourage participants. Areas where fidelity was an issue were progression of intensity, and completion of the post-exercise discussion regarding doing exercises at home due to a lack of time.
How well: Actual	The average attendance rate to the MoveStrong program was 72%. The Arbour Trails site had an average adherence rate of 73%, Kinnect to Wellness, 66%, Winston Park, 73%, and the YMCA, 77%. Approximately 62% of individuals attended at least 70% of the exercise sessions (16 sessions total).

4.3.5.2 Nutrition education

The nutrition intervention included two components: 1) a nutrition education booklet, and 2) two dietitian-led one-hour group seminars to answer questions and discuss topics related to protein intake. The dietitians were not blinded to allocation. The booklet and seminars reviewed the cost of preparing high protein foods, a guide on how and why to spread protein intake through the day, how much protein was in the participant's usual diet, low-cost options to add protein to meals, easy-to-consume protein-rich snacks with minimal preparation, high quality protein supplements (e.g., rapidly digested, high leucine like whey), and how to prioritize high-protein choices in retirement/assisted living home menus or restaurants. During each seminar, the dietitian provided samples of protein-rich snacks. Seminars were held during weeks two and five to allow time to review material, revisit topics, and address questions. We promoted a

protein intake of 1.2 grams of protein per kilogram of body weight per day or 20-30 grams of protein per meal (Morton et al., 2018; Phillips et al., 2016).

4.3.6 Outcomes

Outcome assessors were blinded to allocation. There was one outcome assessor at the southern Ontario sites and two outcome assessors at the northern Ontario site. There were four assessments total; all baseline assessments were completed prior to randomization and an additional three assessments were conducted each six weeks apart. The last evaluation was considered as a follow-up assessment (Figure 2).

4.3.7 Recruitment, retention, and adherence

The primary outcomes were feasibility of implementation, defined by recruitment (number of participants recruited prior to randomization), retention (number of participants retained during the follow-up period), and adherence (percentage of exercise sessions completed). The outcome assessors collected the data for recruitment and retention, while the exercise physiologist tracked adherence rates to ensure the outcome assessors were blinded to allocation. Our criteria for success were to recruit 10 participants at each of the four sites or 40 participants total with a retention of 90% at the end of the study, and an adherence of $\geq 70\%$ (Giangregorio et al., 2018; Gibbs et al., 2015). We selected a recruitment rate of ten participants at each site (four sites total) because of the proposed class ratio of one instructor to five participants. Recruiting ten participants allowed us to observe the feasibility to deliver two nutrition sessions and two groups of exercise sessions at each site. We allowed sites to over-recruit by up to two participants.

4.3.8 Participant and provider experience, adaptations, and fidelity

We conducted exit interviews with participants and the exercise physiologists to understand their experiences (see Table 9 for interview guide). Each interview was audio-recorded, transcribed non verbatim, and analysed using content analysis (Miles & Huberman, 1994). In addition, we provided the exercise physiologists and outcome assessors with a spreadsheet to record deviations from the exercise manual and to report any challenges and successes with MoveStrong to inform a future trial. To determine fidelity, a member of the research team with a background in exercise science observed

a randomly selected exercise session at each site using a three-point fidelity checklist designed by our research team; a score of 0 indicates the goal was not introduced, a score of 1, the goal was partially achieved, and 2, the goal was fully achieved.

4.3.9 Adverse events

Adverse events are unfavourable or unintended occurrence in the health or well-being of a research participant; these events may or may not be related to the intervention (Canadian Association of Research Ethics Boards (CAREB):, 2019). We reported two types of adverse events: 1) serious adverse events defined by Health Canada as "events that result in death, hospitalization, or disability", or 2) minor adverse events. We classified each adverse event as either "not related", "related", or "possibly related" to the intervention. A "not related" category was applied if the participant experienced an adverse event that was not related to the intervention, while a "related" category was utilized if the participant experienced the adverse event that was related to the intervention (Health Canada Guidance for Industry Clinical Safety Data Management:, 1995). A "possibly related" category means there was a reasonable possibility that the event, experience, or outcome may have been caused by the intervention or procedures involved in the trial (Health Canada Guidance for Industry Clinical Safety Data Management:, 1995).

4.3.10 Data safety monitoring committee

The committee comprised of a physiotherapist, a physician, and a biostatistician who reviewed adverse events after three sites completed the program and provided guidance for a future trial. There were no interim analyses and there were no stopping guidelines for the pilot trial.

4.3.11 Statistical analyses

The analyses and reporting of this trial follow the CONSORT extension to pilot trials (Eldridge et al., 2016). Demographic data, fidelity scores and recruitment, retention and adherence data were reported using means and standard deviations or as a count and percentage. Estimates for feasibility outcomes are reported as percent (95% confidence interval [CI]). Descriptive analyses were performed using SPSS Statistics

version 27 (Armonk, New York, USA). We analyzed the exit interviews in NVivo version 12 (QSR International Pty Ltd, 2019) to identify participants' and providers' experiences and suggested adaptations to the MoveStrong program. Adverse events were reported using narrative description.

4.4 Results

Within three months, we screened 75 individuals for eligibility and enrolled 44 participants (Table 3, Figure 3). Within one-week of randomization but prior to the start of the intervention, five individuals dropped out. We enrolled an additional four participants prior to the start of the intervention. Thirty-nine participants started the intervention. After we collected all baseline assessments, each site was randomized to start the intervention at one of four time points between October 2019 to January 2020. One participant attended with a caregiver who was not enrolled in the program.

Table 3. Demographic and health status of trial participants at baseline (n=44)

Characteristics at Baseline	Arbour Trails (n=9)	Kinnect to Wellness (n=15)	Village of Winston Park (n=9)	YMCA (n=11)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age	78 (11.50)	81 (5.39)	84 (8.80)	72 (7.71)
Height (cm)	161 (10.89), n = 7	156 (26.18)	160 (7.63), n=7	161 (7.71)
Body weight (kg)	72 (19.17), n = 7	73 (12.44)	65 (7.64), n=8	67 (12.80)
Characteristics at Baseline	n (%)	n (%)	n (%)	n (%)
Sex (Female)	7 (78)	10 (67)	7 (78)	10 (91)
Ethnicity:				
White	8 (89)	15 (100)	8 (89)	9 (82)
South Asian	0 (0)	0 (0)	1 (11)	2 (18)
Middle Eastern	1 (11)	0 (0)	0 (0)	0 (0)
Marital Status:				
Married	2 (22)	7 (47)	4 (44)	7 (64)
Widowed	4 (44)	6 (40)	5 (56)	2 (18)
Single/Separated/Divorced	3 (33)	2 (13)	0 (0)	2 (18)
Highest level of education:				
Middle school	0 (0)	5 (33)	0 (0)	1 (9)
High School	0 (0)	8 (53)	4 (44)	3 (27)

Characteristics at Baseline	Arbour Trails (n=9)	Kinnect to Wellness (n=15)	Village of Winston Park (n=9)	YMCA (n=11)
Higher education (college or university)	9 (100)	2 (13)	5 (56)	7 (64)
Employment:				
Retired (not working)	6 (67)	15 (100)	9 (100)	11 (100)
Medical leave	2 (22)	0 (0)	0 (0)	0 (0)
Part-time (<40 hours/week)	1 (11)	0 (0)	0 (0)	0 (0)
Annual income (in Canadian Dollars):				
<40,000	3 (33)	7 (47)	3 (33)	4 (36)
40,000 to 60,000	1 (11)	5 (33)	0 (0)	3 (27)
>60,000	3 (33)	0 (0)	2 (22)	0 (0)
Prefer not to say	2 (22)	3 (20)	4 (44)	4 (36)
Place of residence:				
Lives in a retirement home alone	5 (56)	1 (7)	5 (56)	0 (0)
Lives in a retirement home with someone	0 (0)	0 (0)	2 (22)	0 (0)
Lives in the community alone	2 (22)	4 (27)	1 (11)	4 (36)
Lives in the community with someone	2 (22)	10 (67)	1 (11)	7 (64)
Visits from friends and family:				
Daily	3 (33)	9 (60)	2 (22)	1 (9)
Weekly	3 (33)	5 (33)	7 (78)	9 (82)
Monthly	2 (22)	1 (7)	0 (0)	1 (9)
Yearly	1 (11)	0 (0)	0 (0)	0 (0)
Use of homecare in the last 6 months	1 (11)	1 (7)	1 (11)	1 (11)
FRAIL Scale	n (%)	n (%)	n (%)	n (%)
How much of the time during the past 4 weeks did you feel tired	5 (56)	6 (40)	5 (56)	7 (64)
Do you have any difficulty walking up 10 steps without resting	4 (44)	7 (47)	4 (44)	2 (18)
Do you have any difficulty walking several hundred yards	5 (56)	12 (80)	8 (89)	2 (18)
Did a doctor ever tell you that you have ≥5 chronic diseases	3 (33)	2 (13)	1 (11)	0 (0)
Weight change >5% in the last year	3 (33)	4 (27)	1 (11)	4 (36)

Characteristics at Baseline	Arbour Trails (n=9)	Kinnect to Wellness (n=15)	Village of Winston Park (n=9)	YMCA (n=11)
Average FRAIL score [mean (SD)]	2.00 (SD 0.50)	2.07 (0.96)	2.11 (0.60)	1.36 (0.67)
Two or more components on the FRAIL scale [mean (SD)]	8 (89)	10 (67)	8 (89)	3 (27)
Three or more components on the FRAIL scale [mean (SD)]	1 (11)	5 (33)	2 (22)	1 (9)
Comorbidities	n (%)	n (%)	n (%)	n (%)
Cardiovascular diseases	4 (44)	6 (40)	5 (56)	2 (18)
Hypertension	8 (89)	11 (73)	6 (67)	4 (36)
Respiratory illnesses	3 (33)	5 (33)	2 (22)	1 (9)
Bone disease (Osteoporosis)	4 (44)	8 (53)	5 (56)	6 (55)
Joint disease	5 (56)	15 (100)	6 (67)	5 (45)
Type II Diabetes	3 (33)	6 (40)	2 (22)	4 (36)
Low back pain	5 (56)	13 (87)	4 (44)	5 (45)
Falls and Fractures	n (%)	n (%)	n (%)	n (%)
Number of individuals who fell in the last 6 months	1 (11)	4 (27)	1 (11)	0 (0)
Number of individuals who	0 (0)	0 (0)	0 (0)	0 (0)
sustained a fragility fracture in				
the last 6 months				
Assistive Devices	n (%)	n (%)	n (%)	n (%)
Use a walker for mobility	2 (22)	0 (0)	1 (11)	1 (9)
Use a wheelchair for mobility	1 (11)	0 (0)	0 (0)	0 (0)

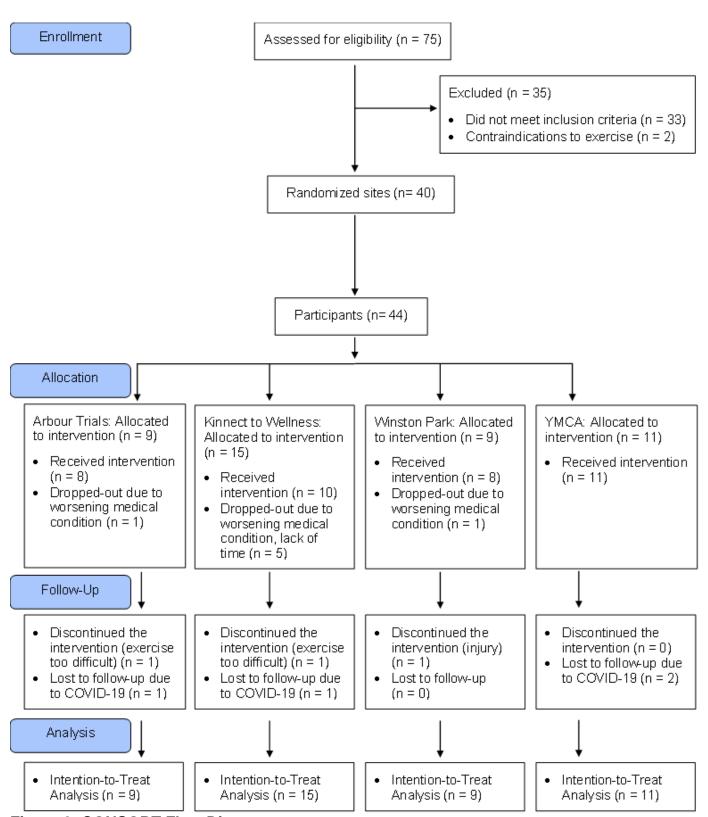


Figure 3. CONSORT Flow Diagram

4.4.1 Recruitment, retention, and adherence

Our pilot study took place during October 2019 to March 2020. All participants completed the exercise and nutrition sessions before the COVID-19 pandemic was declared in Canada; however, as a result of the pandemic, we were not able to complete follow-up visits for all participants. Criterion for success for recruitment were met. Of the 75 individuals that demonstrated interest in the program, the main driver for ineligibility was not classifying as pre-frail or frail (94%) or having a health condition that precluded exercise (i.e., uncontrolled asthma or reoccurring acute respiratory infections) (6%). At the southern Ontario sites, the screening to recruitment ratio was 3 potential participants to 1 enrolled participant; however, at the retirement/assisted living homes the screening to recruitment ratio was 6:1. Five individuals withdrew a few days after randomization, and, since the program had not started, we recruited an additional four participants. Reasons for withdrawing after randomization included worsening medical conditions (Kinnect to Wellness, n = 2; Arbour Trail, n = 1; Winston Park, n = 1) or lacking the time to exercise (Kinnect to Wellness, n = 1); three of these five individuals were men with a FRAIL score of 3 and lived alone in a retirement/assisted living home. Criterion for success related to retention were not met; a total of eight participants left the study before completion of the final data collection and retention was 79% (95% CI 66.2% to 92.8%). Thirty-one of 39 participants completed the study and their follow-up assessment. During the study, two individuals, each from different sites, left due to an injury unrelated to the program. From another site, one individual withdrew due to a minor adverse event possibly related to the intervention, while another participant withdrew because the exercises were too difficult. At follow-up, we lost four participants due to the COVID-19 pandemic (Arbour Trail, n = 1; YMCA, n = 2; Kinnect to Wellness, n = 1). Criterion for success related to adherence to the MoveStrong program were met, with an average adherence rate of 72%, 95% CI 62.7% to 81.6%, 39 participants (Arbour Trails 73%, 8 participants; Kinnect to Wellness 66%, 12 participants; Winston Park 73%, 8 participants, YMCA 77%, 11 participants). Approximately 62% of individuals (95% CI 45.5% to 77.5%) attended at least 70% of the exercise sessions (16 sessions total).

4.4.2 Adverse Events

There were two minor adverse events possibly related to the intervention and one serious adverse event related to the intervention. One participant reported groin strain while exercising but was subsequently diagnosed with hip osteoarthritis. After one-week of rest, this individual returned with a modified exercise program. The second participant had a history of right Achilles tendinitis and complained of ankle pain during the "heel drop" (i.e., impact) movement. Although all lower body exercises were ceased, after one week they withdrew from the study. One participant sustained an inferior pubic ramus fracture after a fall during the "stepping-up" movement; although this participant did not withdraw from the study, we terminated all exercises with this individual.

There were three minor and two serious adverse events not related to the intervention. One participant slipped in the living room and fractured the metatarsal bones of their left foot. Another participant fell while attempting to sit on an unlocked walker and sustained a right inferior and superior pubic ramus fracture; this participant withdrew from the study. Two participants reported to the emergency room: one with high blood pressure and the other after experiencing a transient ischemic attack. The last participant was at home when they experienced a seizure due to unknown causes and was admitted to the hospital for observation. The participants that experienced the pubic ramus fractures and the seizure were categorized as serious adverse events as a result of being hospitalized.

4.4.3 Participant and provider experiences: Successes

We interviewed 31 participants and six exercise physiologists. There were three main reasons participants chose to enroll in the program: 1) they had a medical condition that affected their daily activities; 2) they were encouraged to join with a friend or family member; or 3) they were encouraged to join by a healthcare professional. Participants reported several benefits from the exercise program including improved posture, strength, balance, self-esteem/confidence, and enhanced social interactions with other participants in the program. Most participants found the nutrition sessions helpful, and most individuals were not aware that they lacked protein in their diets. The term "relearning" was a reoccurring concept during the interview, where participants understood the importance of protein but hearing and discussing the concept again was helpful.

All six exercise physiologists enjoyed delivering the program because of its focus on evidence and small class size. The small class size enabled the instructor to have a more detailed conversation with the participants about their goals. When asked how they implemented the exercise program, the exercise physiologists said they delivered the program in one of two ways: 1) a circuit, where exercises alternated between upper or lower body movements; or 2) a buddy system, where participants with similar levels of intensity were paired. Overall, the exercise physiologists enjoyed the MoveStrong program, and they found the one-on-one sessions provided insight on the participants' needs and goals, which helped guide how the exercise physiologists tailored the program. Most participants and instructors enjoyed the MoveStrong program and stated they would like to see a similar program offered in their retirement/assisted living home or the community center.

