# Measuring the Implementation of Lifestyle-Integrated Functional Exercise in Primary Care for Older Adults: Results of a Feasibility Study\*†

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## RÉSUMÉ

Notre étude pilote a évalué la faisabilité, l'efficacité et la mise en œuvre du programme d'exercices fonctionnels en groupe intégrés au mode de vie (Lifestyle-integrated Functional Exercise; Mi-LiFE) créé pour des personnes âgées, dans le cadre d'une pratique interprofessionnelle en soins de première ligne. Un physiothérapeute a enseigné aux participants comment intégrer des exercices de force et d'équilibre dans la routine quotidienne au cours d'une séance individuelle et de quatre séances de groupe, suivis de deux rendez-vous téléphoniques. Les résultats concernant la faisabilité incluaient le recrutement, l'adhésion et la rétention sur une période de six mois. L'activité physique (AP) (accéléromètre, IPAQ), une version courte de la batterie de tests de performance physique (SPPB) et la qualité de vie liée à la santé (EQ5D-3L) ont été évaluées au début de l'intervention et 6 mois plus tard. Des 123 personnes admissibles, 39 % ont participé à l'intervention et 61 % n'étaient pas intéressées ou non joignables. Quarante-huit participants (âge moyen ± ÉT = 81 ± 5 ans ; IMC = 28 ± 5 kg/m2 ; 60 % de femmes ; AP modérée à vigoureuse = 49 ± 87 minutes par semaine) ont pris part à cette étude. Quatre participants se sont retirés avant le début de l'intervention. Trente-deux participants (67 %) étaient présents au suivi. Le taux d'adhésion quotidien documenté dans le journal de bord était de 50 % à 6 mois, et 77 % des participants ont assisté à au moins 4 séances. Aucun changement statistiquement significatif n'a été observé dans les résultats de l'AP modérée à forte et de la SPPB. Cependant, les participants ont déclaré lors du suivi que leur force et leur équilibre dans l'AP se sont améliorés, tout comme leur qualité de vie. Le programme Mi-LiFE présente une bonne faisabilité, avec des taux de recrutement et d'assiduité acceptables. Des modifications pourraient être apportées pour améliorer la rétention et l'adhésion à l'intervention. Ces résultats renseignent sur la faisabilité de programames d'exercices pragmatiques qui pourraient être développés pour être offerts aux personnes âgées se présentant pour des soins de première ligne.

#### **ABSTRACT**

Our pilot study evaluated the feasibility, effectiveness, and implementation of a group-based lifestyle-integrated functional exercise (Mi-LiFE) program for older adults in an interprofessional primary care practice. A physical therapist taught participants how to integrate strength and balance activities into daily routines during one individual and four group sessions, and two follow-up phone calls. Feasibility outcomes were recruitment, adherence, and retention over 6 months. Physical activity (PA) (accelerometer, International Physical Activity Questionnaire [IPAQ]), Short Physical Performance Battery (SPPB), and health-related quality of life (EuroQol Five-Dimensional Questionnaire with 3 Levels [EQ5D-3L]) were evaluated at baseline and 6 months. Of the 123 eligible individuals, 39 per cent participated and 61 per cent were not interested or unreachable. Forty-eight participants (mean  $\pm$  standard deviation [SD] age = 81  $\pm$  5 years; body mass index [BMI] =  $28 \pm 5$  kg/m²; 60% women; moderate-to-vigorous PA =  $49 \pm 87$  minutes/week) enrolled. Four participants withdrew prior to intervention. Thirty-two participants (67%) were retained at follow-up. Daily diary-documented adherence was 50 per cent at 6 months, and 77 per cent attended more than four sessions. No statistically significant changes in moderate-to-vigorous PA and SPPB outcomes were observed; yet self-reported strength and balance PA and quality of life significantly improved at follow-up. The Mi-LiFE program is feasible with acceptable recruitment and attendance rates alongside modifications to address retention and adherence challenges. These findings inform the feasibility of future pragmatic exercise programs in primary care for older adults.

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## Introduction

Less than 15 per cent of older adults 60 years of age and older meet recommendations of at least 150 minutes/week of moderate-to-vigorous physical activity (MVPA) (Colley et al., 2011; Troiano et al., 2008) and as few as 5 per cent regularly perform 2 days/ week of both strength and balance training (Bennie et al., 2016; Merom et al., 2012). Physical inactivity is a leading modifiable risk factor for cardiovascular and other chronic diseases and fall-related injuries, and contributes substantially to the increasing global health care costs (Janssen, 2012; Warburton, Nicol, & Bredin, 2006). Previous studies have demonstrated the efficacy of physical therapist (PT) or other health promoter-led exercise interventions to improve health outcomes and reduce fall risk in older adults (Clemson et al., 2012; Pahor et al., 2014; Sherrington et al., 2016). However, a feasible and cost-effective model of delivery for exercise prescription in a real-world setting remains unknown (Katz, Lambert-Lanning, Miller, Kaminsky, & Enns, 2012). Integration of exercise into lifestyle activities combined with behaviour change counselling can enhance exercise adoption and adherence (Weber et al., 2018) and overcome common barriers to exercise (e.g., time, access to facilities, aversion to structured exercise) (Costello, Kafchinski, Vrazel, & Sullivan, 2011). Therefore, lifestyle-based functional exercise may represent a generalizable and sustainable strategy to increase physical activity (PA) levels (Clemson et al., 2012; Dunn et al., 1999), prevent falls (Clemson et al., 2012) and manage chronic disease in older adults (Clemson et al., 2012; Dunn et al., 1999). Yet, there is limited evidence on how to effectively implement lifestyle exercise interventions into practice, especially for sedentary older adults with multiple chronic conditions.

Primary care represents a real-world setting for identifying older adults in need of PA intervention. However, recent primary care-based exercise referral or counseling trials have not been associated with any major or statistically significant increases in PA in community-dwelling middle-aged and older adults (Fitzsimons et al., 2012; Fortier et al., 2011; Knight & Petrella, 2014; Lawton et al., 2008). Additionally, there

is limited evidence on their effectiveness in improving longer-term objectively-measured MVPA levels in inactive older adults (≥75 years of age) (Pavey et al., 2011). Therefore, we need to identify evidence-based PA programs for older adults with the potential for real-world implementation, including effectiveness in improving PA, health, and functional outcomes. Clemson et al. (2012) found that teaching older adults how to integrate functional strength and balance exercises into daily life activities (known as the Lifestyle-Integrated Functional Exercise (LiFE) program) was associated with an increase in self-reported PA, a reduction in fall rate, and improvements in balance and lower limb strength, as compared with controls. The LiFE program is unique in that it includes theorydriven behaviour change strategies (e.g., action planning, habit reforming) (Clemson & Munro, 2017) as well as exercise training elements (e.g., balance, muscle strengthening) (Clemson et al., 2010). LiFE also demonstrates acceptable adherence (64% completed balance and strength activities ≥3 days/week) and retention rates (76% completed follow-up assessments) in older adults with a high risk of falling (Clemson et al., 2012). Few clinical trials of exercise move beyond establishing efficacy to test implementation in primary care or other health care settings. Thus, a group-based version of the LiFE program (referred to herein as Mi-LiFE) was evaluated as a more generalizable and resource-effective strategy for implementation in an interprofessional primary care context.