4.4.4 Participant and provider experiences: Challenges

Several participants at the retirement/assisted living homes and the Kinnect to Wellness site stated they felt "weaker" and "limper" after an exercise class, while those enrolled at the YMCA site found the exercises were repetitive after a few weeks. Participants with dentures reported difficulties consuming "hard" food samples (e.g., nuts and seeds). The exercise physiologists at the northern Ontario site and at the retirement/assisted living homes reported the program required a longer time commitment than expected. Certain participants required additional one-on-one support during the exercise session, which took time away from other participants. The exercise physiologists at the retirement/assisted living homes and the Kinnect to Wellness site reported that some participants found it challenging to initiate the workout on their own and would often wait for assistance; in these instances, a volunteer was recruited at two sites to help other participants. In addition, the exercise physiologists reported participants at the retirement/assisted living homes and at the Kinnect to Wellness site had trouble learning certain movements, with the hip hinge (i.e., during the lift and carry movement) being the most challenging. All the exercise physiologists reported that they spent the first three to five weeks building participants' confidence and focusing on form during each movement, as some participants felt overwhelmed by the number of exercises. The exercise physiologists also suggested that participants with visual impairments and mild cognitive impairments required additional coaching to use the exercise booklet outside of the program.

4.4.5 Other successes/challenges to implementation

We identified additional challenges during the recruitment and the data collection process using a word document where assessors and exercise physiologists could track successes and challenges. Although we asked all the exercise physiologists to document their experiences with MoveStrong, only one exercise physiologist kept a journal detailing their experiences. Challenges to recruitment observed at the retirement/assisted living home sites were that the participants were not familiar with the research assistant, and some residents felt starting an exercise program at their age was unnecessary. At the YMCA site, there was a response bias with the FRAIL scale, where several participants were enrolled based on the "fatigue" category alone but may not have been pre-frail. We found it challenging to recruit male participants at the southern Ontario sites. There was not enough space or privacy to complete some assessments at the retirement/assisted living homes, some participants were not willing to do the four-square step test for safety reasons or found it difficult, and several participants were not comfortable being weighed. Some participants did not understand certain questionnaire questions. For example, several participants did not associate their children/family members buying groceries and cleaning their homes as assistance with daily activities. Five participants booked vacations between the time of recruitment and the intervention.

4.4.6 Fidelity

The average fidelity score was 1.74 (0.11); the maximum and highest fidelity score was two. All six exercise physiologists arrived on time, delivered the program the way it was intended, prescribed the correct frequency for each movement, and provided positive reinforcement to encourage participants. Areas where fidelity was an issue were progression of intensity, and completion of the post-exercise discussion regarding doing exercises at home due to a lack of time.

4.5 Discussion

Our feasibility trial provides important lessons that can inform future pragmatic exercise trials in older adults that are pre-frail and frail. We successfully recruited 44 pre-frail or frail older adults in our study, and once recruited, participants exhibited satisfactory adherence. We did not reach our retention goal, in part due to the COVID-19 pandemic. A larger trial may be feasible with some modification to the exercise program. Based on feedback and experience from participants and the exercise physiologists we may need to amend some exercises, consider volunteer assistance, and modify the study design. The stepped wedge design may create a large delay between recruitment and intervention implementation to allow for good retention. It was also challenging to teach pre-frail and frail individuals strength training and balance exercises and progress intensity in a group setting over eight weeks, so future studies need to consider whether a longer duration or more frequent initial sessions are needed to allocate time to focus on teaching form/technique prior to progressing intensity.

Recruiting frail older adults, male participants, and underrepresented groups to exercise studies can be a complex process. Although we successfully recruited our target number within three months, most of our sample was comprised of pre-frail, older women of white descent. This suggests better strategies to recruit frail individuals of different genders and ethnic backgrounds may be needed. Another challenge was recruiting frail individuals, especially at retirement/assisted living homes, and only 20% of the individuals we recruited were men. One-third of these men dropped out before starting the program and these male participants were frail with mobility impairments and resided alone in a retirement/assisted living home. Our northern Ontario site employed healthcare provider (i.e., nurse) referrals to recruit participants, and we found this to be the most effective method to enroll frail older adults that were both male and female, although all these individuals were of white descent. At our southern Ontario sites, we attempted to recruit diverse groups from places of worship (i.e., temples, synagogues, and mosques) using recruitment posters, though we were not successful. Most researchers have determined there is no single recommended approach to successfully recruit older adults, particularly when attempting to recruit individuals of diverse ethnic backgrounds and genders (Areán et al., 2003; Katula et al., 2007; Ory et al., 2002). One study found interpersonal face-toface approaches such as community talks, physician referrals, and religious leader endorsements were more effective at recruiting Hispanic and African American women than mass mailing or media techniques (Unson et al., 2004). A systematic review reported social marketing (i.e., the use of marketing to design and implement programs to promote socially beneficial behavior change), health provider referrals, and referrals from friends, family or other participants in the same study may be the most effective at recruiting diverse groups, although the heterogeneity between the studies was high and may not be generalizable (UyBico et al., 2007). More resources are needed to recruit and enroll underrepresented groups in exercise research because the benefits may be extended to all populations.

Retention was poor considering that data collection abruptly ended with lockdown due to the COVID19 pandemic. We also did not meet our criteria for success even after over-recruiting participants to account for some loss to follow-up. We lost five participants within one week of randomization; these participants were enrolled one and a half months prior to randomization and during this time a loss of interest or health issues caused them to drop out. We implemented trust-building communication strategies (i.e., through oneon-one sessions with the instructor) and expressed gratitude (e.g., sending holiday cards) to keep participants connected to the study. We lost an additional four participants, who were all categorized as frail, during the study due to medical reasons or because the exercises were too difficult. Our retention rate of 80% is similar to a systematic review of eight randomized controlled trials on exercise in frail older adults that reported a retention rate of 85% or greater (De Labra et al., 2015). During the follow-up period, we lost an additional four participants due to the COVID-19 pandemic and if it was not for this pandemic, we may have otherwise met our retention criterion. There is a need for community exercise instructors to monitor exercise programs carefully and recognize how medical history, medications, and prior injuries or adverse events can influence risk of future events. As a result, it is difficult to determine the relative cost-effectiveness of group exercise classes versus individualized exercise programs especially among individuals at high risk of falls and fractures. Overall, there was a low rate of adverse events, and this consistent with other studies using similar interventions and populations. Strategies to improve retention in future trials may consider stratifying exercise classes by frailty status

(i.e., pre-frail versus frail individuals), having volunteer "spotters", and considering a different study design to avoid delays between recruitment and intervention implementation.

Our adherence rates were similar to those previously reported in other trials on exercise in frail older adults (Binder et al., 2002; Binder et al., 2005; Frederiksen et al., 2003; Lord et al., 2003). A 2011 systematic review by Theou and colleagues reported adherence to an exercise program in frail older adults ranged between 42% to 100% with a mean adherence rate of 84% (Theou et al., 2011). Although the mean exercise adherence in this systematic review was higher than our trial, there were no adverse events reported in most of the included studies (Theou et al., 2011). A key challenge in exercise trials is that the people that often enroll in the trial want to exercise, so adherence rates may not be representative of pre-frail or frail individuals who may find these exercises difficult. In addition, many exercise studies in older adults exhibit healthy responder bias, whereas in our study, the number of comorbid conditions and incidence of adverse events during follow-up suggest that our sample was more representative of pre-frail older adults. Theou and colleagues supported the use of "exercise as a safe and feasible intervention for this [frail] population"; however, we found that pre-frail and frail older adults require continuous monitoring throughout the program. We experienced several adverse events related and unrelated to the program, which are likely to affect adherence rates and retention.

We acknowledge some limitations in our study. We mainly recruited pre-frail women of white descent so the results may not be generalizable to men, frail populations, or diverse groups. Despite reminding participants at the start of every assessment not to reveal group allocations a few participants forgot or did not understand and by the third outcome assessment all outcome assessors were unblinded. Lastly, we did not conduct an exit interview with the dietitians.

4.6 Conclusion

Our pilot trial demonstrates the feasibility of recruitment and adherence for a larger trial of balance and functional strength training with education on protein intake in pre-frail and frail older adults. Although we did not meet our goal for retention, it was in part affected by the COVID-19 pandemic. Recruiting individuals that were frail, male, and underrepresented groups was a challenge and there was a large learning curve for participants to learn the exercises. Suggestions for future trials include modifying some exercises for pre-frail and frail individuals, considering volunteer assistance, employing recruitment strategies to target men and diverse groups, and considering a different study design to avoid delays between recruitment and starting the intervention.

Chapter 5: Encouraging pre-frail older adults to "MoveStrong": An analysis of secondary outcomes for a pilot randomized controlled trial

Under peer review: Health Promotion and Chronic Disease Prevention in Canada: Research, Policy, and Practice

Title

Encouraging pre-frail older adults to "MoveStrong": An analysis of secondary outcomes for a pilot randomized controlled trial

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DSMB Members

The DSMB chair was represented by Dr. Stephanie Kaiser from the Division of Endocrinology and Metabolism at Dalhousie University. The DSMB clinical investigator was Dr. Christine Friedenreich, a senior director of the Cancer Epidemiology and Prevention Research Alberta Health Services, and the DSMB biostatistician was Dr. Eleanor Pullenayegum from Dalla Lana School of Public Health at the University of Toronto.

Registration

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5.1 Overview

Background: Strategies to prevent falls and improve mobility in older adults include balance and strength training in combination with consuming adequate protein. This study evaluated the MoveStrong program to teach pre-frail/frail older adults about balance and functional strength training, while promoting sufficient protein intake.

Methods: The study was an eight-week pilot stepped wedge randomized controlled trial. We recruited individuals ≥ 60 years who were pre-frail or frail with at least one chronic condition, not currently strength training. The program included sixteen exercise physiologist-led, one-hour group sessions, and two dietitian-led one-hour nutrition sessions. We analyzed secondary outcomes (weight, gait speed, grip strength, physical capacity, lower-limb muscle strength, dynamic balance, health-related quality of life, physical activity levels, and protein intake) using a paired t-test and a generalized estimating equation (GEE).

Results: We recruited 44 participants (average age 79 ± 9.82years) and randomized four sites; 35 participants were pre-frail and nine, frail. At follow-up, participants saw improvements in their grip strength (1.63 kg, 95% confidence intervals [CI] 1.37 to 5.80), lower-limb muscle strength (2 sit-to-stands, 95% CI 1 to 3) using the 30-second chair stand test, and dynamic balance (1.68 seconds, 95% CI 0.47 to 2.89) using the four-square step test. There were no improvements in gait speed (0.06 meters/sec, 95% CI 0.00 to 0.12) measured with the 10-meter walk test, health-related quality of life index scores (-0.02 points,95% CI -0.06 to 0.01) and self-rated health (-6.09 points, 95% CI -12.43 to 0.26) on the EQ-5D-5L, physical activity levels (aerobic training [31.25 minutes/week, 95% CI -8.50 to 71.00], strength training [-1.30 days, 95% CI -2.03 to 0.06]) using the Physical Activity Scale, and protein intake (1.65 g/day, 95% CI -4.44 to 7.73). GEE analysis revealed an interaction between exposure to MoveStrong and gait speed, lower-limb muscle strength, dynamic balance, and health-related quality of life index scores. The total cost to administer the program and purchase equipment was \$14,700 or \$377 per participant.

Conclusion: Exploratory analyses suggest MoveStrong may improve grip strength, lower limb muscle strength, dynamic balance, and strength training levels in pre-frail or frail older adults.

Keywords: frailty, exercise, nutrition, complex intervention, randomized controlled trial

Highlight Box

- The MoveStrong program teaches pre-frail and frail older adults about balance and functional strength training while promoting sufficient protein intake.
- The program may improve frailty indicators such as grip strength, lower-limb muscle strength, and dynamic balance.
- The program may be associated with other outcomes such as health-related quality of life and gait speed.

5.2 Introduction

The Canadian 24-Hour Movement Guidelines for adults aged 65 years and older recommend at least twice a week of muscle strengthening activities and activities to challenge balance (El-Kotob et al., 2020; McLaughlin et al., 2020). There is moderate to high certainty evidence that functional strength and balance training are crucial for promoting functional independence and mobility, and reducing the risk of falls in older adults (Gillespie et al., 2012; Liu & Latham, 2009; Ponzano et al., 2021; Sherrington et al., 2019); however, 88% of Canadian adults 65 years and older are not meeting the exercise guidelines (Public Health Agency of Canada, 2016). Furthermore, inadequate nutrition and low protein intake is common among older adults. Initiating exercise when protein intake is insufficient may cause weight loss and limit gains in muscle strength (Morton et al., 2018). The PROT-AGE group recommends individuals who are 65 years and older consume at least 1.0 to 1.2 grams of protein per kilogram of body weight per day (g/kg/day) to maintain or regain lean body mass and muscle function (Bauer et al., 2013). However, almost 50% of these older adults consume less than 1.0 g/kg/day (Wijnhoven et al., 2018), which is associated with a higher prevalence of frailty (Rahi et al., 2016). A major knowledge gap is in promoting and sustaining programs to increase the uptake of balance and functional strength training as well as protein intake among older adults, particularly among individuals who are pre-frail or frail.

Previous complex interventions (Campbell et al., 2000) evaluating the implementation of specific types of exercises under real-world conditions for older adults include home-based exercise programs such as the Otago Exercise Program (Campbell et al., 1999; Campbell et al., 1997) and the Lifestyle-integrated Functional Exercise (LiFE) program (Clemson et al., 2012) or facility-based exercise programs such as Mi-Life, which is a group-based version of the LiFE program (Gibbs et al., 2015). The goal of these three programs is to promote the uptake of balance and functional strength training to prevent falls and manage chronic diseases in older adults. A meta-analysis found the Otago Exercise Program reduced the number of falls and fall-related injuries (incidence rate ratio [IRR] = 0.65, 95% confidence interval [CI] 0.57–0.75; and IRR = 0.65, 95% CI 0.53–0.81, respectively) compared with the control group (Robertson et al., 2002). Similarly, Clemson and colleagues found that teaching older adults how to integrate functional

strength and balance exercises into daily life activities (the LiFE program) was associated with a reduction in fall rate (IRR 0.69, 95% CI 0.48-0.99) and improvements in static and dynamic balance, and lower limb strength as compared with controls. Yet, there is less evidence on how to effectively implement strength and balance training programs into community-based programs, especially for pre-frail and frail older adults (Gibbs et al., 2015). In addition, it is still unclear which type of program or combination of these programs promotes long-term adherence to physical activity participation and encourages older adults to exercise at a frequency and intensity to confer gains.

The rationale for the current study was to evaluate the feasibility of implementing a balance and functional strength training program with attention to protein intake under real-world settings. Our research team collaborated with several stakeholders to create MoveStrong - a program to teach balance and functional strength training with attention to protein intake to pre-frail and frail older adults. In a previous manuscript, we describe the feasibility of implementation, the adverse events, program fidelity, and the participants' and providers' experience to the MoveStrong program (Rodrigues et al., 2021). The aim of this paper was to report on the effects of the MoveStrong program on secondary outcomes such as frailty indicators (i.e., body weight, physical capacity, lower-limb muscle strength, dynamic balance, grip strength, and gait speed), health-related quality of life, physical activity levels, and protein intake at baseline and follow-up. We also reported on resource utilization six months prior to starting the intervention and at follow-up.

5.3 Methods

We conducted this study in accordance with the extension of the CONSORT 2010 reporting guidelines for stepped-wedge cluster randomized trials (Hemming et al., 2019) and pilot and feasibility trials (Eldridge et al., 2016). We also used the TIDieR (Template for Intervention Description and Replication) checklist to promote full and accurate description of the intervention (Hoffmann et al., 2014).

5.3.1 Trial design

The study design was an eight-week pilot, assessor-blinded, multisite, closed cohort stepped wedge randomized controlled trial (RCT). In a stepped wedge design each site was exposed to the intervention but not at the same point in time. Before the program began, all sites were randomized to start at different time points, each three weeks apart. At regular three-week intervals (the "steps"), one site crosses from the control group to the intervention group (Figure 4) (Copas et al., 2015). This process continues until all sites have been exposed to the MoveStrong program. We selected the stepped wedge design because it provides the advantage that all participants will eventually receive the intervention (Copas et al., 2015). The stepped wedge RCT is also preferred over the traditional parallel RCT when sites are substantially heterogenous (e.g., rural vs urban populations, community-dwelling vs residential) (Hemming et al., 2019). This design also allowed us to determine the feasibility of using a stepped wedge design for a larger pragmatic trial.

	Study start-up, training	Pre- rollout period -					Roll	lout	:, E>	(pos	sure	and	Ma	inter	nand	се					Data cleaning, analysis, dissemination
Time in weeks	1 to 8	9 to 16	17 to 18	19 20	21	22	23 2	24	25	26	27	28	29	30	31	32	33	34	35	36	37 to 52
Site 1			Х					Х						Х						Х	
Site 2			Х					Х						Х						Х	
Site 3			Х					Х						Х						Х	
Site 4			Х					Х						Х						Х	
	[

Training of staff, orientation to study and materials

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

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

Exposure to MoveSTroNg workshop

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

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

Figure 4: Timeline for the MoveStrong Trial

5.3.2 Study setting

We evaluated the program in areas that typically represent real-world practice and we selected three distinct settings: retirement/assisted living homes, community centers, and a family health team in four cities across Ontario. One northern (Sudbury) and three southern Ontario sites were chosen to ensure diversity in city population, structure, and

health service. The MoveStrong program was implemented and delivered at a kinesiologist-led clinic partnered with Arbour Trails (retirement/assisted living home and independent living, Guelph, site 1), the City of Lakes Family Health Team (Sudbury, site 2), the Village of Winston Park (retirement/assisted living home and independent living, Kitchener, site 3), and a YMCA that operated at two locations (Cambridge and Kitchener-Waterloo; site 4). To deliver the exercise program, we contracted exercise physiologists already working at the sites or who were teaching exercise in the community and had at least one-year of experience delivering exercise to older adults, so that we could assess the feasibility of real-world implementation rather than have it delivered in a research setting. We also contracted two registered dietitians to deliver education sessions at the northern and Southern Ontario sites.

5.3.3 Participants

We included participants if they: 1) spoke English or attended with a translator; 2) were ≥ 60 years of age; 3) had a FRAIL (Fatigue, Resistance, Ambulation, Illnesses, and Loss of weight) Scale score ≥1 (i.e., a score of 0 is robust, a score 1 or 2, pre-frail, and a score of 3 to 5, frail) (Abellan van Kan et al., 2008); and 4) had at least one of the following chronic conditions diagnosed by a physician: diabetes, obesity, cancer (other than minor skin cancer), chronic lung disease, cardiovascular disease, congestive heart failure, hypertension, osteoporosis, arthritis, stroke, or kidney disease. We encouraged participants to attend with a caregiver/friend for social or physical support, and the caregiver/friend was given the opportunity to complete the screening and assessment process to determine if they were eligible to enroll in the study. We excluded individuals who: 1) were currently doing a similar resistance exercise ≥2x/week; 2) were receiving palliative care; 3) could not perform basic activities of daily living; 4) had severe cognitive impairment (e.g., unable to follow two-step commands or could not explain the research study to the research assistant); 5) were travelling >1 week during the MoveStrong program; or 6) had absolute exercise contraindications. We determined absolute exercise contraindications to exercise using the American College of Sports Medicine guidelines (American College of Sports Medicine position stand, 1998). We did not exclude individuals who were participating in regular aerobic physical activity.

5.4 Recruitment and randomization

We recruited participants from local primary care practices, retirement/assisted living homes, and via advertisement in the local community (e.g., physiotherapy clinics, libraries, and churches) using face-to-face techniques, traditional and social media (Facebook and Twitter), posters, flyers, and brochures. We set up recruitment booths at the two retirement/assisted living home sites. Due to the delay between recruitment and randomization, we decided a priori that participants that dropped out prior to randomization could be replaced up until the intervention started. A biostatistician, independent of the study, created a computer-generated randomization sequence at St. Joseph's Healthcare in Hamilton to randomize sites to start the program at one of four start times, each three weeks apart. A co-investigator at the University of British Columbia kept the randomization sequence concealed and communicated the sequence to all sites after randomization. Each site was assigned to receive the intervention at calendar weeks 19, 22, 25, or 28; participants that received the intervention at later steps were asked to continue their usual activities until the start of the program.

5.5 Intervention

5.5.1.1 Exercise program

The MoveStrong exercise program includes functional strength training movements for older adults of varying abilities, using minimal equipment. Each exercise was informed by the GLA:D program for arthritis (Skou & Roos, 2017), BoneFit[™] (L. Giangregorio et al., 2014), and meta-analyses on resistance exercise and fall prevention for older adults (Borde et al., 2015; Liu & Latham, 2009; Peterson et al., 2011; Catherine Sherrington et al., 2017; Tricco et al., 2017). We sought input from representatives from the YMCAs of Kitchener and Cambridge, Community Support Connections, and Osteoporosis Canada, as well as patient advocates. The exercises are aligned with functional movements to promote personal relevance such as lunging/stepping, reaching, squatting, pulling, lifting and carrying, and pushing (see Table 2 for the TIDieR checklist (Rodrigues et al., 2021)). Participants were prescribed one exercise from each category: Stepping (e.g., foot stomps, heel drops); Step-up or leg extension (e.g., stationary lunge,

seated leg extension, step-up); Reach (e.g., resisted thoracic extension, back to wall shoulder flexion, shoulder press); Squat (e.g., squat, sit to stand); Pull (e.g., elastic band row, pull apart, bent-over dumbbell row); Hinge with or without carry (e.g., seated back extension, glute bridge, wall tap hip hinge, weighted hinge, hinge plus weighted carry); and Push (e.g., resisted chest press, wall push-up, counter/table push-up). Each site received a standardized toolkit with materials for participant workbooks and a trainer manual. The manual provided guidance on how to deliver the workshop, select and progress exercises, adapt exercises for common impairments, cueing tips, and discussion topics. The research team met with each site for one to two-hours to demonstrate how to deliver the MoveStrong program and to review the manual. Exercise physiologists could decide how to deliver the program in their setting e.g., as an exercise class, or allowing participants to work through the program on their own or in stations.

Each participant received a one-to-one session with an exercise physiologist (not blinded to site allocation) who selected a starting level and variations for each functional movement, intensity, and the number of repetitions and sets. Participant workbooks were assembled to include pictures and instructions of each exercise so the participants could practice and exercise at home or at another location. Participants received their workbooks during the one-on-one session with the exercise physiologist. Participants attended exercise physiologist-led group exercise sessions (1 exercise physiologist to ≤ 6 participants ratio) twice a week for 8-weeks. Other program components included having a warm-up (5 minutes), exercise program (50 minutes) and cool-down (5 minutes) and promoting discussion of when and where to practice the exercise(s) at home or in a setting of choice. During the first two weeks, the focus was on form rather than on intensity. Exercise difficulty, resistance used, or volume (up to 3 sets, up to 8 reps) was progressed over time, with a target intensity of < 8 repetitions maximum.

5.5.1.2 Nutrition education

The nutrition program included two components: 1) a nutrition education booklet, and 2) two, dietitian-led one-hour group seminars to answer questions and discuss topics related to protein intake. The dietitians were not blinded to allocation. The booklet and

seminars reviewed the cost of preparing high protein foods, a guide on how and why to spread protein intake through the day, how much protein was in the participant's usual diet and how much was recommended, low-cost options to add protein to meals, easy-to-consume protein-rich snacks with minimal preparation, high quality protein supplements (e.g., rapidly digested, high leucine like whey), and how to prioritize high-protein choices in retirement/assisted living home menus or restaurants. During each seminar, the dietitian provided samples of protein-rich snacks. Seminars were held during weeks two and five to allow time to review material, revisit topics, and address questions. We recommended 1.2 grams of protein per kilogram of body weight per day and 20-30 grams of protein per meal (Morton et al., 2018; Phillips et al., 2016). As protein intake may be influenced by living conditions (e.g., living in a retirement/assisted living versus independent living), the dietitian reviewed methods on how to select high protein options from the retirement home menu. For example, residents learned how to estimate the amount of protein in common foods listed on the menu (e.g., 3 oz salmon has 19 grams of protein or 1 cup of 2% milk has 8 grams of protein).

5.5.2 Outcomes

5.5.2.1 Frailty indicators

The Fried Frailty Index guided the selection of frailty indicators. The indicators included change in body weight, gait speed, physical capacity, physical activity levels, and handgrip strength (Fried et al., 2001). We measured changes in body weight using a calibrated scale at baseline (study visit 1) and follow-up (study visit 4). We assessed gait speed via the 10-meter walk test (Bohannon et al., 1996), physical capacity (i.e., fatigue levels) using two questions from the Center for Epidemiologic Studies Depression Scale ("I felt that everything I did was an effort" and "I could not get going") (Radloff, 1977), and physical activity levels with the Physical Activity Screen (Clark et al., 2020). The Physical Activity Scale assesses moderate to vigorous aerobic physical activity in minutes/week and strength training in days/week. We did not include the MoveStrong sessions in our calculation for strength training. Grip strength of the non-dominant hand was measured using a digital Jamar Hand Dynamometer measured in kilograms (kg) (National Institute for Health Research, 2016; Wong, 2016). Other predictor variables of frailty (Dayhoff et

al., 1998) included lower-limb muscle strength, assessed with the 30-second Chair Stand Test (Jones, 1999), and dynamic balance, assessed with the Four-Square Step Test (Dite & Temple, 2002). All frailty indicators, except body weight, were measured at baseline (i.e., study visit 1), study visit 2, study visit 3, and follow-up (study visit 4).

5.5.2.2 Health-related quality of life

We assessed health-related quality of life using the EuroQol Group 5 Dimension 5 Level (EQ-5D-5L) questionnaire (Herdman et al., 2011). The first part of the questionnaire comprises five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and each dimension has five levels (no problems, slight problems, moderate problems, severe problems, and extreme problems). Scores range from 0.9489 (highest reported quality of life) to 0.2041 (lowest reported quality of life) (Xie et al., 2016). The second part of the questionnaire records the participant's self-rated health on a vertical visual analogue scale, where the endpoints are labelled "The best health you can imagine" (score of 100) to "The worst health you can imagine" (score of 0).

5.5.2.3 Protein intake

We used the 2018 Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool (epi.grants.cancer.gov/asa24/) to conduct interviewer administered diet recalls. We collected three-day food records (two weekdays and one weekend) to capture an accurate description of each participant's typical daily diet. The ASA24® Dietary Assessment Tool is a free web-based instrument that enables highly standardized multipass recall to obtain detailed information about dietary intake using multiple probes and reminders to enhance recall (Subar et al., 2013). The ASA24® Dietary Assessment Tool generates a "total calorie consumption" across all meals and snacks consumed in a single day and automatically codes carbohydrate, fat, protein, and alcohol intake (Subar et al., 2013).

5.5.2.4 Resource use

We used a resource utilization questionnaire to assess direct and indirect costs of health service utilization developed in consultation with two health economists (WI and DL). We collected data on intervention costs and resource use to assess the feasibility of data collection methods for a larger trial. The resource utilization questionnaire consists of six direct healthcare service categories: 1) primary care visits; 2) emergency department or specialist visits; 3) hospital days; 4) other healthcare provider visits (e.g., nurse, physiotherapist, occupational therapist); 5) adverse events such as falls and fractures; and 6) lab services. The questionnaire also inquiries about participants' out-of-pocket costs such as over the counter medications, supplements or devices, the use of homecare, complementary therapy (e.g., massage therapist, naturopath), and transportation costs. The total cost per person was calculated by multiplying the number of units of service (quantity) by the unit cost (price). We reported costs using the 2020 Canadian dollar (CAD).

5.5.2.5 Costs of the program

We reported the cost of implementing and delivering the MoveStrong program. We obtained costs for implementing the program from financial records. Although there were costs associated with developing the program, these costs were incurred before the trial and thus not included. We also did not include the costs of evaluating the program. We did not include the costs of recruiting the exercise physiologist, because in many instances the organization (e.g., retirement home or YMCA) had existing staff that could deliver the program. Furthermore, we did not put a value on the time participants spent exercising or attending the nutrition sessions as it was assumed these activities were done in their leisure time.

5.5.3 Sample size

We selected a recruitment rate of ten participants at each site because of the proposed class ratio of one instructor to five participants. Recruiting ten participants allowed us to observe the feasibility to deliver two nutrition sessions and two groups of exercise sessions at each site, although, we allowed sites to over-recruit by one to two people.

5.5.4 Data safety monitoring committee

A physiotherapist, a physician, and a biostatistician, not involved in the trial, reviewed adverse events after three sites completed the program and provided guidance

for a future trial. There were no interim analyses and there were no stopping guidelines for the pilot trial.

5.5.5 Statistical analyses

Demographic, resource use, and cost data were reported using means and standard deviations or as 95% confidence intervals for continuous data, and as a count and percentage for categorical outcomes. We conducted a paired t-test ($\alpha = 0.05$) on secondary outcomes at baseline and follow-up using imputed data. We used baseline data for sites 1 and 2 at weeks 17 to 18 and for sites 3 and 4 at week 24. Follow-up data for sites 1 and 2 was from week 30 and for sites 3 and 4 at week 36 (see Figure 4). To model the interaction between exposure to MoveStrong and site on secondary outcomes we applied a generalized estimating equation (GEE). In our protocol, we originally planned to do linear regression, but revised our analysis plan to better account for clustering by site (Barker et al., 2016). We had planned to do a sensitivity analysis with and without caregiver or friend participation but did not have sufficient caregivers/friends participating. We used multiple imputation procedures to impute the missing data values (fully conditional specification method, number of imputations = 5, maximum iterations = 25). For protein intake at baseline, we only collected baseline measures for 40 individuals. We calculated resource utilization by multiplying unit costs from the 2015 Common Billing Codes for family physicians and the 2020 Ministry of Health Ontario Health Insurance Plan Laboratories and Genetics Branch to each resource to calculate direct medical costs. We estimated specialist visits at \$300.00 and allied health professional visits at \$61.25 (Hassan et al., 2020); if there was missing data, we assumed the value to have no associated costs and therefore was not included. Some participants did not consent to measuring their bodyweight, so the average bodyweight for their sex was used to calculate their protein (g/kg/day) and energy (kcal/kg/day) intakes. p values were reported to three decimal places, and statistical significance was defined as p < 0.05. No correction (e.g., Bonferroni correction) for multiple testing was made because of the exploratory nature of the analyses. All analyses were performed using SPSS Statistics version 27 (Armonk, New York, USA).

5.6 Results

We screened 75 individuals for eligibility and enrolled 44 participants prior to randomization (Table 4, Figure 5); only 39 individuals started the intervention. One participant attended with a caregiver, but the caregiver was not enrolled.

Table 4: Demographic and health status of trial participants at baseline (n=44)

Characteristics at Baseline	Site 1: Arbour Trails (n=9)	Site 2: Kinnect to Wellness (n=15)	Site 3: Village of Winston Park (n=9)	Site 4: YMCA (n=11)
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Age	78 (11.50)	81 (5.39)	84 (8.80)	72 (7.71)
Height (cm)	161 (10.89),	156	160 (7.63),	161 (7.71)
	n = 7	(26.18)	n=7	
Weight (kg)	72 (19.17),	73 (12.44)	65 (7.64),	67 (12.80)
	n = 7		n=8	
Body Mass Index	24.96 (3.52)	29.17	24.99	25.65
	n = 7	(4.27)	(4.12) n = 7	(4.56)
Characteristics at Baseline	n (%)	n (%)	n (%)	n (%)
Sex (Female)	7 (78)	10 (67)	7 (78)	10 (91)
Ethnicity:				
White	8 (89)	15 (100)	8 (89)	9 (82)
South Asian	0 (0)	0 (0)	1 (11)	2 (18)
Middle Eastern	1 (11)	0 (0)	0 (0)	0 (0)
Marital Status:				
Married	2 (22)	7 (47)	4 (44)	7 (64)
Widowed	4 (44)	6 (40)	5 (56)	2 (18)
Single/Separated/Divorced	3 (33)	2 (13)	0 (0)	2 (18)
Highest level of education:				
Middle school	0 (0)	5 (33)	0 (0)	1 (9)
High School	0 (0)	8 (53)	4 (44)	3 (27)
Higher education (college or university)	9 (100)	2 (13)	5 (56)	7 (64)
Employment:				
Retired (not working)	6 (67)	15 (100)	9 (100)	11 (100)
Medical leave	2 (22)	0 (0)	0 (0)	0 (0)
Part-time (<40	1 (11)	0 (0)	0 (0)	0 (0)
hours/week)				
Annual income (in Canadian				
Dollars):				
<40,000	3 (33)	7 (47)	3 (33)	4 (36)
40,000 to 60,000	1 (11)	5 (33)	0 (0)	3 (27)

Characteristics at Baseline	Site 1: Arbour Trails (n=9)	Site 2: Kinnect to Wellness (n=15)	Site 3: Village of Winston Park (n=9)	Site 4: YMCA (n=11)
>60,000	3 (33)	0 (0)	2 (22)	0 (0)
Prefer not to say	2 (22)	3 (20)	4 (44)	4 (36)
Place of residence:				
Lives in a retirement home alone	5 (56)	1 (7)	5 (56)	0 (0)
Lives in a retirement home with someone	0 (0)	0 (0)	2 (22)	0 (0)
Lives in the community alone	2 (22)	4 (27)	1 (11)	4 (36)
Lives in the community with someone	2 (22)	10 (67)	1 (11)	7 (64)
Visits from friends and family:				
Daily	3 (33)	9 (60)	2 (22)	1 (9)
Weekly	3 (33)	5 (33)	7 (78)	9 (82)
Monthly	2 (22)	1 (7)	0 (0)	1 (9)
Yearly	1 (11)	0 (0)	0 (0)	0 (0)
Use of homecare in the last 6 months	1 (11)	1 (7)	1 (11)	1 (11)
FRAIL Scale	n (%)	n (%)	n (%)	n (%)
How much of the time during the past 4 weeks did you feel tired	5 (56)	6 (40)	5 (56)	7 (64)
Do you have any difficulty walking up 10 steps without resting	4 (44)	7 (47)	4 (44)	2 (18)
Do you have any difficulty walking several hundred yards	5 (56)	12 (80)	8 (89)	2 (18)
Did a doctor ever tell you that you have ≥5 chronic diseases	3 (33)	2 (13)	1 (11)	0 (0)
Weight change >5% in the last year	3 (33)	4 (27)	1 (11)	4 (36)
Average FRAIL score (mean)	2.00 (SD = 0.50)	2.07 (0.96)	2.11 (0.60)	1.36 (0.67)
Two or more components on the FRAIL scale	8 (89)	10 (67)	8 (89)	3 (27)
Three or more components on the FRAIL scale	1 (11)	5 (33)	2 (22)	1 (9)
Comorbidities	n (%)	n (%)	n (%)	n (%)
Cardiovascular diseases	4 (44)	6 (40)	5 (56)	2 (18)
Hypertension	8 (89)	11 (73)	6 (67)	4 (36)
Respiratory illnesses	3 (33)	5 (33)	2 (22)	1 (9)
Bone disease (Osteoporosis)	4 (44)	8 (53)	5 (56)	6 (55)