The objectives of our pilot study were to evaluate the feasibility, potential effectiveness, and implementation of the Mi-LiFE program in a primary care-based family health team (FHT) practice for older adults 75 years of age and older. The primary objectives were related to feasibility outcomes (recruitment, retention, and adherence) and aimed to determine over the 6-month implementation period: (1) the number of participants that we could recruit, (2) retention at follow-up, and (3) adherence to the Mi-LiFE program. It was hypothesized that the Mi-LiFE program would be considered feasible without modifications if 30 participants were recruited (Lee et al., 2017); 75 per cent of participants were retained (Clemson et al., 2012); and 50 per cent of participants completed the LiFE strength and balance activities ≥ 3 days/week (Clemson et al., 2012). Secondary objectives of this pilot study evaluated the potential effectiveness of the Mi-LiFE program in improving participants' PA levels, physical performance, and quality of life. We also examined process outcomes to inform future trials and implementation. A detailed description of the study objectives and hypotheses has been published elsewhere (Gibbs et al., 2015).

# **Materials and Methods**

Study Overview

We conducted a pre-post pilot study to evaluate the feasibility, potential effectiveness, and implementation of the Mi-LiFE program delivered by a PT in a primary care-based FHT practice (ClinicalTrials.gov: NCTO2266225). In Ontario, Canada, FHTs consist of groups of health professionals (family physicians, nurses, pharmacists, and other interdisciplinary health care providers) working together to provide primary care using a patient-centred approach (Rosser, Colwill, Kasperski, & Wilson, 2010). In the present study, the FHT setting comprised 18 family physician practices with a combined population of 27,997 patients (Lee et al., 2017).

The Reach Effectiveness Adoption Implementation Maintenance (RE-AIM) framework was used to guide the selection, evaluation, and reporting of implementation outcomes (Glasgow, Vogt, & Boles, 1999), which was described in detail elsewhere (Gibbs et al., 2015). The Mi-LiFE program involved one individual session and four group sessions with a PT, which occurred every 1–2 weeks, and two follow-up phone calls. Participants completed assessments at baseline and after 6 months. All assessments and Mi-LiFE program sessions took place at the same site affiliated with the FHT practice. The study protocol was published according to the Consolidated Standards of Reporting Trials (CONSORT) extension for pilot and feasibility trials (Eldridge et al., 2016) and Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statements (Chan et al., 2013). Research ethics approval was received at the University of Waterloo and Hamilton Integrated Research Ethics Boards.

## **Participants**

We planned to recruit a minimum of 30 individuals or 15 per cent of potentially eligible individuals based on data collected from the FHT geriatric screening program (Lee et al., 2017). The FHT geriatric screening was a part of a larger, comprehensive program to identify older adults who are frail (including physically inactive) and might be at risk for co-morbid conditions underlying their frailty. We used two recruitment modes: (1) the FHT geriatric screening program participant pool, which was established between April 2013 and June 2014 (prior to the program start date) and (2) in-clinic physician/nurse referral from the FHT geriatric screening program, which took place prospectively over a 6 month period (July - December 2015). Before regularly scheduled medical appointments, all patients aged 75 years and older without an acute illness were screened for PA levels through the FHT geriatric screening program (Gibbs et al., 2015) and asked to choose which statement best described their activity status (Topolski et al., 2006):

- 1. Not physically active beyond moving around or walking during activities of daily living;
- Physically active occasionally or during certain seasons more than others;
- 3. Physically active and participating in ≥ 30 minutes of moderate-intensity physical activity ≥ 5 days/week.

Patients who were physically inactive or only occasionally active were approached at the clinic by their physician or nurse who would ask them whether they were interested in receiving notification about future exercise programs offered at the FHT practice (recruitment mode 1) or specific participation in the Mi-LiFE program (recruitment mode 2). If interested, the research coordinator called the potential participants to describe the Mi-LiFE program and invite them to enroll. Physicians of interested participants assessed whether their patient met the eligibility criteria, and ruled out exercise contraindications (American College of Sports Medicine, 2013).

Participants were eligible for the program if they were: (1) ≥75 years of age and (2) able to understand instructions in English. Exclusion criteria were: (1) current participation in lower-extremity strength and balance training  $\geq 3$  days/week, (2) a known diagnosis of dementia, (3) any significant lung disease or moderateto-severe chronic obstructive pulmonary disease (COPD), and (4) exercise contraindications as determined by their FHT physician. A two stage screening process was used to determine final clearance for capacity to consent (Gibbs et al., 2015). If participants had cognitive impairment, they were required to attend the program with a caregiver. Regardless of cognitive status, all participants were encouraged to attend the program with a spouse/partner, family member, or caregiver. If the spouse/partner, family member, or caregiver was over 65 years of age, they were invited to complete all assessments. All participants provided written informed consent.

## Mi-LiFE Program

The theoretical basis of the original LiFE program and the details pertaining to the strength and balance training exercises have been previously described (Clemson et al., 2010; Clemson et al., 2012). Strength LiFE activities were tied to specific strength training principles that were taught in the program (e.g., move slowly—bend your knees or squat; increase the number of times that you use a muscle—sit-to-stands). Balance LiFE activities were tied to specific balance training principles (e.g., reduce your base of support—tandem stand; shifting weight to the limits of stability—lean from side-to-side). The Mi-LiFE program was delivered

by a PT over one individual and four group sessions, and two follow-up phone calls after completion of the final group session (approximately week 6) and 1 month later (approximately week 10) (Clemson et al., 2010; Clemson et al., 2012). The PT received training on the delivery of the LiFE program through the review of the LiFE Trainer's Manual (Clemson & Munro, 2014b) and instruction from Dr. Clemson (creator of LiFE program) via teleconference. A pre-pilot test of the program with four older adults 76–85 years of age was conducted to test the format and delivery of the program sessions and evaluate the PT's fidelity. The prepilot study findings were published elsewhere (Gibbs et al., 2015). In brief, we learned that the LiFE Trainer's Manual is an adequate resource for deliverer training; LiFE can be adapted as a group format; and participants are highly satisfied with the group program aside from some challenges with planning the activities and preference for more demonstration.

In the individual session, the PT administered: (1) a 10 item LiFE functional balance and strength assessment tool and (2) a daily routine chart (Clemson & Munro, 2014b; Clemson et al., 2010). All participants received a participant's manual (Clemson & Munro, 2014a). Participants were taught the LiFE strength and balance training principles and how to document their plans, and execution of the activities using an activity planner (Clemson & Munro, 2014b). In the group sessions, the PT worked with the participants to determine how and where they could embed the strength and balance activities into their daily routine; increasing the intensity and upgrading the activities in small groups formed by convenience (five or fewer people). The prescribed frequency was daily or "as often as you can" with the activities ideally done multiple times throughout the day. The PT and participants discussed ways to increase the number of times they performed each activity safely and effectively (e.g., where and when to embed each activity) and how to move more (e.g., park further away, take the stairs instead of the elevator).

The PT used the LiFE model of behaviour change to encourage self-efficacy and adherence to the program, which included positive reinforcement, habit reforming, discussing benefits, and self-monitoring (Clemson & Munro, 2017; Clemson et al., 2010; Clemson et al., 2012). During the group sessions, activities were planned as a group and ideas for how, when, and where to perform the activities were shared among participants and recorded using the activity planner. Participants demonstrated the activities in the group setting, which represented peer-to-peer learning opportunities among participants (Burke, Carron, Eys, Ntoumanis, & Estabrooks, 2006). All participants were encouraged by the PT to continue with the program on their own following the final group session.

In the follow-up phone calls, the PT discussed the progression of the LiFE activities, strategies to increase PA, and any successes and challenges related to the program, which lasted 5–10 minutes in length.