Characteristics at Baseline	Site 1: Arbour Trails (n=9)	Site 2: Kinnect to Wellness (n=15)	Site 3: Village of Winston Park (n=9)	Site 4: YMCA (n=11)
Joint disease	5 (56)	15 (100)	6 (67)	5 (45)
Type II Diabetes	3 (33)	6 (40)	2 (22)	4 (36)
Low back pain	5 (56)	13 (87)	4 (44)	5 (45)
Falls and Fractures	n (%)	n (%)	n (%)	n (%)
Number of individuals who fell in the last 6 months	1 (11)	4 (27)	1 (11)	0 (0)
Number of individuals who sustained a fragility fracture in the last 6 months	0 (0)	0 (0)	0 (0)	0 (0)
Assistive Devices	n (%)	n (%)	n (%)	n (%)
Use a walker for mobility	2 (22)	0 (0)	1 (11)	1 (9)
Use a wheelchair for mobility	1 (11)	0 (0)	0 (0)	0 (0)
Physical Activity Screen	n (%)	n (%)	n (%)	n (%)
Achieved at least 75-minutes of vigorous or at least 150-minutes of moderate aerobic physical activity	2 (22)	1 (7)	0 (0)	7 (64)

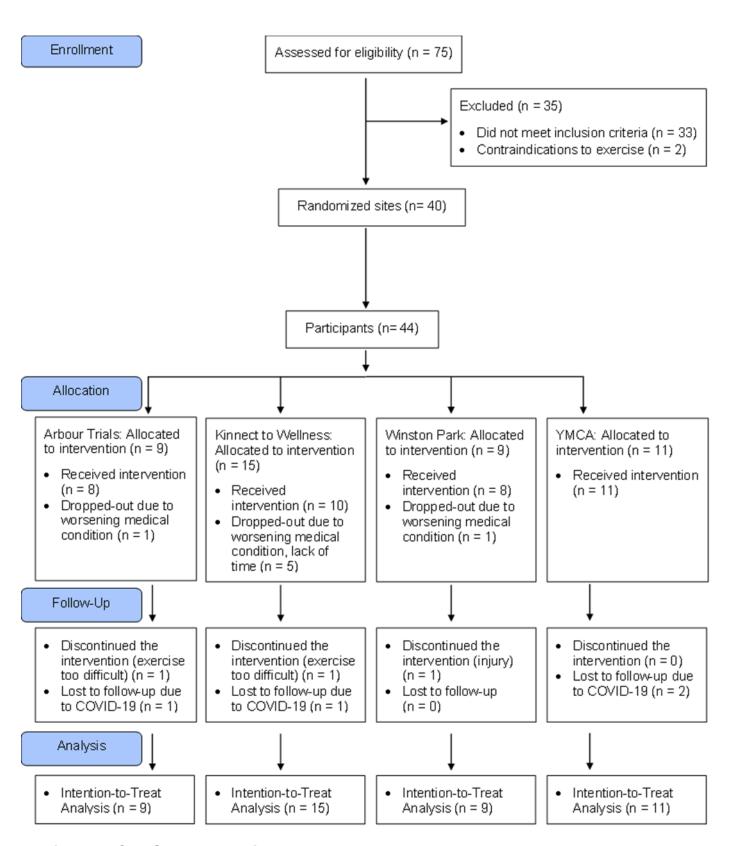


Figure 5: CONSORT Flow Diagram

5.6.1 Frailty indicators

Intention-to-treat analyses revealed a significant difference from baseline to follow-up for grip strength, lower limb muscle strength, and dynamic balance (Table 5). There were no significant differences in body weight, gait speed, physical capacity, and physical activity levels at baseline to follow-up. The GEE analysis (linear response, factor = exposure to MoveStrong*site, covariates = site, within-subject variable = study visit, maximum likelihood estimate, Wald Chi-Square) suggests a significant interaction for exposure to MoveStrong on the following variables: gait speed (10-meter walk test), lower-limb muscle strength (30-second chair stand test), dynamic balance (four-square test), and health-related quality of life (EQ-5D-5L index score) (Table 6). GEE analysis indicated there were no interactions for body weight, grip strength, physical activity levels, or protein intake. We conducted a similar GEE analysis for physical capacity using an ordinal response and found there was no interaction for exposure to MoveStrong and physical capacity.

Table 5: Mean values and 95% CI of secondary outcomes and pair sample statistics (n=44)

Secondary Outcomes	Baseline	During MoveStrong	Follow-up	Paired samples T-test (Baseline versus Follow-up)
Frailty Indicators	Mean	Mean	Mean	Mean change score
	(95% CI)	(95% CI)	(95% CI)	(95% CI)
Body weight (kg)	69.79	69.80	69.62	0.17
	(65.92 to 73.66)	(65.93 to 73.65)	(65.73 to 73.52)	(-0.34 to 0.68)
Gait Speed (10-meter walk test in meters/second)	1.06	1.06	1.12	0.60
	(0.95 to 1.18)	(0.95 to 1.16)	(1.00 to 1.24)	(0.00 to 0.12)
Physical capacity ("I felt that everything I did was an effort" on the CESD-S¹)	0.70	0.86	1.00	-0.30
	(0.45 to 0.96)	(0.53 to 1.20)	(0.67 to 1.33)	(-0.65 to 0.06)
Physical capacity ("I could not get going" on CESD-S¹)	0.73	0.82	1.00	-0.27
	(0.48 to 0.98)	(0.49 to 1.15)	(0.65 to 1.35)	(-0.63 to 0.08)
Grip Strength (non-dominant hand in kg)	20.45	21.82	22.07	1.63
	(17.95 to 22.95)	(18.96 to 24.69)	(19.44 to 24.71)	(0.62 to 2.63)*

Physical activity levels (Physical	100.00	150.20	118.64	31.25
Activity Screen - aerobic physical activity in minutes/week)	(49.59 to 150.41)	(111.37 to 189.04)	(84.22 to 153.05)	(-8.50 to 71.00)
Physical activity levels (Physical	0.41	2.18	1.70	-1.30
Activity Screen - strength training in days/week)	(0.03 to 0.79)	(1.57 to 2.79)	(1.09 to 2.32)	(-2.03 to 0.06)
Lower-limb muscle strength (30-	9.18	9.70	11.32	2.14
second Chair Stand Test)	(7.73 to 10.63)	(8.23 to 11.18)	(9.60 to 13.04)	(1.07 to 3.20)*
Dynamic balance (Four-Square Step	14.86	14.10	13.17	1.68
Test in seconds)	(13.09 to 16.62)	(12.06 to 16.15)	(11.49 to 14.87)	(0.47 to 2.89)*
Health-related quality of life	Mean	Mean	Mean	Mean change score
	(95% CI)	(95% CI)	(95% CI)	(95% CI)
EQ-5D-5L Index Score	0.79	0.83	0.82	-0.02
	(0.75 to 0.83)	(0.80 to 0.85)	(0.78 to 0.85)	(-0.06 to 0.01)
Self-Rated Health on the visual	71.01	75.42	77.10	-6.09
analogue scale	(65.16 to 76.87)	(71.30 to 79.54)	(72.35 to 81.85)	(-12.43 to 0.26)
Protein Intake	Mean	Mean	Mean	Mean change score
ASA24® Dietary Assessment Tool ²	(95% CI)	(95% CI)	(95% CI), n = 33	(95% CI)
Protoin (a/dov)	69.46		70.88	1.65
Protein (g/day)	(69.46 to 22.29)		(54.80 to 77.00)	(-4.44 to 7.73)
Drotoin (a/ka/dov)	1.01		1.00	0.01
Protein (g/kg/day)	(0.91 to 1.11)		(0.91 to 1.09)	(-0.07 to 0.10)
0/ Energy from Protein	16.76		17.83	0.92
% Energy from Protein	(15.80 to 17.70)		(16.60 to 19.00	(-0.37 to 2.20)
Energy (keel/kg/dey)	23.81		22.52	-0.64
Energy (kcal/kg/day)	(21.40 to 26.30)		(20.20 to 24.80)	(-1.69 to 0.40)

¹Center for Epidemiologic Studies Depression Scale (CESD-S); ²Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool * p < 0.05

5.6.2 Health-related quality of life

Intention-to-treat analysis revealed there was not a significant difference from baseline to follow-up on the EQ-5D-5L index score and on the self-rated health score using the visual analogue scale of the EQ-5D-5L (Table 5); however, GEE analysis indicates there may be an interaction for exposure to MoveStrong on EQ-5D-5L index scores (Table 6).

Table 6: Generalized Estimating Equation Analysis of secondary outcomes modeled for exposure and site (n=44)

Secondary Outcomes	Estimate of difference adjusted clustering within a site	95% Confidence Intervals	p- value
Frailty Indicators			
Body weight (kg)	-2.94	-6.77 to 0.90	0.13
Gait Speed (10-meter walk test in meters/second)	0.15	0.06 to 0.24	<0.05
Physical capacity ("I felt that everything I did was an effort" on the CESD-S¹)	-0.19	-0.66 to 0.28	0.43
Physical capacity ("I could not get going" on CESD-S¹)	-0.277	-0.71 to 0.15	0.21
Grip Strength (non-dominant hand in kg)	1.59	-0.69 to 3.88	0.17
Physical activity levels (Physical Activity Screen - aerobic physical activity in minutes/week)	-0.11	-23.16 to 22.94	0.99
Physical activity levels (Physical Activity Screen - strength training in days/week)	-0.11	-0.42 to 0.21	0.51
Lower-limb muscle strength (30- second Chair Stand Test)	2.78	1.56 to 3.97	<0.05
Dynamic balance (Four-Square Step Test in seconds)	-1.61	-3.14 to -0.08	<0.05
Health-related quality of life			
EQ-5D-5L Index Score	0.03	0.01 to 0.06	<0.05
Self-Rated Health on the visual analogue scale of the EQ-5D-5L	2.29	-1.18 to 5.76	0.19
Protein Intake (ASA24® Dietary Ass	sessment Tool ²)		
Protein (g/day)	1.05	0.89 to 1.22	0.06

Protein (g/kg/day)	77.90	72.78 to 83.03	0.08
Energy (kcal/kg/day)	26.24	20.65 to 31.83	0.13

¹Center for Epidemiologic Studies Depression Scale (CESD-S); ²Automated Self-Administered 24-Hour (ASA24®) Dietary Assessment Tool

5.6.3 Protein intake

Intention-to-treat analyses of average protein (g/day and g/kg/day) and energy (kcal/kg/day) intake revealed no significant differences from baseline to follow up (Table 5). The GEE analysis revealed no significant interaction between exposure to Movestrong on energy intake in kcal/kg/day or protein intake in g/day (Table 6). We found participants do not consume an equal amount of protein at each meal; the meal which participants consumed the highest amount of protein was dinner (baseline: 32.60 ± 13.07 , n = 33, follow-up: 30.71 ± 8.55 , n =33) and it was also the only meal where the average protein intake was within the recommended 20-30 g/meal. After attending the nutrition sessions, participants reported consuming new protein-rich foods (i.e., foods they did not report eating at baseline) including meat (fish, chicken, turkey, pork, beef), dairy (milk, yogurt, cheese), plant-based (whole wheat, rice, quinoa), and alternatives/other (eggs, seeds, nuts, protein powder). The average protein intake at baseline was 69.46 g/day (95% CI [62.5, 76.5], n = 39) or 0.98 g/kg/day (95% CI [0.86, 1.09], n = 33) and was above the recommended dietary allowance (RDA; 0.8 g/kg/day). However, 14 participants (35%) had a protein intake below the RDA while 27 participants (67%) consumed less than our target of 1.2 g/kg/day. At baseline, the average percentage of energy from protein was within the Acceptable Macronutrient Distribution Range (AMDR) of 10-35%. The average energy intake at baseline was 23.81 kcal/kg/day (95% CI 21.40 to 26.30, n = 39) and was less than the RDA (30 kcal/kg/day). Twenty-eight participants (70%) had an average energy intake less than the RDA and 20 participants (50%) consumed less than 21 kcal/kg/day.

5.6.4 Resource use

The total cost to administer the program and purchase equipment at all four sites was \$14,700 or \$377 per participant. The total direct medical cost during the study was \$22,430, while the total indirect medical costs was \$21,609.56. Participants reported a direct medical cost of \$6,148 six-months prior to starting the intervention, while after the intervention (i.e., at follow-up) it was \$7,389. Six-months prior to starting the intervention, participants reported an indirect medical cost of \$6,464 and after the intervention it was \$5,916. The main cost drivers were identified to be physician visits, test procedures, and transportation.

5.7 Discussion

The main challenge in evaluating complex interventions arises due to the number of components that act both independently and inter-dependently (Campbell et al., 2000; Shiell et al., 2008). For this reason, Campbell and colleagues suggest evaluating complex interventions in several phases. This pilot study is considered part of phase II (Campbell et al., 2000) and involves testing the feasibility of delivering the intervention and piloting outcomes for a larger trial. We piloted several secondary outcomes and found there was an interaction between participating in MoveStrong and gait speed (10-meter walk test), lower-limb muscle strength (30-second chair stand test), dynamic balance (four-square step test) and health-related quality of life (EQ-5D-5L index score). There was no interaction between MoveStrong and body weight, grip strength, physical capacity (i.e., fatigue levels), self-rated health on the visual analogue scale of the EQ-5D-5L, and protein intake. Future trials on balance and functional strength training in pre-frail and frail older adults should consider the responsiveness of frailty indicators when selecting study outcomes, such as those reported in our pilot study.

Maintaining adequate strength and balance using functional movements intuitively makes sense for improving physical function and preventing falls because specificity is important in exercise prescription, and MoveStrong aimed to mimic activities performed

in real-life situations. The efficacy of balance in combination with functional training as types of exercise that can mediate fall risk and mobility impairments has been highlighted in several systematic reviews (Gill et al., 2016; Liu & Latham, 2009; Sherrington et al., 2019; Sherrington et al., 2017). We found that exposure to the MoveStrong program may improve activities that involve grip strength, lower-limb muscle strength, and dynamic balance. We saw improvements in outcomes that were directly related to movements in our exercise program. For example, the 30-second sit-to-stand is a feasible outcome to measure peripheral muscle strength in the lower limbs, and daily activities that use these muscles include getting up from a chair. The participants completed two additional sit-tostands by the end of the study and an increase of equal to or greater than 2 repetitions for the 30-second sit-to-stand represents the minimum clinically important difference (MCID) (Wright et al., 2011). In addition, foot clearance is an important function in everyday life and the ability to accomplish this in different directions is essential when reacting to stimuli in the real world (i.e., navigating a busy street or walking on uneven pavement) (Moore & Barker, 2017). The four-square step test incorporates rapid stepping whilst changing direction; however, we found this test was difficult for frail older adults. There were six participants, who were all categorized as frail (≥ 3 on the FRAIL scale), that were not able to complete the four-square step test. Future studies should consider adding another test of dynamic balance and a static balance test feasible for frail older adults. If a research study includes both pre-frail and frail older adults, at least two tests to measure balance should be considered, such as the Berg Balance Scale and the foursquare step test. Lastly, we did not see an improvement in gait speed using the 10-meter walk test; however, the average gait speed at baseline was average for older adults over the age of 75 (mean gait speed 1.06 meters/second, 95% CI 0.95 to 1.18); high functioning gait speed is > 1.1 meters/second (Montero-Odasso et al., 2005). In addition, three of the four sites did not have enough space to conduct the 10-meter walk test, which requires a 14-meter cleared pathway. As a result, we had to perform several 10-meter walk tests in the hallway where other residents were walking, and this could have interfered with our results. Future trials should consider specificity and target population in program design and outcome selection and ensure that they select outcomes that are feasible and responsive in the target population.

The interactions between the MoveStrong program and health-related quality of life in pre-frail and frail older adults were significant but were not significant for physical capacity levels (i.e., fatigue levels). Several systematic reviews suggest that exercise may make little difference to health-related quality of life in older adults (McLaughlin et al., 2020; Ponzano et al., 2021; Rodrigues et al., 2021; Sherrington et al., 2019). However, many exercise studies in older adults may be exhibiting healthy responder bias and ceiling effect. Most participants that enroll in exercise trials may already have high healthrelated quality of life scores at baseline so there would be little room for improvement; however, the individuals in our study had multiple chronic conditions and were pre-frail or frail. Although, in our study, the mean change EQ-5D-5L score was significant (mean score 0.04 points, 95% CI 0.00 to 0.07), the MCID is for this scale is 0.18 (95% CI 0.03 to 0.54, 18 studies) (Coretti et al., 2014). It is possible that a longer study may result in a more meaningful change. In addition, we found no significant interaction between exercise exposure and site on protein intake. Among Canadian older adult residents in long-term care that protein intake is significantly associated with eating occasion, with the greatest protein intake at dinner (Trinca et al., 2020). In the current study, dinner was the only meal where the average amount of protein consumed was within 20-30 g/meal. There is evidence that higher protein intake and more even distribution of daily protein intake across meals are associated with greater muscle mass and strength (Farsijani et al., 2016, 2017). In terms of energy, the average intake was less than the RDA (i.e., 30 kcal/kg/day) but above 21 kcal/kg/day; a daily energy intake of less than 21 kcal/kg/day is associated with frailty (Bartali et al., 2006). The current intervention was mainly focused on increasing protein intake while maintaining energy intake; however, it may be

important for future interventions to also emphasize maintaining or increasing energy intake to meet the RDA and to avoid a level that may be associated with frailty.

In Canada, the total healthcare costs of physical inactivity have been estimated at \$6.8 billion (Janssen, 2012). The total cost to implement and to deliver our program was \$14,700 or \$377 per participant, which is similar to other strength and balance training interventions (Apóstolo et al., 2018; Balzer et al., 2012; Davis et al., 2010). A 2016 study found the cost to implement a community-based version of the Otago program to \$585 USD per client, inclusive of administrative costs (Shubert et al., 2017). Assuming an average exchange rate 1 CAD to 0.7553 USD in 2016 with an inflation of 1.74% per year, \$585 USD would be equivalent to \$830 CAD per client in 2020, which is substantially more than our cost of \$377 per participant. Our program was designed to use as little equipment as possible to help reduce costs. A larger multisite trial is now needed to determine the cost-effectiveness of implementing the MoveStrong program at a larger scale.

We could not perform a subgroup analysis by sex/gender, living arrangement, or frailty level due to the sample size, and the small number of males or individuals who were frail at each site, and the potential of conflating differences between sites with differences in living arrangement. If subgroup analyses are not performed under the correct circumstances or if several subgroup analyses are performed, the likelihood of false negative and false positive significance tests may increase rapidly (Sun et al., 2010, 2014). A subgroup analysis by sex/gender, living arrangements (i.e., retirement/assisted living versus community dwelling), and frailty level should be considered in future, larger trials.

We acknowledge some limitations in our study. Some individuals had trouble completing the balance assessment. To impute the missing data we used multiple imputation, which could have led to a type II error. In addition, data collection during the last assessment was abruptly stopped due to the COVID-19 pandemic and we were not

able to collect the performance-based outcomes for eight participants. Protein intake was based on three days. Although three days are a commonly used time frame to assess changes in food intake, it may not have been a sufficient length to demonstrate significant clinical and statistical change. Furthermore, the capacity of participants in retirement homes to recall protein consumption may have been impacted by not preparing their own meals. To mitigate the challenge of protein recall, we attained menus from the home to ensure some reliability in data collection. Lastly, statistical analysis of stepped wedged trials is complex, and we opted to use a GEE analysis. One of the limitations of using GEE with few clusters is the risk of type I error.

5.8 Conclusion

Participating in the MoveStrong program may improve grip strength, lower-limb muscle strength, and dynamic balance. We did not see improvements in gait speed, physical capacity, health-related quality of life, or protein intake. There may be an interaction between exposure to MoveStrong and gait speed, lower-limb muscle strength, dynamic balance, and health-related quality of life index scores. Future trials on balance and functional strength training in pre-frail and frail older adults should consider specificity of the exercises and the potential for ceiling or floor effects of certain outcomes.

Chapter 6: General discussion and conclusion

Aging is a heterogeneous process where some individuals of the same age vary widely in their health and functional status (Heckman & Braceland, 2016; Mitnitski et al., 2002). Certain conditions such as being frail are not a natural consequence of aging and can affect a person's health and functional status. In some cases, individuals can have overlapping pathogenic pathways, where they are frail and have osteoporosis. There is emerging data that suggests frailty may be a predictor of osteoporotic fractures (Li et al., 2017). There is moderate to strong certainty evidence for the benefits of certain types of exercise to manage frailty and osteoporosis; however, over 75% of Canadian adults do not meet the physical activity guidelines (Public Health Agency of Canada, 2020). While there are services to support exercise for older adults, there are several barriers to participating in exercise programs, especially for people with osteoporosis and frailty.

There are several strategies or pathways to move evidence into practice. Common strategies (i.e., policy categories) include developing clinical practice guidelines, communication or marketing schemes, legislation, service provision, fiscal measures, or regulations (see Figure 6) (Michie et al., 2014). Within each policy category, there are several pathways' researchers can select to implement a knowledge translation strategy; for example, when attempting to increase exercise participation among older adults one may decide that implementing an educational model is an appropriate approach to teach patients or healthcare providers about information in clinical practice guidelines. Alternatively, one may seek to incentivize appropriate exercise prescriptions or in some way penalize inappropriate prescriptions. The process of identifying and implementing intervention functions and policy categories is a long and time-consuming process. This thesis sought a strategy to develop clinical practice guidelines for healthcare providers and patients and to pilot test a service provision model to teach exercise and nutrition education to improve exercise participation among people with osteoporosis and frailty.

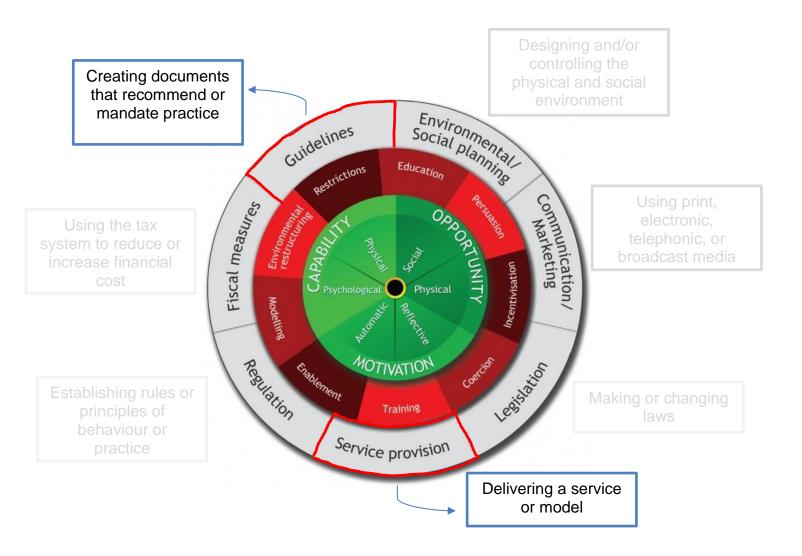


Figure 6: Developing and implementing strategies to improve participation in exercise guided by the Behaviour Change Wheel (strategies used in this thesis are highlighted in red). Reproduced with permission from Michie et al., 2013 in Appendix E.

The first study focused on developing two systematic reviews and meta-analyses to inform the 2021 Clinical Practice Guidelines for the Management of Osteoporosis in Canada. The second study pertained to understanding perceptions to starting or continuing moderate or high impact exercise or strength training to help identify future intervention functions and policy categories. The third study implemented a service provision model to enhance the uptake of balance and functional strength training with

attention to consuming enough protein in pre-frail and frail individuals. The three studies in this doctoral thesis, when taken together, highlight both the potential barriers and supports to developing and implementing knowledge translation strategies to improve exercise uptake among people with osteoporosis and frailty.

Developing clinical practice guidelines

One method to move evidence into practice is through clinical practice guidelines. Clinical practice guidelines are a type of knowledge tool designed to facilitate evidencebased decision making (Graham et al., 2013). Several guideline developers recommend the use of systematic reviews and overviews of systematic reviews to underpin guideline recommendations (World Health Organization, 2012). The biggest strength of systematic reviews/meta-analyses is when limitations and heterogeneity are appropriately acknowledged and handled, systematic reviews/meta-analyses have the potential to provide the best evidence for efficacy, safety, and/or effectiveness in exercise science research. However, a large limitation of a well-conducted systematic reviews/metaanalysis is it is dependent on the data available and on the quality of those studies from which the data was obtained. Failure to consider the quality of evidence can lead to misguided recommendations. More importantly, systematic reviews provide evidence to estimate the benefits and harms of an intervention, but systematic reviews alone do not integrate factors that consider patient's values, preferences, or resources (Atkins et al., 2004). It is important to consider patient's values when designing guidelines since guidelines are not enough to change behaviour (Graham et al., 2013).

Since 1996, three clinical practice guidelines for community dwelling individuals living with osteoporosis have been published for professional use (Brown et al., 2002; Hanley & Josse, 1996; Papaioannou et al., 2010); two major differences between the 2021 guideline and previous guidelines were the consideration of patient values and preferences, and the use of the GRADE approach to guide recommendations. As part of

the Osteoporosis Guidelines update process, we administered a survey to the Canadian Osteoporosis Patient Network members to inquire about: 1) items to address in the 2021 Canadian Osteoporosis Clinical Practice Guidelines; and 2) questions to identify on safety or effectiveness of exercise, or safe performance of physical activities of leisure or daily living (Morin et al., 2020). We also assembled a diverse exercise working group consisting of healthcare professionals, a patient advocate, graduate students, and researchers with expertise in osteoporosis and exercise science to gain a broader perspective when developing the osteoporosis exercise guidelines. Engaging patients in research studies is becoming more common because it makes research and its results more relevant for patients (Armstrong et al., 2018). Many guidelines only focused on the effects of exercise on bone mineral density, which may not be directly meaningful to patients (Morin et al., 2020). Indeed, a 2016 review that compared 19 clinical practice guidelines for people with osteoporosis from around the world found the most reported recommendation was for the effects of exercise on bone mineral density (Armstrong et al., 2016). However, in a survey of over 1,000 patients, over 75% of respondents said outcomes such as preservation of autonomy, mobility, and quality of life were essential to consider when developing guidelines, while outcomes such as bone mineral density were ranked as less important (Morin et al., 2020). The survey by Morin and colleagues demonstrates a shift from the previous osteoporosis guidelines whose focus was on outcomes such as bone mineral density. In addition, in Chapter three we learned that the language we use in guidelines and providing meaningful and purposeful recommendations are important to patients. By having the patient voice, we were able to think about results as being meaningful to patients and not just data for academic journals. With patient partners, our discussions have changed to make us more cognizant of how patients might be directly affected by the research results and how to use the information (Johnson et al., 2016). Conducting research studies with patients raises the question of how the research changed if patient partners were not involved in the research program. If we had not asked patients about

outcomes meaningful to them, at the end of the study the production of the statistical results in academic journals would have likely been similar to the previous guidelines. Instead, our discussions and interpretation of the results have been markedly changed by patient partners. The patient survey was pivotal in informing what outcomes were selected in the impact exercise and walking/Nordic walking systematic reviews. In our exercise working group, we often referred to the expertise of our patient partners when making decisions. There are obviously several benefits to engaging patient partners in research studies, such as generating more relevant patient-important research questions, methods, and results that aim to facilitate translation of research into practice. The patient perspective is now recognized as fundamental in health research and guideline development (de Wit et al., 2019).

Classifying behaviour change interventions

Improving the implementation of evidence-based practice depends on understanding what influences behaviour (Michie et al., 2011). In the context of exercise, developing interventions to improve participation in exercise behaviour depends on understanding what works to change behaviour and why. Behaviour theory is useful to examine a range of factors that influence health-related behaviours to inform appropriate interventions. Behaviour change interventions, which are a coordinated set of activities designed to change specific behaviour patterns, are fundamental to the effective practice of clinical medicine and public health (Michie et al., 2011). Often, interventions are designed without evidence of having identified behaviour change factors or theories to predict mechanisms of action (Michie et al., 2011). However, even when models, frameworks, or theories are chosen to guide the intervention, they do not cover the full range of possible behavioural influences (Johnston & Dixon, 2008). For example, the Theory of Planned Behaviour and the Health Belief Model are commonly used in exercise interventions; however, they do not address important behavioural factors such as

impulsivity, habit, self-control, associative learning, and emotional processing (Michie et al., 2011). The Behaviour Change Wheel was developed to address behaviour change interventions (Michie et al., 2011). The Behaviour Change Wheel is a framework designed to inform interventions and policy development based on identified facilitators and barriers (Michie et al., 2011). By identifying facilitators of and barriers to behaviour change using the COM-B model (inner circle of the Behaviour Change Wheel; see Figure 6), researchers can inform interventions to identify what needs to change and why it needs to change by selecting intervention functions and policy categories.

Previous work by our lab identified several barriers to specific recommendations in the Too Fit to Fracture recommendations among healthcare providers, exercise professionals, and people with osteoporosis (Clark et al., 2020; McArthur et al., 2018; Ziebart et al., 2018); themes were mapped to intervention functions using the Behaviour Change Wheel. Intervention functions identified among individuals with osteoporosis include 'training', 'enablement', 'education', 'restriction', 'environmental restructuring', 'modelling', 'persuasion', 'coercion', and incentivization (Ziebart et al., 2018). Using the APEASE criteria, the authors then determined if each intervention was affordable, practical, cost-effective, acceptable, safe, and equitable; the results revealed that training, education, persuasion, and modelling met the APEASE criteria (Ziebart et al., 2018). The four intervention functions (i.e., training, education, persuasion, modelling) guided the selection of several behaviour change techniques that were used to develop MoveStrong (see Table 6).

Table 7: Definitions of interventions function and behaviour change techniques to consider for the intervention type

Intervention	Definition	Possible examples of behaviour change techniques
Training	Imparting skills	 Demonstration of the behaviour Instruction on how to perform the behaviour

Education	Increasing knowledge and understanding	- Feedback on behaviour - Prompts/cues - Self-monitoring of behaviour
Persuasion	Using communication to induce positive or negative feelings or stimulate action	- Credible source - Information about health consequences
Modelling	Providing an example for people to aspire to or imitate	- Demonstration of the behaviour

Implementing policy categories guided by intervention functions and behaviour change techniques

The other part of the thesis built on the development of MoveStrong by piloting the service provision model to integrate several intervention functions and behaviour change techniques identified from previous work (Ziebart et al., 2018). Specifically, MoveStrong used a combination of intervention functions such as education, persuasion, training, modelling, and enablement. Each intervention function has several behaviour change techniques that are listed in Table 6. However, to date, it is unclear whether exercise science in people with frailty utilize behaviour change techniques to develop and implement interventions. Behaviour change techniques are the active ingredients of a behaviour change intervention; they are observable, reliable, and irreducible (Michie et al., 2009, 2013). The Diet and Exercise for FRAILty (DEFRAIL) study is described as a knowledge translation strategy designed to combine exercise and protein supplementation that can be easily replicated in non-clinical settings (Bambrick et al., 2021). The possible active ingredients in the DEFRAIL study are the supervised exercise sessions by a non-medical instructor to provide demonstrations of the exercises (i.e., demonstration of the behaviour through modelling) and the logbook to encourage adherence (i.e., self-monitoring of behaviour); however, the authors state the main characteristics (i.e., active ingredients) of the study are: 1) the inclusion of a broad range of levels of frailty; 2) group classes in the community with limited specialist equipment; 3)

the delivery of program by a non-medical professional with minimal training; and 4) the inclusion of activities participants enjoy (Bambrick et al., 2021). The DEFRAIL study is an example of an exercise and nutrition intervention that may not be utilizing behaviour change techniques. A meta-regression found the most effective behaviour change interventions to promote physical activity and healthy eating include self-monitoring and at least one of four other self regulatory techniques (i.e., intention formation, specific goal setting, feedback on performance, and review of behavioral goals) (Michie et al., 2009, 2013). The systematic method to develop exercise and nutrition interventions guided by frameworks such as the Behaviour Change Wheel may provide a more robust starting point for developing effective interventions (Michie et al., 2009, 2013).

Other service provision models such as the LiFE model use a combination of behaviour change techniques to encourage self-efficacy and adherence to the exercise program, which include positive reinforcement, habit reforming, discussing benefits, and self-monitoring (Clemson et al., 2012). The MiLiFE model, is a group-based version of the LiFE model. During the group sessions of the MiLiFE program, activities were planned as a group and ideas for how, when, and where to perform each exercise were shared among participants and recorded using the activity planner. While behaviour change techniques such as 'self-monitoring' and 'specific goal setting' were part of MoveStrong, we learned there are barriers to implementing such techniques. During our exit interviews with the exercise physiologists, we learned that time was a barrier to implement the "specific goal setting" technique; we asked each instructor to spend 10-minutes at the end of each exercise session to discuss ways participants could incorporate a selected "exercise of the week" in their daily activity. Similarly, the Mi-LIFE study found barriers to using the "goal setting" behaviour change technique (Gibbs et al., 2015). The authors of the Mi-LIFE study reported barriers to goal setting included: 1) diversity in participants' goals/intentions and outcome expectancies in group sessions; and 2) difficulty identifying cues and prompts for activities (Gibbs et al., 2015). A potential feasible solution may be

to include follow-up phone calls with participants to cue habit reforming, discuss benefits, and encourage self-monitoring (examples of other behaviour changing techniques). In chapter three of this thesis, participants reported that accountability was an important factor to participating in exercise programs and so phone calls with participants to cue habit reforming may be a potential technique to consider. In addition, the exercise physiologists from the MoveStrong program said participants had trouble utilizing the "self-monitoring" technique. The exercise physiologists suggested that participants with visual impairments or mild cognitive impairments required additional coaching to use the exercise booklet to monitor their exercises at home. In fact, several participants did not use the booklet outside of the program. Nevertheless, deliverer training, social dynamics, and long-term behaviour change strategies are key components of the implementation process. A larger study of the MoveStrong model is warranted, but behaviour change techniques to promote long-term adherence should be addressed before implementing the next phase (i.e., phase III of a complex intervention). One suggestion is to conduct a review of service provision models and map barriers to the behaviour change techniques.