# Feasibility Outcomes

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The primary outcomes were related to feasibility, including the number of participants who were recruited and retained over 6 months (recruitment and retention), and the number of days/week that the exercises were completed (adherence). Retention was defined as completing or partially completing (questionnaires only) the 6 month follow-up assessment. Adherence was self-reported daily on calendar-style diaries and as attendance rates for the five sessions. Adherence was 100 per cent if a participant completed strength and balance activities ≥ 3 days/week. For participants who had missing data or chose to discontinue diary completion, adherence was retrospectively selfreported by phone or in person during follow-up. We analyzed adherence data wherein the withdrawals were included and considered non-adherent or the withdrawals were excluded from the analysis to examine the sensitivity of the withdrawals on the adherence results. We also reported on the combined adherence to the program sessions (four or more sessions) and the home exercise participation (≥ 3 days/week over 6 months) as a post-hoc analysis of the program maintenance at the participant level. Participants who withdrew prior to the program (n = 4) were not included in the adherence analyses.

Based on the results of the present pilot feasibility study, the program will be either (Eldridge et al., 2016; Thabane et al., 2010): (1) not feasible, (2) feasible with modifications, (3) feasible with close monitoring, or (4) feasible without modifications.

# Change in PA, Physical Performance, and Quality of Life

Participants wore a commercially available accelerometer (ActiGraph GT3x, ActiGraph, Pensacola, FL 32502) over the hip for 7 days following baseline assessment, and then again for the 7 days after follow-up as an objective measure of PA levels. Acquisition and analysis protocols for the accelerometer data were previously reported (Gibbs et al., 2015). Cut-points were applied to objectively determine sedentary time (hours/day) ( $\leq$  100 counts/minute), light PA (100–1,952 counts/minute) and MVPA (minutes/week) ( $\geq$ 1,952 counts/minute) (Freedson, Melanson, & Sirard, 1998). Tri-axial data were analyzed in 60 second epochs. Non-wear time was excluded if  $\geq$  60 minutes of continuous zeros (Troiano et al., 2008). Only participants who wore the accelerometer for at least 4 days and

10 hours/day were analyzed (Chase, Lockhart, Ashe, & Madden, 2014).

Changes in self-reported MVPA (minutes/week), walking (minutes/week), and sedentary time (hours/day) were measured using the International Physical Activity Questionnaire (IPAQ) at baseline and follow-up. Additional non-validated questions were added to ask participants about the amount of time that they had engaged in strength and balance activity (minutes/week) during the past 7 days. Reliability and validity data of the IPAQ have been reported (Craig et al., 2003). Both accelerometer- and IPAQ-measured PA levels were compared with the initial self-reported PA classification to determine representativeness of the participants (Topolski et al., 2006). Physical performance was measured using the validated Short Physical Performance Battery (SPPB) (4 m walk test, five times sit-to-stand test, and timed stance balance tests) at baseline and 6 months (Guralnik et al., 1994). A score on the SPPB of 9 or lower is indicative of physical limitations and higher risk of major mobility disability. Health-related quality of life was assessed using the EuroQol Five-Dimensional Questionnaire with 3 Levels (EQ5D-3L) at baseline and 6 months. The EQ5D visual analogue scale (VAS) self-perceived health rating (0-100) and mobility, self-care, usual activities, pain/discomfort, and anxiety/depression subscale results were reported. The mean (standard deviation [SD]) EQ5D VAS rating in a population-based survey of adults 70-79 years of age was 75 (19) (Kind, Dolan, Gudex, & Williams, 1998). Evidence of construct validity and good testretest reliability for the EQ5D-3L has been shown (Brazier, Jones, & Kind, 1993).

## Implementation Outcomes

Implementation outcomes, including barriers and facilitators, participant feedback on the program, and fidelity, were measured according to the RE-AIM framework to summarize lessons learned and provide a guide for adaptation in future trials (Glasgow et al., 1999; Harden et al., 2018). Barriers and facilitators to implementation from the perspectives of the PT, research staff, and participants (and caregivers if necessary) were identified using a variety of methods including a success/challenge tracker, journaling, and in-person or teleconference semi-structured interviews (Gibbs et al., 2015). A success/challenge tracker was filled out by the research coordinator throughout the 6 month implementation period. PTs also kept a journal of notes detailing their experience delivering the program and follow-up phone calls. Semi-structured interviews were conducted in person with the research coordinator, PT, and all participants at the 6 month follow-up. The interviews with the research coordinator and PT included open-ended questions about barriers and facilitators to implementation and program delivery (successes/challenges, lessons learned, available resources, group format modifications, feasibility for future larger-scale implementation). The interviews with the participants included open-ended questions to understand their experience and level of satisfaction with the program (reasons for joining the program, observed benefits, areas for improvement, what they liked/disliked, general strategies for PA).

Two members of the research staff coded data from these sources (research team's success/challenge tracker, PT journal notes, interviews transcribed verbatim) for major categories of information using descriptive content analysis and identified the emerging themes (Graneheim & Lundman, 2004). Coding and final themes were developed using a process of collaboration and consensus amongst the reviewers via memoranda and analysis meetings. Using the behaviour change wheel (BCW) framework, final themes related to barriers and facilitators were categorized into capability, opportunity, and motivation (COM-B model) (Michie, West, Campbell, Brown, & Gainforth, 2014). Trustworthiness of the data was established using a combination of techniques including memorandum writing and peer debriefings (Eakin & Mykhalovskiy, 2003). Feedback on the Mi-LiFE program was described via in-person and teleconference semi-structured interviews with the participants (or caregivers if necessary) at the program completion (~week 6) and after 6 months.

Program fidelity by the PT was evaluated through an audit of videotaped individual and group sessions for the first and last five participants enrolled in the program. Two members of the research staff reviewed the videotaped sessions. The video reviewers received at least one training session from the research coordinator on the intervention and fidelity evaluation procedures. They also pilot tested the fidelity evaluation form on one video session prior to review of the other videos. Fidelity rating forms were filled out with 34 program criteria for the individual session (e.g., purpose and aims of LiFE program explained), and 17 program criteria for group sessions (e.g., PT demonstrated the activity to the group and identified situations to embed the activity). Each program criterion was scored out of 2 (0 = not done atall, 1 = done but could be better, 2 = done well) with any disagreement resolved via a third party. Written consent was obtained from all participants involved in the videotaped sessions assessed for fidelity.

Additional process outcomes were collected to inform future trials or implementation, including number of individuals eligible/ineligible, number of eligible individuals interested in participation, descriptive characteristics of those who declined participation (e.g., age, sex), reasons for declining participation, number of physician/nurse referrals from the 13 local FHT individual practices and the 5 non-local FHT individual practices, and number of falls per participant.

# Descriptive Data, Falls, and Adverse Events (AEs)

A medical history and health status questionnaire was used to collect information on demographic characteristics, past and present health conditions, and fall history. Height was measured without shoes using a measuring tape mounted on a wall to the nearest 0.1 cm. Weight was measured without shoes or any heavy clothing using a calibrated electronic scale (Hometrends EB9313H) to the nearest 0.1 kg.

Via calendar-style diaries, participants were instructed to report whether a fall occurred throughout the 6 month program, and to report AEs or injuries by phone and at program sessions. When a fall occurred, a fall incident form was completed by the research coordinator. When an AE occurred, an AE reporting form was completed by the research coordinator and reviewed by the primary investigator and a physician affiliated with the trial. Three types of AEs were reported: (1) serious AEs (SAEs, Health Canada definition events that result in death, hospitalization, or disability), (2) AEs related to the program, and (3) AEs leading to study withdrawal or program cessation. We also reported on falls as a process outcome to inform the implementation of a larger-scale version of this trial with falls as a secondary outcome.