6.1 Future directions

There are several directions and projects to build on this thesis work. For example, after clinical practice guidelines for professional use have been developed, a next step may be to develop clinical practice guideline for the public or knowledge translation tools for patients (Santesso et al., 2016). There is an increasing interest to develop derivative products for the public to assist patients with their healthcare decisions (Loudon et al., 2014). When disseminating the updated osteoporosis exercise guidelines, it is crucial for patient groups to not only be aware of the guidelines but also know how to interpret them (Graham et al., 2013). Leaflets and other information packages such as video and audio tapes, computer programs, and websites (communication and marketing policy category) have long been seen as an integral part of an education strategy to promote health, persuade healthy lifestyles, and increase uptake of screening (Coulter, 1998).

Development of leaflets and other information packages are a type of communication and marketing strategy. However, influencing participation in exercise programs depends on behaviour change. Behaviour change interventions are fundamental to the effective practice of clinical medicine and public health. Developing and implementing successful knowledge translation interventions is dependent on identifying behaviour change techniques and intervention mapping. While there are many examples of successful interventions, there are also countless examples of ones in a systematic review by Grimshaw and colleagues that were not effective (Grimshaw et al., 2001). To improve the success of an intervention and the translation of research into practice, we need to develop the science and technology of behaviour change and intervention mapping to those designing interventions and planning policy. In addition, using theoretical models, theories, and frameworks and considering patient values and preferences are an important component to knowledge translation work.

6.2 Limitations

The limitations of each chapter are described within each manuscript; however, there are some general limitations. Most participants identified as female and Caucasian, which limits the generalizability of the findings to other genders and diverse groups. Recently there has been a push by funding organizations such as the Canadian Institutes of Health Research to integrate sex and gender into research. We now need to pressure funding organizations to include a section on integrating equity and intersectionality into research grants. Secondly, a major limitation were the underlying assumptions when collecting facilitators and barriers; for example, through equity lenses researchers are prompted to consider who is collecting the data and the power dynamics between the researcher and participants. Reflecting on unconscious biases is an important consideration for future studies. Third, we used the GRADE approach to assess the certainty of evidence in both systematic reviews to inform the new exercise guidelines for people with osteoporosis. The GRADE approach has two fundamental limitations which

should be acknowledged: the first limitation is the empirical evidence supporting each criterion in the approach is limited and the second is the relative weight one should put on the criteria is subjective. Lastly, there are some limitations to using a stepped wedge design. One of the biggest limitations is the analysis and considering time as a factor. Many researchers suggest that the method of analysis in a stepped wedge RCT needs to be adjusted for time, but the impact of doing so decreases the statistical power of the analysis. Despite these limitations, this work represents an incredible effort towards a knowledge translation strategy to improve management of osteoporosis and frailty in practice. The results of this thesis should be considered in combination with future implementation work.

6.3 Conclusion

In summary, this dissertation contributes to the literature by identifying a strategy to move evidence on exercise and nutrition into practice for people with osteoporosis and frailty. There are several methods to move evidence into practice. This thesis built on prior work on barriers to exercise to identify intervention functions and policy categories. I led two systematic reviews to inform the Osteoporosis Clinical Practice Guidelines and conducted interviews with people living with osteoporosis to understand their perspectives to specific suggestions in the guidelines. However, we still require more evidence on the benefits of certain types of exercise not only on bone mineral density and fracture risk, but on several other outcomes such as falls, quality of life, physical performance outcomes, and mortality. In addition, we identified several barriers to implementing a service provision model in older adults who are frail. Collectively, this thesis used the Knowledge to Action framework to test and implement a strategy to bridge the gap and incorporate exercise evidence into practice for people with osteoporosis and people who are frail. The methods applied to this thesis may be translatable to other populations with and without chronic conditions.

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Appendix A: Interview Guide

Table 8. Semi-Structured Interview Samples (Chapter 3)

- 1. What is your understanding of the types of exercises that can keep bones strong?
- 2. Research suggests that impact exercise is good for your bones. What activities come to mind when you hear about impact exercises?
- 3. The word impact refers to forces exerted on bones and joints. Walking would be a low impact exercise, while hopping or jumping would be a moderate or high impact exercise. How do you feel about doing moderate or high impact exercises?
 - a. Prompt One: It is not acceptable then ask:
 - i. What is it about moderate or high impact exercises that you think is not acceptable?
 - ii. If it were safe for you to do moderate or high impact exercise, what would you need to support you doing this type of activity?
 - b. Prompt Two: If it is acceptable, but they are not doing it, then ask:
 - i. How do you feel about starting a moderate or high impact exercise program?
 - ii. If it were safe for you to do moderate or high impact exercise, what would it take for you to consider it? What would you need to support your involvement in this type of activity?
 - c. Prompt Three: If they are <u>already doing moderate-to-high</u> impact exercises ask them:
 - i. Tell me about the type of moderate or high impact exercises that you do (e.g., location (home or outside), who they do it with, how many times per week, do they progress the activities, is it a paid program, is it supervised)?
 - ii. What motivates you to do them?
- 4. Research suggests that resistance training is also good for you. What comes to mind when you think of resistance training?
- 5. Resistance training is when we use our muscles to work against a resistance until the muscles are fatigued. Examples of resistance training are squats, pushups or using weights or resistance bands to do exercises. Some research suggests that it has to be done at moderate or high intensity, or an exercise that you can only do about 6-10

repetitions before your muscles fatigue. How would you feel about doing resistance training at a moderate or high intensity?

- a. Prompt One: It is not acceptable then ask:
 - i. What is it about moderate or high intensity resistance training that you think is not acceptable?
 - ii. If it were safe for you to do moderate or high intensity resistance training, what would you need to support you doing this type of activity?
- b. Prompt Two: If it is acceptable, but they are not doing it, then ask:
 - i. How do you feel about starting a moderate or high intensity resistance training program?
 - ii. If it was safe for you to do moderate or high intensity resistance training, what would it take for you to consider it? What would you need to support your involvement in this type of activity?
- c. Prompt Three: If they are <u>already doing moderate-to-high</u> intensity resistance training program ask them:
 - i. Tell me about the type of moderate or high intensity resistance training that you do (e.g., location (home or outside), who they do it with, how many times per week, do they progress the activities, is it a paid program, is it supervised)?
 - ii. What motivates you to do them?
- 6. Guidelines suggest that people with osteoporosis consult with an exercise professional before starting an exercise program. In our healthcare system, there is no funding for getting someone to teach you how to perform impact exercise or resistance training. Hearing this, what does this mean for you? How might this affect you?

Table 9. Interview guide to conduct exit interviews with each participant and the exercise professional for MoveStrong (Chapter 4)

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

Appendix B: Codebook

Table 10: Codebook of salient nodes (chapter 3)

Codes	Description
Activities participants	List of activities participants enjoy doing for pleasure - may
enjoy	not be specifically for bone health
Comfortable with	Reasons participants may be comfortable engaging in
moderate impact	moderate or high impact exercise
exercise	
Energy levels	Participants do not want to be tired after an exercise session
Pain free	Participants are willing to engage in moderate or high impact
	exercise as long as they do not experience pain
Did it previously	Participants are comfortable engaging in moderate or high
	impact exercise because they have done these exercises
	previously
Under guidance	Willing to engage in moderate or high impact exercise as
	long as there is an experienced exercise professional present
Comfortable with	Reasons participants are comfortable engaging or
moderate or high	participating in moderate or high intensity strength training
intensity strength training	
Safe	Participants are willing to engage in moderate or high
	intensity strength training as long as the activity is safe
Current strength training	Examples of strength training activities participants are
routine	currently involved in
Exercises that are good	Any activity participants indicate may be good for bone health
for bone health	(i.e., improve bone mineral density).
Aerobic exercises	Any time of cardiovascular conditioning (can include both
	activities that are good for bone health and those that may
	reduce bone health like cycling or swimming)

Impact exercise	Ground reaction force greater than 1 x body weight other
	than walking or Nordic walking
Loadbearing	Any weightbearing exercise
activities	
Strength training	Any activity designed to improve muscular strength
Walking	Ground reaction force GRF less than 1.5 x body weight
Weightbearing	Any exercise with a ground reaction force or joint reaction
exercises	force
Weightlifting	Synonym to strength training
Yoga	
Hesitant about moderate	Reasons why participants may be hesitant to participate in
or high impact exercise	moderate or high impact exercises
Fear of experiencing	Participants fear that engaging or participating in moderate or
pain	high impact exercises may be painful due to their chronic
	condition
Fear of falling	Participants are worried that if they engage in moderate or
	high impact exercises they will fall
Fear of fracture	Participants are worried that if they engage in moderate or
	high impact exercises they will fracture (again or sustain a
	new fracture)
Fear of injury	Participants are worried that if they engage in moderate or
	high impact exercises will result in an injury other than a
	fracture (e.g., bruising)
Low impact is good	Participants believe low impact exercises such as walking
enough	are enough to maintain or increase BMD
Low impact is	Participants believe low impact exercise is safer than
safe	moderate or high impact exercises
No evidence	There is no evidence for the benefits of moderate or high
	impact exercise vs low impact exercise on BMD

Medical condition	Participants have a medical condition that they believe would
	preclude them from engaging in moderate or high impact
	exercise
Professional told not	A healthcare professional (e.g., physician, allied health
to do moderate or	worker, exercise physiologist) has told the participant that
high impact	moderate or high impact exercises is not safe
Misconceptions	Healthcare professionals may have misconceptions about
	impact exercises
Impressions of impact	Initial impressions about the term impact exercise
exercise	
Negative language	Participants describe impact exercise using negative
when talking about	language
impact exercise	
Impressions of strength	Initial impressions of the term strength training
training	
Misconceptions about	Types of activities that participants may be miscategorising
exercise activities	(e.g., categorizing yoga as a strength training activity)
Claims to do high	Participants believe that are doing high impact exercises
impact exercise	
Strength training vs	Participants perceive strength training as a safer exercise
Impact exercise	than impact exercises
Osteoporosis drugs	Strong negative reactions to osteoporosis medications
Resources	Resources participants requested to support their
	involvement in moderate or high impact exercise and
	strength training
Accountability	Participants want to be accountable to someone
Different levels with	Participants want levels of difficulty
modifications	
Encouragement	Participants need positive reinforcement
	I.

Enjoy the activity	Participants are more likely to engage in activities that they
	enjoy
Environment	What does the external environment look like?
Exercise classes	Group sessions
Safety	Participants want the exercises to be modified for their
	condition to improve safety
Schedule	Exercise sessions need a schedule to keep them
	accountable
Social connection	Group sessions with people of their own age so they can
	engage with
Trained	Want exercise sessions to be led by a trained exercise
professionals	professional with knowledge of osteoporosis who can watch
	them
Videos	Online videos posted on YouTube
Willing to pay	Paying for classes will help motivate participation
Sources of information	Where participants get their information regarding
	osteoporosis and exercise

Appendix C: Search Strategy

Table 11. Level 1 and 2 screening (Chapter 2)

Level 1 Screening – Review of Abstracts

Incl	IICIAN	criteria	chac	Viiet:
	usivii	CHICHA	CHEC	NIISL.

		Diagnorial distory Modera BARV/ Other (isk) of partion are distordical distord	esis of oster of fragility ate/high ris AN calcularies. bone of the calcularies of the carring ance exercises.	eoporosis or I y fracture(s) sk of a fragilit ators ultrasound, C aged ≥ 50 + (e any of the foor impact activ im cise	ow BMD (7 y fracture b T, X-ray to inclusion collowing ex	characteristics: T-score ≤ -1.00) based on CAROC, FRAX, or c assess bone quality or for fracture criteria ≥ or average age is >50) xercises groups:	;
	Compar	ator g	roup not	performing ar	active phy	ysical activity; i.e., education	
			ipplement 4 weeks	s/urugs long in duration	on		
	The stud	dy is a ht-bea	n RCT, a aring activ	quasi RCT, a	ı systemati	tic review or a meta-analysis - Only a resistance training program, or a	
	The stud	dy car	be any ty	pe of study o	lesign if the	e intervention is Yoga or Pilates	
Does t	the artic	le me	et inclusi	ion criteria?			
	Yes		□ No	☐ Unsu	ıre	☐ Excluded but of interest	

Table 12. Level 2 Screening – Full-Text Review (Impact)

Population:
Inclusion Criteria
 At least 80% of men or postmenopausal women aged ≥ 50 Participants have at least one of the following characteristics: Low BMD at femoral neck or lumbar spine (T-score ≤ -1.00) Diagnosis of osteoporosis or osteopenia (BMD g/cm²) History of fragility fracture(s); fracture due to minimal or no trauma (e.g., fall from standing height or less) often at hip, wrist, spine, humerus, rib or pelvis Moderate or high-risk of a fragility fracture based on 10 year risk using eithe the CAROC, FRAX, or GARVAN calculators (e.g., GARVAN calculator, if the area under the ROC curve greater than 0.64 - predictive of a major osteoporotic fracture)
 ☐ Glucocorticoid induced osteoporosis ☐ Target population is individuals with secondary osteoporosis (e.g., spinal cord injury, breast cancer, diabetes, etc) ☐ Individuals with pathological fractures other than those caused by osteoporosis Intervention:
Inclusion Criteria
 Any impact exercise defined as any activity that involves impact on the lower extremities ≥ 1 ground reaction force Trials that combine impact exercises with other types of exercise (e.g., resistance training, yoga, etc) Intervention ≥ 4 weeks long in duration Exclusion Criteria
 □ Trials where pharmacological therapy is only to the control group □ Trials that combine impact exercises with whole body vibration Control:
Inclusion Criteria
 □ There is at least one control group or comparator that:: ○ Receives no intervention ○ Receives a non-exercise or a non-physical therapy intervention (e.g. educational intervention, drug supplementation, or stretching) ○ Receives a placebo or sham intervention Type of study:
☐ All randomized controlled trials or quasi-randomized trials

Table 13. Search Strategies for Osteoporosis Review Protocol

MEDLINE search strategy

1	osteopor* or osteopenia or low bone density or low bone mineral density
	or low bone mass or bone loss* or bone remodel\$ing).ti,ab,kw.
2	((fragility or spine or spinal or vertebra* or hip* or femoral neck or
_	compression) adj2 fracture*).ti,ab,kw.
3	exp osteoporosis/ or bone density/ or exp bone remodeling/ or exp hip
O	fractures/ or
	spinal fractures/ or fractures, compression/ or osteoporotic fractures/
4	1 or 2 or 3
5	(older or elder or elderly or frail or senior* or middle age* or geriatric).ti,ab,kw.
6	middle aged/ or exp aged/
7	5 or 6
8	(Exercis* or Physical activit* or Physical fitness or Weight bearing or
· ·	Load bearing or Axial bearing or Running or Dancing or Stair climb* or
	treadmill* or walk or walking or
	weight lifting or yoga or pilates).ti,ab,kw.
9	((Resistance or strength or strengthening or weight or high impact) adj2
	(train* or
	exercis*)).ti,ab,kw.
10	(Balance adj2 (exercis* or train*)).ti,ab,kw.
11	exp exercise/ or exp sport/ or dancing/ or dance therapy/ or exp
	exercise therapy/ or weight bearing/ or osteoporosis/rh or walking/ or
	plyometric exercise/ or resistance
40	training/ or yoga/ or postural balance/
12	8 or 9 or 10 or 11
13 14	(Meta analys* or metaanalys*).ti,ab,kw.
15	((Systematic or methodologi*) adj5 (review* or overview*)).ti,ab,kw. (Cochrane or Embase or Psyclit or Psychlit or Medline or pubmed).ab.
16	(quantitativ* adj5 synthesi*).ti,ab,kw.
17	((pooled or pooling) and analys*).ti,ab,kw.
18	(randomized controlled trial* or Randomised controlled trial* or rct or
10	clinical trial* or
	(allocated adj2 random*)).ti,ab,kw.
19	Randomized controlled Trials as Topic/ or Randomized controlled trial/
	or Random
	allocation/ or Double blind method/ or single blind method/ or exp
	Clinical trial/ or exp clinical trials as topic/
00	10 11 15 10 17 10 10
20	13 or 14 or 15 or 16 or 17 or 18 or 19 4 and 7 and 12 and 20

22	exp animals/ not humans/
23	21 not 22
24	23 not (case reports or letter or editorial or comment).pt.

EMBASE search strategy

26	(osteopor* or osteopenia or low bone density or low bone mineral
	density or low bone
	mass or bone loss* or bone remodel\$ing).ti,ab,kw.
27	((fragility or spine or spinal or vertebra* or hip* or femoral neck or
	compression) adj2 fracture*).ti,ab,kw.
28	
20	exp osteoporosis/ or osteopenia/ or bone density/ or bone remodeling/ or bone atrophy/ or bone demineralization/ or fragility fracture/ or exp
	spine fracture/ or exp hip
	fracture/
29	26 or 27 or 28
30	(older or elderly or frail or senior* or middle age* or
	geriatric).ti,ab,kw.
31	middle aged/ or exp aged/
32	30 or 31
33	(Exercis* or Physical activit* or Physical fitness or Weight bearing or
	Load bearing or Axial bearing or Running or Dancing or Stair climb* or
	treadmill* or walk or walking or
	weight lifting or yoga or pilates).ti,ab,kw.
34	((Resistance or strength or strengthening or weight or high impact) adj2
	(train* or
35	exercis*)).ti,ab,kw.
36	(Balance adj2 (exercis* or train*)).ti,ab,kw.
30	exp exercise/ or exp sport/ or dancing/ or dance therapy/ or exp
	kinesiotherapy/ or weight bearing/ or osteoporosis/rh or walking/ or
	plyometrics/ or resistance training/ or yoga/ or pilates/ or body equilibrium/
37	33 or 34 or 35 or 36
38	(Meta analys* or metaanalys*).ti,ab,kw.
39	((Systematic or methodologi*) adj5 (review* or overview*)).ti,ab,kw.
40	(Cochrane or Embase or Psyclit or Psychlit or Medline or pubmed).ab.
41	(quantitativ* adj5 synthesi*).ti,ab,kw.
42	((pooled or pooling) and analys*).ti,ab,kw.
43	exp meta analysis/ or systematic review/
44	(randomized controlled trial* or Randomised controlled trial* or rct or
	clinical
	trial*).ti,ab,kw.
45	(allocated adj2 random*).ti,ab,kw.
46	randomized controlled trial/ or exp randomization/ or random allocation/
	or double
	blind method/ or single blind method/ or exp clinical trials as topic/
	ιτιαίο αο τοριο/

47	38 or 39 or 40 or 41 or 42 or 43 or 44 or 46
48	29 and 32 and 37 and 47
49	(exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal
	tissue/ or animal cell/ or nonhuman/) and (human/ or normal human/ or human cell/)
50	(exp animals/ or exp invertebrate/ or animal experiment/ or animal model/ or animal
	tissue/ or animal cell/ or nonhuman/) not 49
51	48 not 50
52	51 not (case study/ or letter/ or abstract report/ or editorial.pt. or note.pt.)

CINAHL search strategy

S18	S13 AND S14 AND S15 AND S16
	Limiters – Peer reviewed
S17	S13 AND S14 AND S15 AND S16
	((MH "Meta Analysis") OR (MH "Systematic Review")) OR TX (meta
	analy* OR metaanaly*) OR TX ((systematic or methodologi*) N5
S16	(review or overview)) OR AB (Cochrane or Embase or Psyclit or
510	Psychlit or Medline or pubmed) OR TX quantitativ* N5 synthesi* OR
	TX ((pooled or pooling) and analys*) OR TX (randomized controlled
	trial* or randomised controlled trial* or rct) OR TX (allocat* random*
	OR placebo* OR random* allocate* OR randomi* control* trial*) OR TX
	clinical N1 trial* OR ((MH
	"random assignment") OR (MH "clinical trials+"))
	((MH "Exercise+") OR (MH "Sports+") OR (MH "Dancing+") OR (MH
	"Dance Therapy") OR (MH "Therapeutic Exercise+") OR (MH "Weight-
	Bearing") OR (MH "Walking+") OR (MH "Resistance Training") OR (MH
S15	"Muscle Strengthening+") OR (MH "yoga") OR (MH "pilates") OR (MH
	"balance training, physical") OR (MH "balance, postural")) OR TX (
	Exercis* or Physical activit* or Physical fitness or Weight bearing or
	Load bearing or Axial bearing or Running or Dancing or Stair climb* or
	treadmill* or walk or walking or weight lifting or yoga or pilates) OR TX (
	(Resistance or strength or strengthening or weight or
	"high impact") N2 (train* or exercis*)) OR TX (Balance adj2 (exercis* or
	train*))
04.4	((MH "Middle Age") OR (MH "Aged+") OR (MH "Aging") OR (MH
S14	"Rehabilitation, Geriatric")) OR TX (older or elder or elderly or frail or
	senior* or middle age* or geriatric
	or "old age")
	(MH "Osteoporosis+") OR (MH "Bone Density") OR (MH "Bone
S13	Remodeling+") OR (MH "hip fractures+") OR (MH spinal fractures+")
	OR TX (osteopor* or osteopenia or low bone density or low bone
	mineral density or low bone mass or bone loss* or bone remodeling or
	bone remodelling) OR TX ((fragility or spine or spinal or vertebra* or

hip*
or femoral neck or compression) N2 fracture*)

Web of Science search strategy

#6	#4 AND #3 AND #2 AND #1
	Refined by: DOCUMENT TYPES: (ARTICLE OR PROCEEDINGS
	PAPER OR REVIEW)
	Indexes=SCI-EXPANDED, SSCI Timespan=1900-2018
#5	#4 AND #3 AND #2 AND #1
	Indexes=SCI-EXPANDED, SSCI Timespan=1900-2018
#4 TS=("Meta analys*" or "metaanalys*") OR TS=("systematic"	
	("review" or "overview")) OR TS=(("pooled" OR "pooling") AND
	"analys*") OR TS=("randomized controlled trial*" OR "randomised
	controlled trial*" OR "rct" OR "clinical trial*" OR "random allocat*")
	Indexes=SCI-EXPANDED, SSCI Timespan=1900-2018
#3	TS=("Exercis*" or "Physical activit*" or "Physical fitness" or "Weight
	bearing" or "Load bearing" or "Axial bearing" or "Running" or "Dancing"
	or "Stair climb*" or "treadmill*" or "walk" or "walking" or "weight lifting" or
	"yoga" or "pilates") OR TS=(("Resistance" or "strength" or
	"strengthening" or "weight" OR "high impact") NEAR/2 (train* or
	exercis*))
	OR TS=(Balance NEAR/2 (exercis* or train*))
#2	TS=("older" OR "elder" or "elderly" or "frail" or "senior*" or "middle age*"
	or "geriatric")
	Indexes=SCI-EXPANDED, SSCI Timespan=1900-2018
#1	TS=("osteopor*" or "osteopenia" or ("low" NEAR/2 ("bone density" OR
	"bone mineral
	density" or "bone mass")) or bone loss* or "bone remodeling" or "bone
	remodeling") OR TS=(("fragility" OR "spine" OR "spinal" OR "vertebra*"
	or "hip" OR "compression") NEAR/2 "fracture*")
	Indexes=SCI-EXPANDED, SSCI Timespan=1900-2018

Cochrane Library search strategy

#1	osteopor* or osteopenia or low bone density or low bone mineral density or	
	low bone mass or bone loss* or bone remodeling or bone remodeling or	
	((fragility or spine OR spinal OR	
	vertebra* or hip* or femoral) NEAR/2 fracture*)	
#2	MeSH descriptor: [Osteoporosis] explode all trees	
#3	MeSH descriptor: [Bone Density] explode all trees	
#4	MeSH descriptor: [Bone Remodeling] explode all trees	
#5	MeSH descriptor: [Hip Fractures] explode all trees	
#6	MeSH descriptor: [Spinal Fractures] explode all trees	
#7	MeSH descriptor: [Fractures, Compression] explode all trees	

#8	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7	
#9	older or old or elder or elderly or frail or senior* or middle age* or geriatric	
#10	MeSH descriptor: [Middle Aged] explode all trees	
#11	MeSH descriptor: [Aged] explode all trees	
#12	#9 OR #10 OR #11	
#13	3 Exercis* or Physical activit* or Physical fitness or Weight bearing or Load	
	bearing or Axial bearing or Running or Dancing or Stair climb* or	
	treadmill* or walk or walking or ((Resistance or strength or strengthening	
	or weight) NEAR/2 (train* or exercise*)) or weight	
	lifting or yoga or pilates or (Balance NEAR/2 (exercis* or train*))	
#14	MeSH descriptor: [Exercise] explode all trees	
#15	MeSH descriptor: [Sports] explode all trees	
#16	MeSH descriptor: [Dance Therapy] explode all trees	
#17	MeSH descriptor: [Dancing] explode all trees	
#18	MeSH descriptor: [Exercise Therapy] explode all trees	
#19	MeSH descriptor: [Weight-Bearing] explode all trees	
#20	MeSH descriptor: [Walking] explode all trees	
#21	MeSH descriptor: [Resistance Training] explode all trees	
#22	MeSH descriptor: [Yoga] explode all trees	
#23	MeSH descriptor: [Postural Balance] explode all trees	
#24	#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22	
	OR #23	
#25	#8 AND #12 AND #24	

Epistemonikos search strategy

(title:(osteopor* OR osteopenia OR low bone density OR low bone mineral density OR low bone mass OR bone loss* OR bone remodeling OR bone remodeling OR ((fragility OR spine OR spinal OR vertebra* OR hip* OR femoral OR compression) AND fracture*)) OR abstract:(osteopor* OR osteopenia OR low bone density OR low bone mineral density OR low bone mass OR bone loss* OR bone remodeling OR bone remodeling OR ((fragility OR spine OR spinal OR vertebra* OR hip* OR femoral OR compression) AND fracture*)))

AND

(title:((older OR old OR elder OR elderly OR frail OR senior* OR middle age* OR geriatric)) OR abstract:((older OR old OR elder OR elderly OR frail OR senior* OR middle age* OR geriatric)))

AND

(title:(Exercis* OR Physical activit* OR Physical fitness OR Weight bearing OR Load bearing OR Axial bearing OR Running OR Dancing OR Stair climb* OR treadmill* OR walk OR walking OR ((Resistance OR strength OR strengthening OR weight) AND (train* OR exercise*)) OR weight lifting OR yoga OR pilates OR (Balance AND (exercis* OR train*))) OR abstract:(Exercis* OR Physical activit* OR Physical fitness OR Weight bearing OR Load bearing OR Axial bearing OR Running OR Dancing OR Stair climb* OR treadmill* OR walk OR walking OR ((Resistance OR strength OR strengthening OR weight) AND (train* OR exercise*)) OR weight lifting OR yoga OR pilates OR (Balance AND (exercis* OR train*))))

Appendix D: Consent Forms

Study 2 (Chapter 3): <u>Informed Consent Form for Participation in a Research</u> Study

Study Title: Perspective on starting or continuing moderate-to-high impact exercise and

resistance training

Principal Investigator: Dr. Lora Giangregorio

Department of Kinesiology University of Waterloo

Phone: 519-888-4567, ext. 46357 Email: Imgiangr@uwaterloo.ca

Student Investigator: Isabel B. Rodrigues, Ph.D. candidate

Department of Kinesiology University of Waterloo

Phone: 519-888-4567, ext. 38779 Email: ibrodrig@uwaterloo.ca

Funding Source: No funding

The Bone Health and Exercise Science Lab at the University of Waterloo is recruiting participants for a research study titled "Patients' perspectives on starting or continuing moderate-to-high impact exercise and resistance training". This research study is a PhD student-led project. There are no conflicts of interest to declare related to this study.

INTRODUCTION

This form describes the research study so that you can make an informed choice about participating. Taking part in this study is voluntary. Please read this document carefully. If you have questions about participating in the study, you can contact Dr. Lora Giangregorio or Isabel Rodrigues. Take your time in making your decision.

WHY IS THIS STUDY BEING DONE?

Physical activity is an important strategy to help manage osteoporosis, and research tells us that certain types of activities are good for bone health. Our research team wants to develop tools and resources to help individuals living with osteoporosis use physical activity to help manage their condition. The purpose of this study is to understand your perspective on starting or continuing certain types of activities.

WHO MAY PARTICIPATE IN THE STUDY?

We are inviting people who are 50 years or older with a diagnosis of low bone mass or osteoporosis to participate in the study. We plan to recruit and interview people until we feel we have enough information.

You are **eligible to participate** if you: 1) are 50 years or older; 2) have a self-reported or physician diagnosis of low bone mass or osteoporosis (T score < -1); 3) can speak and read English or can attend with a translator; and 4) have access to a computer with internet, or a telephone. Unfortunately, participants who have been diagnosed with bone cancer or bone metastasis are not eligible to participate.

WHAT WILL HAPPEN DURING THIS STUDY?

We will first ask you to read over this form and provide verbal consent of your participation in this study. If you decide to take part in this study, you will be asked to complete a questionnaire and participate in a one-on-one interview. All information will be collected over the phone or through a video application like Microsoft Teams by the student investigator. Due to the COVID-19 pandemic, there will be no in-person data collection. We require a total time commitment of approximately 1 hour to 1.5 hours.

Questionnaire:

We will ask questions about your age, gender, education level, ethnicity, use of mobility aids, total family income, living situation, medical conditions, exercise habits in the last week, the number of falls you experienced in the last six months, and fracture history. This questionnaire will take 15 to 20 minutes to complete and will be done over the telephone or a web conference application. If you do not feel comfortable answering a question, you may choose to skip it.

One-on-One Interview:

After completing the questionnaire, we will conduct a one-on-one interview by telephone or web conference. We will ask you about your perspectives on participating in moderate-to-high impact exercises or resistance exercises. We anticipate the interview to take about 30 to 45 minutes to complete. If you do not feel comfortable answering a question, you may choose to skip it.

If you choose to participate via web conference, the web conference platform we use is Microsoft Teams, which is an externally hosted cloud-based service. A link to their privacy policy is available here: https://www.microsoft.com/en-ca/trust-center/privacy?rtc=1. There is a small risk that the data collected on external servers falls outside the control of the research team. If you are concerned about this, you can participate via telephone. If you choose to participate via Microsoft Teams, a private meeting invite will be sent directly to your e-mail to prevent unauthorized access. To ensure accurate data analysis, we will be audio recording the interviews using Microsoft Teams or a hand-held device.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You may withdraw from this study at any time. You may also request to withdraw your data that has already collected as long as we have not analyzed or published the data.

To withdraw or to ask questions you may contact: Isabel Rodrigues at ibrodrig@uwaterloo.ca or via telephone at 519-888-4567 ext. 38779.

Please note that communication via e-mail is not absolutely secure. Please do not communicate personal information via e-mail. If the university research laboratories are closed due to the COVID19 pandemic, we may not be able to answer the phone right away. Please leave a message and we will check messages at regular intervals and return your call.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

There are no anticipated risks or harms in participating in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There are no direct benefits of participating in this study. The information you provide us will help us develop tools and resources for people with osteoporosis.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study. Some of the information we will collect includes your name, phone number, and an email address or home address. You will be assigned an ID number that will be reported on all data collection forms. A key file linking your contact information with your ID will be kept in a separate password protected file on the University of Waterloo network drive. Only research personnel directly involved in this study will be allowed to access, view, or analyze your data. Any quotations used in the write-up of the study will be anonymous; this means your name will never be associated to a quotation. The interview audio recording will be moved within 12-hours of the study visit to a password protected folder on the University of Waterloo network drive and permanently deleted from the hand-held device. The audio recording will be transcribed and stored as a password protected word document on the University of Waterloo network drive server. We will remove all identifying information from the transcribed documents. All data will be password protected. All the data collected will be stored on the University of Waterloo server for at least 7 years.

If the results of this study are published, but your identity will remain confidential. It is expected that the information collected during this study will be used in analyses and will be published and presented to the scientific community at meetings and in journals.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any costs.

ARE STUDY PARTICIPANTS REMUNERATED TO BE IN THIS STUDY?

You will not be remunerated for taking part in this study.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to be informed of the results of this study once the entire study is complete. We will mail or email all enrolled participants a feedback letter with the results of the study. The results will be sent within four months of the study being completed.

By providing consent, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

You will be provided with an electronic or hard copy of this form documenting the date you provided verbal consent prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

Isabel B. Rodrigues

Name

If you have questions about taking part in this study, please contact the student investigator listed on the next page:

Hamo	Тоюрноно
This study has been reviewed and received ethics clearance	through a University of
Waterloo Research Ethics Board (ORE#42322). If you have	questions for the Board

contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or oreceo@uwaterloo.ca.