# Statistical Analyses

Participant characteristics, feasibility, falls, AEs, and process outcomes were summarized using mean (SD) for continuous variables and number (per cent) for categorical variables. Change in PA levels, physical performance, and quality of life over the 6 month program were reported as absolute change values and analyzed using paired t-test and Wilcoxon rank-sum test analyses (for non-normally distributed data). Perprotocol and intention-to-treat (ITT) analyses were performed for PA, physical performance, and quality of life data. Missing values analysis examined patterns of missing data. Multiple imputation procedures were used to impute the missing data values (fully conditional specification method, model for scale variables = linear regression, number of imputations = 5, maximum iterations = 25) and pooled results were reported. Barriers and facilitators to implementation were analyzed using thematic content analysis (Graneheim & Lundman, 2004) and the BCW framework

(Michie et al., 2014). Participant feedback on the Mi-LiFE program was presented using descriptive feedback. Mi-LiFE program fidelity was reported using mean ratings of compliance. p values were reported to three decimal places, and statistical significance was defined as p < .05. No correction for multiple testing was made because of the exploratory nature of the analyses. Analyses were performed with SPSS Statistics v.24 (Armonk, NY, USA). A sample size calculation was previously reported (Gibbs et al., 2015).

# **Results**

Feasibility of Recruitment, Adherence, and Retention

During the FHT geriatric screening, 44 per cent (335/759) of the individuals were not referred to the program because they self-reported regular PA ( $\geq$  30 minutes of moderate-intensity PA on  $\geq$  5 days/week) and 38 per cent (290/759) did not consent to future contact (Figure 1). One hundred and thirty-four individuals were referred to the Mi-LiFE program, with most individuals being from the clinic (78.4%; n = 105) and a smaller proportion being from the FHT geriatric screening program participant pool (21.6%; n = 29). Physician referral was a more successful recruitment strategy (54.2%; n = 26) than nurse referral (29.2%; n = 14) and other strategies (16.7%; n = 8). Referrals were

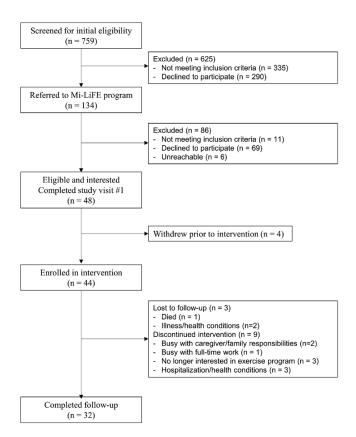


Figure 1: CONSORT study flow diagram

distributed similarly across the 13 local physician practices (mean = 3.2, total: 41) with a smaller proportion recruited from the five non-local practices (mean = 1.4, total: 7). Of those referred, 8 per cent were ineligible (contraindications to exercise – n = 4; participation in a similar exercise program – n = 2; moderate-to-severe lung disease/COPD – n = 2; dementia diagnosis – n = 1; physician chose not to refer – n = 2).

Of the 134 potentially eligible individuals referred to the program, 36 per cent agreed to participate (n = 48), while 52 per cent were not interested (access to exercise–n = 18; illness/health condition – n = 17; lack of transportation – n = 14; not interested in exercise -n = 12; too busy/lack of time -n = 4; away/travelling during program – n = 2; difficulty understanding program – n = 2), 8 per cent were ineligible (n = 11) and 4 per cent were unreachable by phone (n = 6) (Table 1). Forty-eight participants consented to enroll in the program (representing 39% of those eligible [48/123] and 6% of those screened [48/759]). Most uninterested individuals were referred by a nurse (79.8%; 59/75) and a smaller proportion were referred by a physician (20.2%; 16/75). Individuals who declined participation were  $81 \pm 5$  years of age and 57 per cent (n = 43) were female. Six participants were a spouse or friend referred by another participant. Three caregivers attended the program to assist participants with cognitive/physical limitations but did not enroll. One female participant with multiple sclerosis and cognitive impairment who enrolled in the program with her spouse did not agree to data collection and subsequently withdrew from the program. Therefore, data from 47 individuals were analyzed for the secondary objectives.

Most participants mentioned that referral from their physician/nurse was a factor in their decision to participate (see Table A1 in supplementary Appendix). Primary reasons for joining the program included to improve health and physical function, become more active, or prevent falls. Other incentives were to: join with caregiver, spouse, or friend; learn new information; try a new exercise program; participate in a low-intensity program; and join a free exercise program at their family physician's practice (Table A1).

Participants attended (mean  $\pm$  SD) 4 $\pm$ 1 sessions, with 77 per cent (34/44) attending four or more sessions.

Adherence to the exercise program (including withdrawals) decreased across the program: 61 per cent (weeks 1–8), 57 per cent (weeks 9–16), and 50 per cent (weeks 17–24) (Table 1). However, the combined adherence to the session attendance (four or more sessions) and the home exercise participation (≥ 3 days/week over 6 months) was 36 per cent (16/44). Excluding withdrawals, adherence increased at the mid-point of

Table 1: Feasibility of recruitment, adherence, and retention to the Mi-LiFE program (n = 48)

Feasibility Outcome	<b>n</b> (%)
Recruitment mode	
FHT geriatric screening program—participant pool	12 (25)
FHT geriatric screening program—in-clinic	23 (47.9)
FHT mobility clinic	5 (10.4)
Spouse/caregiver/friend	8 (16.7)
Referral mode	
Physician	26 (54.2)
Nurse	14 (29.2)
Spouse/caregiver/friend	8 (16.7)
Session attendance	
Withdrew prior to program	4 (8.3)
1–2 sessions	7 (14.6)
3-4 sessions	8 (16.7)
5 sessions	29 (60.4)
Retention at follow-up	
Completed study	27 (56.3)
Completed study (questionnaires only)	5 (10.4)
Withdrew from program	9 (18.8)
Withdrew prior to program	4 (8.3)
Lost to follow-up	3 (6.3)
Adherence (including withdrawals)	
Weeks 1-8	27/44 (61.4)
Weeks 9-16	25/44 (56.8)
Weeks 17-24	22/44 (50.0)
Adherence (excluding withdrawals)	
Weeks 1-8	27/44 (61.4)
Weeks 9-16	25/38 (65.8)
Weeks 17-24	22/36 (61.1)

# Note. FHT = family health team.

the program and returned to its baseline level in the final weeks: 61 per cent (weeks 1–8), 66 per cent (weeks 9-16), and 61 per cent (weeks 17-24). Sixteen participants discontinued daily diary completion (discontinued exercises – n = 9, not agreeable or forgot to fill out forms – n = 5, started new exercise program – n = 2) and retrospectively self-reported adherence data. Two participants temporarily discontinued diary completion while on vacation and retrospectively selfreported their adherence. Four participants withdrew prior to the program. Of the remaining 44 participants, 9 discontinued the program and 3 were lost to follow-up. Retention at follow-up was 67 per cent, with 27 participants completing all follow-up assessments and 5 participants completing questionnaires only (Table 1).

#### Descriptive Characteristics

Twenty-nine women and 18 men were enrolled in the Mi-LiFE program with a mean (SD) age of 81 (5) years, body mass index (BMI) of 28 (5) kg/m², and MVPA of 49 (87) minutes/week. Twenty-three per cent of participants reported one or more falls in the past year (Table 2). Most participants (74.5%) engaged in

< 150 minutes/week of accelerometer-measured MVPA. However, participants self-reported 153  $\pm$  159 minutes/week of aerobic PA (IPAQ-measured MVPA and light-intensity walking). More than half of the participants demonstrated a total SPPB score > 9 (62%) and  $\geq$  75 on the EQ5D VAS self-perceived health status (66%).

# Change in PA, Physical Performance, and Quality of Life

No statistically significant changes in accelerometermeasured PA outcomes were demonstrated at follow-up using per-protocol and ITT analyses (Table 3). For two participants, there was a change  $\geq 200$ minutes/week of MVPA over 6 months (representing possible outliers). Sensitivity analyses excluding these participants did not significantly influence the results for change in MVPA (mean change: 1.6 [16.5] minutes/week, p = .686; n = 19). Self-reported strength (mean change = 27.2 [70.3] minutes/week, p = 0.026, per-protocol; mean change = 41.6 minutes/ week, p < .001, ITT) and balance activity increased from baseline to follow-up (mean change = 34.4 [55.0] minutes/week, p < .001, per-protocol; mean change = 51.2 minutes/week, p < .001, ITT). However, no statistically significant changes in self-reported MVPA, walking, and sedentary time were observed. Also, a small proportion of participants reported other strength and balance training (performed on their own or in exercise classes) at follow-up either alongside (19%, 6/32) or instead of the LiFE activities (19%, 6/32).

Total SPPB score did not significantly change in the per-protocol and ITT analyses (Figure 2). There were also no statistically significant changes in the SPPB individual components (4 m walk, five times sit-tostand, timed stance tests) (Table 3). There was a significant increase in EQ5D VAS self-perceived health status (mean change = 5.33, p = .019, per protocol) (Figure 3). However, this finding was not statistically significant in the ITT analysis (mean change = 2.2, p = .282). Results for the EQ5D subscales were similar for most subscales at baseline and follow-up (Table 4) with minor increases in the number of participants who reported no problems in walking about and engaging in usual activities. Sixty-three percent of participants (n = 20) reported moderate pain/discomfort at baseline, which slightly increased to 78 per cent (n = 25) at follow-up.

# Falls and AEs during the Program

Ten participants (21.3%) fell during the 6 month program (19 falls with 6 resulting in non-serious injuries) with none related to the program. Seven participants

Table 2: Baseline descriptive characteristics of participants in Mi-LiFE program

	All Participants	Range	
	(n = 47°)	(Min–Max)	
Age (years) – Mean (SD)	80.6 (5.1)	71-92	
Female - n (%)	29 (61.7)	-	
Height (cm) - Mean (SD)	163.5 (8.1)	145.4-176.5	
Weight (kg) – Mean (SD)	74.3 (13.9)	47.4-109.9	
BMI (kg/m²) – Mean (SD)	28.0 (4.9)	16.9-38.8	
Assistive devise use - n (%)	15 (31.9)	_	
No. of medications/supplements - Mean (SD)	10 (4)	2–21	
No. of falls in last 12 months – Mean (SD)	0.5 (1.1)	0-5	
Co-morbidities	. ,		
Osteoarthritis – n (%)	24 (51.1)	_	
Osteoporosis – $n$ (%)	8 (17.0)	_	
Cardiovascular disease – n (%)	27 (57.4)	_	
Diabetes - n (%)	12 (25.5)	_	
High blood pressure - n (%)	33 (70.2)	_	
Chest pain/angina - n (%)	6 (12.8)	_	
Accelerometer-measured PA levels <sup>b</sup>	, ,		
MVPA (min/week) - Mean (SD)	48.5 (87.2)	0-493	
Light PA (min/week) - Mean (SD)	1315.9 (593.2)	155.4-2359	
Sedentary time (hr/day) - Mean (SD)	10.8 (1.9)	6.3-15.2	
IPAQ-measured PA levels	. ,		
Strength PA (min/week) – Mean (SD)	26.8 (62.5)	0-315.0	
Balance PA (min/week) - Mean (SD)	6.2 (23.6)	0-120.0	
Vigorous-intensity PA (min/week) - Mean (SD)	4.5 (19.8)	0-120.0	
Moderate-intensity PA (min/week) – Mean (SD)	31.9 (71.7)	0-360.0	
Walking (min/week) - Mean (SD)	116.6 (139.2)	0-630.0	
Sedentary time (hr/day) - Mean (SD)	6.7 (3.1)	1.5-13.5	
Physical performance outcomes	. ,		
4 m walk test - gait speed (sec) - Mean (SD)	4.40 (2.30)	2.80-15.97	
Five times sit-to-stand test (sec) <sup>c</sup> – Mean (SD)	12.98 (3.22)	7.34-20.50	
Timed stance balance tests (points) - Mean (SD)	3.30 (0.93)	1–4	
Total SPPB score (points) – Mean (SD)	9.53 (2.34)	3–12	
Quality of life outcomes			
EQ5D VAS self-perceived health – Mean (SD)	74.5 (14.7)	40-100	

Note. BMI = body mass index; PA = physical activity; MVPA = moderate-to-vigorous physical activity; IPAQ = International Physical Activity Questionnaire; SPPB = Short Physical Performance Battery; EQ5D = EuroQol Five-Dimensional Questionnaire; VAS = visual analogue scale.

- <sup>a</sup> 1 participant did not agree to data collection for secondary outcomes.
- b 37 participants completed accelerometer data collection at baseline; data according to Freedson et al. (1998) cut-points are presented.
- c 6 participants used arms to stand or were unable to complete a single chair test and did not have data for five times sit-to-stand test.

reported one fall each and three participants reported one or more falls over 6 months. Four participants reported SAEs resulting in hospitalization (infection in big toe secondary to diabetes, worsening of COPD-related symptoms, severe chest/abdominal pain, diabetic episode) and one participant died (intracerebral hemorrhage) during the program. None of the SAEs were related to the program as adjudicated by the research staff, physician affiliated with the trial, and ethics boards. Of the SAEs, three led to permanent or temporary program discontinuation. Fourteen participants reported non-serious AEs, with two possibly related to the program (heel pain and hamstring strain)

and 12 not related to the program (pneumonia/flu—n = 2, chronic leg pain—n = 2, fall-related injury—n = 2; low back pain, racing heart rate, strained rotator cuff, hip tendonitis, dementia diagnosis, heel spur, n = 1 each). Eight participants with non-serious AEs permanently or temporarily discontinued the program.

# Implementation Results

Physical and psychological capability represented a barrier and facilitator from the participant's perspective, such that chronic illness or injury and difficulty understanding the goals of the program affected their

Table 3: Change in physical activity levels and physical performance outcomes in participants of Mi-LiFE program from baseline and follow-up (n = 32)—per-protocol analysis

	Baseline	Follow-up	Change	
	Mean (SD)	Mean (SD)	Mean (95% CI)	<i>p</i> value
Accelerometer-PA levels <sup>a</sup>				
MVPA (min/week)	58.6 (111.1)	52.5 (96.8)	-6.1 (-19.2, 7.0)	.881 <sup>b</sup>
Light activity (min/week)	1323 (559)	1223 (505)	-99.5 (-291.5, 92.4)	.292
Sedentary time (hr/day)	10.7 (1.9)	11 (2.1)	0.3 (-0.4, 0.9)	.404
IPAQ-PA levels				
Strength PA (min/week)	37.1 (73.1)	64.3 (94.5)	27.2 (1.84, 52.5)	.026 <sup>b</sup>
Balance PA (min/week)	6.9 (26.1)	41.3 (48.4)	34.4 (14.6, 54.2)	<.001b
MVPA (min/week)	41.2 (80.6)	60.6 (125.1)	19.4 (-30.8, 69.5)	.881 <sup>b</sup>
Walking (min/week)	116.8 (143.0)	107.2 (123.0)	-9.6 (-57.5, 39.2)	.709
Sedentary time (hr/day)	6.8 (3.1)	7.5 (3.5)	0.7 (-0.6, 1.9)	.314
SPPB outcomes <sup>c</sup>				
4m walk test – shortest trial (sec)	4.02 (0.91)	4.15 (0.95)	0.13 (-0.19, 0.46)	.477 <sup>b</sup>
4m walk test – shortest trial (points)	3.85 (0.46)	3.81 (0.56)	-0.04 (-0.24, 0.17)	.705 <sup>b</sup>
Five times sit-to-stand test (sec)d	13.05 (3.56)	12.97 (3.98)	-0.08 (-1.31, 1.16)	.896
Five times sit-to-stand test (points)	2.56 (1.31)	2.48 (1.48)	-0.07 (-0.55, 0.40)	.718 <sup>b</sup>
Timed stance tests (points)	3.37 (0.84)	3.33 (0.96)	-0.04 (-0.48, 0.41)	.971 <sup>b</sup>

Note. PA = physical activity; MVPA = moderate-to-vigorous physical activity; IPAQ = International Physical Activity Questionnaire; SPPB = Short Physical Performance Battery.