Screening and Recruitment
Date of screening and recruitment interview:
YYYY - MM – DD
Was verbal consent received to conduct the screening and recruitment interview \(\subseteq \text{Yes} \subseteq \text{No} \)

519-888-4567 x 38779

Who completed the screening and recruitment interview	?
Name	
Informed Consent	
When was the consent form sent to the participant? Email Mail	
YYYY - MM – DD Time	
When was verbal consent given by the participant to enroll in the study? YYYY - MM - DD Time	
<u> </u>	
Did the participant provide verbal consent to have the interview audio recorded? \(\subseteq \cdot \)	'es ∐ No
If Yes, when:	
YYYY - MM – DD Time	
Did the participant provide verbal consent to the use of anonymous quotations? \square Y	es 🗌 No
If Yes, when:	
YYYY - MM – DD Time	
Please initial next to each row to verify that the consent interview addressed the aspects of the trial:	e following
The purpose of the study was explained to the participant	Yes
The procedures of the study were explained to the participant	Yes
The possible risks and benefits of participation were explained to the participant	Yes
The scope of privacy and confidentiality were explained to the participant	Yes
The voluntary nature of the study and its components were explained to the	Yes
participants	
Signature of Research Team Member: Date:	

Consent Questions:

1. Eligibility – Phone script: Complete page 4 of the Informed Consent Form ("Screening and Recruitment")

- a. "Before I continue, I need to make sure you are eligible to participate in this study. The information you provide me will be used for screening purposes only, and securely stored on the University of Waterloo server that only approved users can access. The screening form will contain no identifying information. If you are deemed ineligible, the only data collected will be the completed screening questionnaire, which will be permanently deleted from the University of Waterloo server. Can I ask you a few questions to determine if you are eligible for the study?" If "Yes", proceed to ask the following questions:
 - i. "This year, will you be 50 year or older"?;
 - ii. "Has a doctor or healthcare professional ever told you that you have low bone mass or osteoporosis"?
 - iii. "Do you have access to a computer with internet"?
 - iv. "Has a doctor or healthcare professional ever told you that you have bone cancer or metastasis to the bone"?
- b. If the participant is eligible to enroll:
 - i. "Thank you for your answers. You are eligible for the study. If you are still interested in participating may I register your name, the best number and time to contact you, and an email or home address. I ask for an email or home address so I can send you the informed consent letter before the start of the study and a feedback letter at the end of the study".
- c. If the participant is not eligible to enroll:
 - i. "Thank you for your interest in our study. Unfortunately, we are unable to include you in the study because you do not currently meet our inclusion criteria <state the reason>. If you have any questions or concerns about the study, I would be happy to answer them for you. You can also reach out to the Principal Investigator, Lora Giangregorio, at 519-888-4567 ext. 46357 for additional information"

2. Consent Form – Enrollment: Complete page 4 of the Informed Consent Form ("Informed Consent")

- a. "Did you have a chance to read over the informed consent form"?
 - i. If "Yes", continue to question b

- ii. If "No", review the form with the participant and give them time to read over the form. If necessary, book a follow-up appointment to give the participant the chance to read the form. After reviewing the form, continue to question b.
- b. "Do you have any questions about the informed consent form"?
 - i. If "Yes", answer the questions and then proceed to question c.
 - ii. If "No", proceed to question c.
- c. Ask the participant the following questions below. If the answer is "Yes", proceed until all questions are asked. If the answer is "No" explain the purpose to the participant and ask the question again.
 - i. "Do you understand the purpose of the study"?
 - ii. "Do you understand the procedures of the study"?
 - iii. "Do you understand the possible risks and benefits of participating in this study"?
 - iv. "Do you understand the scope of privacy and confidentiality related to this study"?
 - v. "Do you understand that participating in this study is voluntary, and you may withdraw at any time"?
- d. "Do you provide verbal consent to participate in the research study: 'Patients' perspectives to starting or continuing moderate-to-high impact exercise and resistance training'"?
 - i. If "Yes", continue to question d.
 - ii. If "No", thank the participant for their time and let them know they are not eligible to participate without providing verbal consent.
- e. "Do you provide verbal consent to have the interview audio recorded"?
 - i. If "Yes", continue to question e.
 - ii. If "No", continue to question e.
- f. "Do you provide verbal consent to have anonymous quotations used in the published manuscript"?
 - i. If "Yes", continue to question f.
 - ii. If "No", continue to question f.

Study 3 (Chapter 4 and 5): <u>Informed Consent Form for Participation in a Research Study (For Participants)</u>

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

Primary Investigator: Dr. Lora Giangregorio

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Funnell, Ms. Sheila Brien, Mr. Zachary Weston

Students or Trainees: Isabel Rodrigues, Justin Wagler

Sponsors: Canadian Institutes of Health Research

Introduction

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

Why is this research being done?

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

What is the purpose of the study?

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

Who is eligible to partake in the study?

You are **eligible** if you: speak English or attend with translator, are \geq 60 years, have a 1+ FRAIL scale, and have 1 or more chronic conditions (i.e., diabetes, obesity, cancer, chronic lung disease, cardiovascular disease, congestive heart failure, hypertension, osteoporosis, arthritis, stroke, or kidney disease). You are **not eligible** if you: are exercising \geq 2x/week, are in palliative care, cannot perform basic activities of daily living, have moderate or severe cognitive impairment, are travelling > 1 week during the study or cannot exercise as recommended by a physician.

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

You will be asked to attend four study visits during the study. Each study visit will take approximately one to one and a half hours, and will include the assessments listed below. If you cannot complete an assessment, or do not wish to, you can still remain in the study. The study visit at the end of the program will be conducted 20 weeks after the first study visit. The assessments are voluntary and you can choose to skip any question you prefer not to answer. The only assessments that are required are the screening assessments at the start to confirm that you are eligible to participate. We may also ask you to describe the study back to us in your own words so we can be sure you understand what we are asking you to do.

Study assessments:

- A physical assessment that includes assessing your height, weight, and walking speed over 10 meters. Balance and mobility tests include your ability to get up from a chair and sit back down for 30 seconds, and your ability to step over low objects while moving forward, backward, and sideway. We will also provide you with a number of questionnaires to assess your exhaustion levels, quality of life, and diet.
- 2. We will ask questions about your health and medical history, your perceived quality of life, the health services you use, your physical activity levels, your diet, and assess your exercise techniques during **one** exercise session. We will also ask about illness or injuries that happen during the study. We may complete some of these over the phone. Your exercise technique will be assessed by observing or videotaping only one of the of exercise sessions you attend and notes may be taken.
- We will ask you to complete a demographic questionnaire that inquire about your place of residence, race, occupation, gender/sex, socioeconomic status and social capital.
- 4. At the end of the study we will ask for you to participate in a voluntary exit interview that will be audio recorded. If we choose to publish the results of this paper, we may use your quote to disseminate your thoughts about the program. We will not reveal any identifiable information, except your age, gender, and any

major chronic disease(s) (e.g., "<insert quotation>" – Female, 70 years, type II Diabetes and osteoarthritis").

Other assessments:

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

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

Will you be accessing my medical history from my physician?

Typically, we do not require your medical history from your physician unless we need to establish a diagnosis or confirm that it is safe for you to exercises. If we need to speak to your physician we will ask your permission before contacting them. We will also ask you to sign a release of medical history form. You are welcome to opt out, in which case we will not contact your doctor, however, if we believe it is not safe for you to exercise we may not enroll you in the study.

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

We will provide you with the results of your assessments at the end of the study, so that you can see how you did. You will be allowed to keep all of the exercise and nutrition materials and you will receive an exercise program from the kinesiologist. You will exercise in small groups where you will meet other participants.

What are the possible risks and discomforts?

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

The kinesiologist will also be present at all exercise sessions and may act as a spotter in case you fall.

What information will be kept private and confidential?

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

Information about your health may be obtained from your health records held at this and other health services for the purpose of this research. If we need to access this information we will ask you to sign a Release of Medical Records Form.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the University of Waterloo or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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

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

Can I end my participation early?

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part. If you volunteer to be in this study, you may withdraw at any time. If you are considering withdrawing, you will be asked if there are some parts of the study you are still willing to complete (e.g., exit interview). You can opt out of only some parts of the study, or withdraw

altogether. You can request your data be removed from the study up until August 31, 2020 as it is not possible to withdraw your data once papers and publications have been submitted to publishers. If you decide to withdraw from the project, please notify a member of the research team. If you request that you would like your data to be removed we will remove it. When you withdraw, we will ask you if we can use your data for analysis purposes and if you do not agree we will withdraw it. 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, consistent with protocol for a loss to follow-up.

Will I be remunerated to participate in the study?

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

What happens if I have a research-related injury?

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

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

If you have any urgent medical problem, injury or illness that is related to your participation in this study or have any questions, concerns or would like to speak to the study team for any reason please call: Dr. Lora Giangregorio at 519-888-4567 EXT 36357

Consent of Participant

I have read the information presented in the information letter about a study, a model for delivering strength training and nutrition education for older adults (MoveStrong), being conducted by Dr. Giangregorio and colleagues or I have had it read to me in a language that I understand. I have had the opportunity to ask any questions related to this study, to receive satisfactory answers to my questions, and any additional details I requested. I understand the purposes, procedures and risks of the research described in the project. I am aware that I may withdraw from the study without penalty at any time by advising the researchers of this decision. With full knowledge of all foregoing, I agree, of my own free will to participate in this study. I have been advised that I will receive a signed copy of this form.

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#31752). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca."

Consent Statement

Audio and video

recording for

□ I agree to my interview being audio recorded to ensure

transcription analysis purposes only	☐ I agree to my study session being video recorded. The videos will only be seen by the research team.
Audio/video clips, images for public use:	☐ I agree to allow audio/video clips, digital images or photographs in which I appear to be used in teaching, scientific presentations and/or publications with the understanding that I will not be identified by name. If the clip or image includes a participant's face or other identifying features, the image will be blurred/obscured
Use of attributed quotations:	☐ I agree that the research can use direct quotes from the interview

NOTE: One copy should be given to the participant and the other to the research assistant to store in a locked cabinet.

Study 3 (Chapter 4 and 5): <u>Informed Consent Form for Participation in a Research Study (For Exercise Physiologists)</u>

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

education for older adults

Primary Investigator: Dr. Lora Giangregorio

Professor and Schlegel Research Chair in Mobility and

Aging

University of Waterloo, Department of Kinesiology

Tel: (519) 888-4567 Ext. 36357

Email: lora.giangregorio@uwaterloo.ca

Co-investigators: Professor Heather Keller, Dr. Angela Cheung, Dr. Wanrudee Isaranuwatchai, Dr. Maureen C. Ashe, Dr. Alexandra Papaioannou, Dr. Marina Mourtzakis, Dr. Lehana Thabane, and Dr. Sharon Straus, Dr. Jamie Milligan, Mr.

Larry Funnell, Ms. Sheila Brien, Mr. Zachary Weston **Students or Trainees**: Isabel Rodrigues, Justin Wagler **Sponsors:** Canadian Institutes of Health Research

Introduction

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

Why is this research being done?

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

What is the purpose of the study?

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

What will your responsibilities be if you decide to take part in the study? We would like to observe one exercise session that you deliver for the MoveStrong Program. An individual who is either part of the research team or a hired kinesiologist will observe one session and take notes using a fidelity questionnaire we have created. At the end of the study, we will also ask you to participate in a voluntary exit interview to understand your experience with the program. The

interview can last between 10 minutes to 45 minutes and with your verbal permission we will audio record the interview. In case we publish a paper on this topic, we may use a direct quotation that is not attributed to you. The quotation will not include any identifiable information, just your occupation and the number of years you have been practicing as a kinesiologist. You may skip any questions you prefer not to answer.

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

Your participation will help us compare how kinesiologists deliver the intervention across sites and determine if our model of training leads to it being delivered as intended. If variations are made, we can learn how it varies.

What are the possible risks and discomforts?

There are no foreseeable risks or discomforts involved in this study. Any data collected for research puporses will not affect your role as an instructor.

What information will be kept private and confidential?

Any personal information we collect will be stored in a locked cabinet at the University of Waterloo. We will collect data on one exercise session that you lead and will deidentify the data by just including the site name and the date on the "Fidelity form". The fidelity form will be used to see how accurately the exercise sessions are taught. We will only observe one exercise session and determine accuracy (i.e., "fidelity) using a fidelity questionnaire. The interview transcripts will be stored in a locked cabinet at the University of Waterloo. Your name and identify may be revealed to other participants enrolled in the program given the exercise sessions will be run in groups.

Can I end my participation early?

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You can request your data be removed from the study up until August 31, 2020 as it is not possible to withdraw your data once papers and publications have been submitted to publishers. When you withdraw, we will ask you if we can use your data for analysis purposes and if you do not agree we will withdraw it. 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, consistent with protocol for a loss to follow-up. Paper and electronic records will be retained for 7 years after the study is complete. All anonymized forms and study data will be stored in a locked office. Only the research team will have access to the data. Some of the data may be examined by students doing thesis projects or research internships, but your name or other identifying information will not appear with the data. Data will be secured in accordance with UW policies available at http://ist.uwaterloo.ca/security/policy/.

Will I be remunerated to participate in the study?

As a participant, you will not receive payment for your participation in the study.

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

Consent of Participant

Consent Statement

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

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

By signing this consent form, you are not waiving your legal rights or releasing the investigator(s) or involved institution(s) from their legal and professional responsibilities.

This study has been reviewed and received ethics clearance through a University of Waterloo Research Ethics Committee (ORE#31752). If you have questions for the Committee contact the Office of Research Ethics, at 1-519-888-4567 ext. 36005 or ore-ceo@uwaterloo.ca."

Name of Participant		
Signature of Participant	Date	
Person obtaining consent: I have discussed this study in deunderstands what is involved in	• •	lieve the participant
Name, Role in Study	Signature	Date

Other consent options available: Please initial beside the boxes you check

Audio recording for transcription analysis purposes only	☐ I agree to my interview being audio recorded to ensure accurate transcription and analysis
Audio/video clips, images for public use:	☐ I agree to allow audio/video clips, digital images or photographs in which I appear to be used in teaching, scientific presentations and/or publications with the understanding that I will not be identified by name. If the clip or image includes a participant's face or other identifying features, the image will be blurred/obscured
Use of attributed	☐ I agree that the research can use direct quotes from the interview
quotations:	

NOTE: One copy should be given to the participant and the other to the research assistant to store in a locked cabinet.

Appendix E: Agreement of Copyright Permission

Figure 1 (Chapter One): Knowledge-to-Action Cycle

Dear Ms. Isabel Rodrigues,

Your Wolters Kluwer Health, Inc. request has been denied for the following reason:

Other. This article is published as Open Access, which means content from the article can be reused in non-profit endeavors without requiring permission. Since use in a thesis is non-profit, you do not need permission to include this content.

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Request Summary:

Submit date: 23-Jun-2021 Request ID: 600046346

Publication: JOURNAL OF CONTINUING EDUCATION IN THE HEALTH

PROFESSIONS

Title: Lost in knowledge translation: time for a map? Type of Use: Republish in a thesis/dissertation

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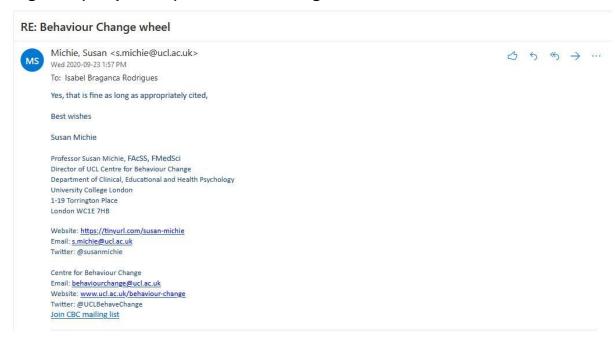
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Figure 5 (Chapter Six): Behaviour Change Wheel



Glossary

Balance training involves activities with one or more of the following components: 1) reducing base of support or reliance on support objects; 2) moving to limits of stability; or 3) transferring weight from one body part to another.

Complex interventions are defined as interventions with several interacting components.

Diffusion of evidence is a passive, unplanned, and untargeted spread of information ("letting it happen").

Dissemination research is the scientific study of targeted distribution of information and interventions to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and encourage the adoption of evidence-based interventions ("helping it happen").

Family Health Team is a primary healthcare team that is created based on the health needs of the community it serves. Family Health Teams can be made up by a team of diverse healthcare providers and include physicians, nurse practitioners, registered nurses, social workers, mental health professionals, pharmacists, registered dietitians, occupational therapists, physiotherapists, speech language pathologists, and case manager.

Educational materials are the distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials, and electronic publications. The materials may be delivered personally, through social media, or through mass mailing.

Educational meetings are when healthcare providers participate in conferences, lectures, workshops, or traineeships.

Educational outreach is the use of a trained person who met with providers in their practice setting to give information with intent to change the provider's practice. The information given may include feedback on the performance of the providers.

Frailty a medical syndrome with multiple causes and contributors that is characterized by diminished strength, endurance, and reduced physiological function that increases an individual's vulnerability for developing increased dependency and/or death.

Functional training involves assessment and prescription of exercises aligned with activity of daily living (e.g., getting up from seated position, walking, and stair climbing), and includes progression of the difficulty, type, pace, repetitions, or resistance.

Ground Reaction Force is a force exerted by the ground (i.e., normal force) on the part of the body that contacts with the ground.

Impact Exercises involves any exercises or movements with a ground reaction force ≥ 1 x body weight on the lower extremities. In this thesis were discern between three levels of impact exercises: low, moderate, or high impact.

Implementation research is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health ("making it happen"). **Knowledge Translation** is defined as a dynamic and iterative process that includes synthesis, dissemination, exchange, and ethically sound application of knowledge to improve the health of Canadians to provide more effective health and products and strengthen the healthcare system.

Mass media varied use of communication that reached a large audience

Patient-mediated knowledge translation tools are tools that improve patient's involvement in their own care and communicate with their provider(s) (e.g., booklet, brochure, website, computer program, print material, counseling session, video).

Reminders are patient or encounter specific information provided verbally, on paper, or on a computer screen, which is designed or intended to prompt a health professional to recall information. This would usually be encountered through general education, in medical records, or through interactions with peers.

Resistance Training is any activity where the muscles contract against a resistance, such as body weight, weights, or resistance bands, to overload and bring about a training effect in the muscular system to improve muscular strength or hypertrophy. This term is used synonymously with strength training in this thesis.

Sarcopenia is a progressive and generalized skeletal muscle disorder that is associated with increased likelihood of adverse outcomes including falls, fractures, physical disability and mortality. It is characterized by quantitative and qualitative alterations in muscles that may emerge from middle age onwards – EWGSOP2.