- a 21 participants completed accelerometer data collection at baseline and follow-up.
- <sup>b</sup> Wilcoxon rank-sum tests were performed for non-normally distributed data.
- <sup>c</sup> 27 participants completed SPPB data collection at baseline and follow-up.
- <sup>d</sup> 3 participants failed the single chair stand test and did not complete five times sit-to-stand test.

participation (Table 5). One participant reported that, "I am trying to follow through on the exercises, but my back gets quite tired and my energy levels are not good." Another participant felt "The purpose of the exercises was sometimes unclear. Is it the number of times or how long we do the exercises that matters?" Barriers related to physical opportunity included limited one-on-one attention and lack of home-based visits.

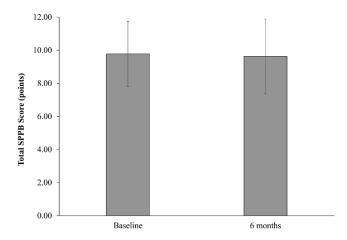


Figure 2: SPPB scores in Mi-LiFE program at baseline and follow-up (n = 27)—per-protocol analysis.

Note. Thirty-two participants were retained at follow-up; five participants were unable/did not agree to complete in-person follow-up assessments (questionnaires only). Wilcoxon rank sum tests were performed for non-normally distributed data

One participant explained, "I would have preferred the PT come to my home to teach me exercises. My husband gets taught exercise in our home and that works for us." PT instruction and caregiver support were identified as facilitators. Additionally, the group-based program facilitated social and learning opportunities (e.g., "...being a part of a group and seeing other people's points of view and issues they are dealing with"). However, certain participants would have preferred individual exercise prescription over the group

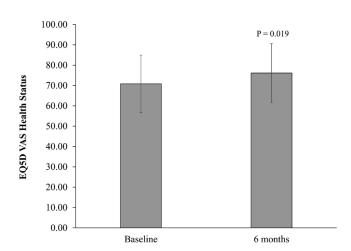


Figure 3: EuroQol Five-Dimensional Questionnaire (EQ5D) VAS of self-perceived health status in Mi-LiFE program at baseline and follow-up (n = 32)—per-protocol analysis

Table 4: EQ5D subscale results of Mi-LiFE program at baseline and follow-up (n = 32)

	Baseline n (%)	Follow-up n (%
Mobility		
I have no problems in walking about	15 (46.9)	17 (53.1)
I have some problems in walking about	17 (53.1)	15 (46.9)
I am unable to walk about	0 (0.0)	0 (0.0)
Self-care	• •	
I have no problems washing or dressing myself	32 (100.0)	30 (93.8)
I have moderate problems washing or dressing myself	0 (0.0)	2 (6.3)
I am unable to wash or dress myself	0 (0.0)	0 (0.0)
Usual activities	, ,	, ,
I have no problems doing my usual activities	19 (59.4)	23 (71.9)
I have moderate problems doing my usual activities	13 (40.6)	9 (28.1)
I am unable to do my usual activities	0 (0.0)	0 (0.0)
Pain/discomfort	, ,	, ,
I have no pain or discomfort	12 (37.5)	7 (21.9)
I have moderate pain or discomfort	20 (62.5)	25 (78.1)
I have extreme pain or discomfort	0 (0.0)	0 (0.0)
Anxiety/depression	• •	
I am not anxious or depressed	26 (81.3)	28 (87.5)
I am moderately anxious or depressed	6 (18.8)	4 (12.5)
I am extremely anxious or depressed	0 (0.0)	0 (0.0)

approach (e.g., "Need to be careful with a group... don't want to lose people or emphasize competition with others"). Behaviour change techniques (e.g., activity planning, positive reinforcement) encouraged reflective motivation, including: "a greater appreciation of balance and coordination" and a "change in my mental attitude toward exercise". Yet, some participants had difficulty planning activities or preferred structured exercise prescription. One participant stated, "I still haven't quite figured out the best way to incorporate them into my daily activities but would like to be able to eventually." By modifying their home environments and daily routines, participants reported some habit change that led to automatic motivation. For example, one participant explained, "I have a paper route and would incorporate the tandem walk and the stairs into my route." A detailed description of the participants' feedback on the program is provided in Table A1.

From the PT and research staff's perspectives, training was important to facilitate physical and psychological capability, including the experience of trialing the program, the LiFE Trainer's Manual, and teleconference meetings with the LiFE program creators (Table 5). The LiFE Trainer's Manual was used by the PT "to inform how to manage and lead the group, the organizational factors—where to sit and where to stand." The prepilot test was beneficial to both the PT and research staff to "see if this would logistically work, give [us] the opportunity to familiarize ourselves with the program." The PT and research staff would have preferred more intensive training on the behaviour change strategies central to the LiFE program, ideally in person. Barriers to physical opportunity were the scheduling

complexity, single deliverer and inability to assess the participants' home environment (e.g., "...they would have to imagine what their house looked like and where they could do it because we were not in their house"). Access to space and resources affiliated with the FHT practice facilitated implementation and program oversight. Activity planning and social interaction in the group sessions were considered facilitators by the PT and research staff. For example, "There was one group that attended every session together...they did the protocol exactly how you would intend for it to be. Everyone was engaged, supporting one another." However, the PT found it challenging to promote behaviour change when participants were disengaged in activity planning or social interaction (e.g., "Some people were good at just fitting in with new people. There was the odd person that struggled with it more than others...they felt new and behind even if they weren't.") Diversity in participants' goals, intentions, and plans were identified as a barrier for the PT in the group sessions (e.g., "Especially seeing that this person is very high functioning and someone else is very low functioning, so how am I going to address that in a group setting?") Yet the individual session provided an initial assessment to guide program adoption and "get a sense of what they do every day". Follow-up phone calls allowed the PT to cue exercise progression and positive reinforcement, especially when participants "stopped doing [the activities] as often and would say 'Now that you called me I'm going to start doing them again' or 'That's a good idea, I'm going to try that." All mean ratings of program fidelity by the PT were  $\geq 1.8$  (/2) with 62 criteria (/68) met in the

Table 5: Thematic analysis of barriers and facilitators to implementation of the Mi-LiFE program using the BCW framework

Themes	Barriers	Facilitators
Participants' perspectives Physical capability	Perceived and actual physical limitations to activities	Perceived and actual physical benefits of activities
Psychological capability	Difficulty understanding the purpose of certain aspects of the LiFE program	<ul> <li>Understanding purpose and principles of LiFE program</li> <li>Learning opportunities from the PT, Participant's Manual, and other participants</li> </ul>
Physical opportunity  Social opportunity	<ul> <li>Limited one-on-one attention in group sessions</li> <li>No home-based support from PT</li> <li>Did not relate to other group members</li> <li>Preference for individual/one-on-one exercise prescription</li> </ul>	<ul> <li>PT and research staff leadership and instruction</li> <li>Caregiver/spouse/family member support</li> <li>Engaged in social interaction through group format</li> </ul>
Reflective motivation  Automatic motivation	<ul> <li>Preference for structured exercise prescription</li> <li>Lack of intentions to plan and execute activities</li> <li>Difficulty finding home-based cues for activities</li> </ul>	<ul> <li>Activity planning with PT and other participants</li> <li>Intentions to exercise for health and functional reasons</li> <li>Home modifications to change habits/identify cues</li> </ul>
PT and research staff's perspectives Physical capability	Desire for more in-person training on LiFE program	Pre-pilot study to train PT and staff on program delivery
Psychological capability	<ul> <li>Desire for more training on behaviour change techniques</li> </ul>	<ul> <li>Learning opportunities from Trainer's Manual and teleconference with LiFE program creators</li> </ul>
Physical opportunity	PT unable to assess participants' home environment	Support from research staff at each session
Social opportunity	<ul> <li>Scheduling challenges for group sessions</li> <li>Disengagement in activity planning and less social interaction in group sessions</li> </ul>	<ul> <li>Access to space affiliated with FHT practice</li> <li>Activity planning and social interaction in group sessions</li> </ul>
Reflective motivation	Diversity in participants' goals, intentions and outcome expectances in group sessions	<ul> <li>Individual session with PT to assess participants' goals, intentions, and outcome expectancies</li> </ul>
Automatic motivation	<ul> <li>Difficulty identifying cues and prompts for activities</li> </ul>	<ul> <li>Follow-up phone calls with participants to cue habit reforming, discuss benefits, and encourage self-monitoring</li> </ul>

Note. BCW = behaviour change wheel; PT = physical therapist; FHT = family health team.

individual sessions and 33 criteria (/34) met in the groups sessions.

# **Discussion**

The present pilot study suggests that the Mi-LiFE program delivered in a primary care-based FHT practice is feasible because of acceptable recruitment and attendance rates alongside modifications to address retention and adherence challenges (Table 6). Like other primary care-based exercise interventions (Elley, Kerse, Arroll, & Robinson, 2003; Fortier et al., 2011; Pinto, Goldstein, Ashba, Sciamanna, & Jette, 2005), no changes in MVPA and sedentary time were observed, yet increases in self-reported strength and balance-related activity were found in per-protocol and ITT analyses. Mi-LiFE was associated with a significant increase in health-related quality of life in those participants who completed the program, with no statistically significant changes in physical performance, including gait speed, lowerextremity strength, and balance. High program fidelity and participant satisfaction were observed, with participant and deliverer capability, social and environmental support, and behaviour change techniques to increase motivation and habit change emerging as key themes for implementation. Program modifications, such as an initial home visit, more intensive follow-up counselling using the LiFE model of behaviour change, and targeted screening to enroll older adults at higher risk of falls and functional disability, may improve future implementation of Mi-LiFE.

To our knowledge, our pilot pragmatic trial represents the first to evaluate the feasibility of implementing a group-based version of the LiFE program in an interdisciplinary primary care practice. Our findings suggest that the recruitment and attendance rates to the Mi-LiFE program are feasible, yet like most exercise interventions in real-world settings, retention and adherence to home exercise remain challenges. In-clinic recruitment involving the physician was the most feasible referral strategy compared with recruitment through a retrospective participant pool with 48 participants enrolled (representing 39% of those eligible and 6% of those screened). The FHT geriatric screening program involving self-reported PA classification

## Table 6: Tips for implementing group-based exercise programming in primary care

- 1. Adopt in-clinic screening and recruitment strategies involving a physician (or nurse if more feasible) to engage older adult patients and streamline referral
- 2. Provide adequate deliverer and participant instruction to exercise program (e.g., in-person/phone training, manuals) and opportunities for continuing education and progression
- 3. Offer opportunities to attend sessions with spouse, caregiver, family, or friends to encourage adoption and sustainability of exercise (especially for those with physical and cognitive limitations)
- 4. Balance individualized attention and social interaction with group members by offering one-on-one and group sessions, and a home visit to assess environmental support (if feasible)
- 5. Maintain as intensive a follow-up as feasible including behaviour change counselling and assessment to emphasize longer-term self-monitoring, habit reforming, and coping with barriers

resulted in a representative sample of older adults with 75 per cent engaging in fewer than 150 minutes/ week of MVPA. Our retention rate was comparable to other exercise trials longer than 6 months wherein fewer than 75 per cent were retained (Iliffe et al., 2014; Pahor et al., 2014). Fleig et al. (2016) reported a 23 per cent drop-out rate from their group LiFE program in a smaller sample of 13 older women (mean age 66 years) over 4 months. The withdrawal reasons reported by our participants were consistent with prior exercise trials in older adults (e.g., change in health status, loss of interest, too busy, having moved) (Clemson et al., 2012; Fleig et al., 2016; Iliffe et al., 2014; Pahor et al., 2014). Adherence rates vary widely across studies (18–100%) (Shier, Trieu, & Ganz, 2016) and are typically higher in supervised, laboratory settings than in the real world using self-report methods (Morey et al., 2003). It was not surprising that 77 per cent of our participants attended four or more supervised sessions; whereas the daily diary-documented adherence was much lower (50%) and reflective of the challenges of engaging older adults in unsupervised PA. More intensive behaviour change counseling during follow-up with a focus on long-term selfmonitoring, habit reforming, and coping with barriers is advised to improve adherence for future implementation (Clemson & Munro, 2017).

Like other primary care exercise interventions, the Mi-LiFE program was not effective at increasing MVPA, despite increases in self-reported strength and balance activity (Elley et al., 2003; Fortier et al., 2011; Pinto et al., 2005). Notably, the effects on self-reported strength and balance activity align with the findings from the LiFE efficacy trial (Clemson et al., 2012), and reflect compliance with the program's training principles and behaviour change techniques. The focus of the LiFE program is to integrate strength and balance exercises into daily lifestyle activities through activity planning and habit reforming, which may explain the lower incentive to increase structured, aerobic-based MVPA. Also, accelerometers have a limited capacity to objectively detect increases in strength and balance exercise, which may be classified as light-intensity

physical activity or even sedentary time. Several other trials have found a discrepancy in effectiveness to change physical activity depending on the assessment measures (Elley et al., 2003; Fortier et al., 2011; Pinto et al., 2005). Therefore, overestimation of PA using self-report measures, experimental bias related to accelerometer use, and contrasts in PA dimensions are all considerations when interpreting our findings.

Improvements in physical performance and quality of life have been well documented following strength and balance exercise interventions in older adults (Clemson et al., 2012; Martin et al., 2013; Pahor et al., 2014). Improvement in health-related quality of life following the Mi-LiFE program was expected given its socially interactive nature and lifestyle-focused approach. However, the lack of effectiveness to improve physical performance conflicted with the home-based LiFE efficacy trial wherein static balance, tandem walk time, and lower limb strength significantly improved after 6 months (effect sizes = .40–.63) (Clemson et al., 2012). The home-based LiFE efficacy trial recruited a higher risk group who had a history of two or more falls or an injurious fall, and they had a lower perceived health status at baseline (EQD5 VAS < 75). Pahor et al. (2014) also observed a significant increase in total SPPB score (1.1 points) following 6 months of moderate-intensity PA in sedentary older adults at risk for major mobility disability (Life Study Investigators et al., 2006). Yet, similar to our study, Fleig et al. (2016) reported no significant changes in SPPB outcomes after 4 months of a group LiFE program. It is possible that the Mi-LiFE program was associated with maintenance of already reasonable mobility and functional status wherein 62 per cent of participants had an SPPB score > 9, reflective of ceiling effects with the measure (Guralnik et al., 1994). Also, the intensity of the strength and balance activities may have been insufficient to elicit significant results in some participants, especially those at the highest end of the functional spectrum. Qualitative feedback from participants reflected potential benefits related to confidence while walking, ability to perform daily activities, and perceived balance and strength improvements. Therefore, an exercise program involving higher load strength training of all major muscle groups alongside teaching the LiFE balance and strength principles may be an alternate approach for more functionally capable and less at-risk older adults.

Our pilot study provides valuable insight into barriers and facilitators to the real-world implementation of the evidence-based LiFE intervention into practice using the BCW framework (Michie et al., 2014). Certain themes that emerged were consistent with previous research on translating exercise interventions into practice (e.g., physical and psychological capability of participants and deliverers, environmental support, resources) (Flocke, Crabtree, & Stange, 2007; Yarnall, Pollak, Ostbye, Krause, & Michener, 2003). However, our findings also highlight new perspectives on the importance of social support, behavior change techniques, and training for deliverers of group exercise in a FHT context. The training resources for the LiFE program (e.g., Trainer's and Participant's Manuals) (Clemson & Munro, 2014a, 2014b) were identified as facilitators by deliverers and participants, and would allow widespread delivery of the program. Future implementation should consider more physical support through in-person/online training of the deliverers and at least one instructional session in the participants' homes, if feasible. As expected, social support was a key factor in implementing the group program (Burke et al., 2006), such that the participants' level of social interaction during the sessions may have influenced their response (Corbett et al., 2017). The smaller group size in the Mi-LiFE program likely affected the group dynamics, and adaptation for larger group classes (more than five people per session) may present with different results. Inclusion of interactive activities to enhance teamwork and positive social participation would be beneficial in future implementation.

Strengths of our pilot trial include its theory-driven behaviour change strategies and evidence-based training elements, comprehensive evaluation frameworks (RE-AIM, BCW) and pragmatic design with generalizable eligibility. Using both accelerometer and self-report measures of PA provide valuable pilot data on the effects of the Mi-LiFE program on PA levels in inactive older adults. Also, our exercise delivery approach (including the training) could be implemented per protocol by other rehabilitation professionals, such as kinesiologists, occupational therapists, and exercise physiologists, working in interprofessional primary care settings using the LiFE Trainer's and Participant's manuals (Clemson & Munro, 2014b). The lack of a control group and shorter follow-up period represented limitations, which precluded our ability to report the long-term effectiveness and maintenance of our program within the FHT context. Because our pilot feasibility trial was implemented in one primary care practice with one expert deliverer, we were unable to examine adoption of the Mi-LiFE program at the organization level (Glasgow et al., 1999).

In conclusion, Mi-LiFE represents a feasible exercise program to implement in a primary care-based FHT practice for older adults with an emphasis on in-clinic screening involving a physician, individualized and group exercise training elements, and opportunities for caregiver participation. Recommended modifications to improve retention and adherence include an individual session in the participant's home to assess environmental support, targeting people at higher risk of falls/disability, and incorporating more intensive follow-up counselling using the LiFE model of behaviour change. As expected, increased self-report strength and balance activity and health-related quality of life were observed, but no clinically significant improvements in MVPA and functional outcomes were demonstrated. For clinical populations with better function and no specific fall risk, a hybrid group approach could be considered where more than 150 minutes/week aerobic MVPA and higher load strength training would be added to the LiFE balance and functional principles. Deliverer training, social dynamics, and longer-term behaviour change strategies are key components of the implementation process for future lifestyle-based group exercise programs in primary care for older adults. Prior to scale-up and widespread implementation, a multicentre pragmatic trial is required to evaluate acceptance and readiness to adopt the modified Mi-LiFE program in FHT practices, variation across deliverers and sites, and real-world effectiveness versus a comparator.

# **Supplementary Material**

To view supplementary material for this article, please visit https://doi.org/10.1017/S0714980818000739

## References

American College of Sports Medicine. (2013). *ACSM's guidelines* for exercise testing and prescription (9th ed.). Indianapolis, IN: Lippincott Williams & Wilkins.

Bennie, J. A., Pedisic, Z., van Uffelen, J. G., Gale, J., Banting, L. K., Vergeer, I., et al (2016). The descriptive epidemiology of total physical activity, muscle-strengthening exercises and sedentary behaviour among Australian adults—Results from the National Nutrition and Physical Activity Survey. *BMC Public Health*, 16, 73. doi:10.1186/s12889-016-2736-3

Brazier, J., Jones, N., & Kind, P. (1993). Testing the validity of the Euroqol and comparing it with the SF-36 health survey questionnaire. *Quality of Life Research*, 2(3), 169–180.

Burke, S. M., Carron, A. V., Eys, M. A., Ntoumanis, N., & Estabrooks, P. A. (2006). Group versus individual approach? A meta-analysis of the effectiveness of

- interventions to promote physical activity. *Sport and Exercise Psychology Review*, 2(1), 19–35.
- Chan, A. W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gotzsche, P. C., Krleza-Jeric, K., et al (2013). SPIRIT 2013 statement: Defining standard protocol items for clinical trials. *Annals of Internal Medicine*, 158(3), 200–207. doi:10.7326/0003-4819-158-3-201302050-00583
- Chase, J. M., Lockhart, C. K., Ashe, M. C., & Madden, K. M. (2014). Accelerometer-based measures of sedentary behavior and cardio-metabolic risk in active older adults. *Clinical and Investigative Medicine*, 37(2), E108–116.
- Clemson, L., Fiatarone Singh, M. A., Bundy, A., Cumming, R. G., Manollaras, K., O'Loughlin, P., et al (2012). Integration of balance and strength training into daily life activity to reduce rate of falls in older people (the LiFE study): Randomised parallel trial. *BMJ*, 345, e4547. doi:10.1136/bmj.e4547
- Clemson, L., & Munro, J. (2014a). *Lifestyle-integrated functional exercise program to prevent falls: Participants manual*. Sydney: Sydney University Press.
- Clemson, L., & Munro, J. (2014b). *Lifestyle-integrated functional exercise program to prevent falls: Trainers manual.* Sydney: Sydney University Press.
- Clemson, L., & Munro, J. (2017). Conceptual model of habit reforming to improve balance and prevent falls. In N.A. Pachana (Ed.). *Encyclopedia of geropsychology* (pp. 587–596). Singapore: Springer.
- Clemson, L., Singh, M. F., Bundy, A., Cumming, R. G., Weissel, E., Munro, J., et al (2010). LiFE Pilot study: A randomised trial of balance and strength training embedded in daily life activity to reduce falls in older adults. *Australian Occupational Therapy Journal*, 57(1), 42–50. doi:10.1111/j.1440-1630.2009.00848.x
- Colley, R. C., Garriguet, D., Janssen, I., Craig, C. L., Clarke, J., & Tremblay, M. S. (2011). Physical activity of Canadian adults: Accelerometer results from the 2007 to 2009 Canadian Health Measures Survey. *Health Reports*, 22(1), 7–14.
- Corbett, D. B., Rejeski, W. J., Tudor-Locke, C., Glynn, N. W., Kritchevsky, S. B., McDermott, M. M., et al (2017). Social participation modifies the effect of a structured physical activity program on major mobility disability among older adults: Results from the LIFE study. *Journals of Gerontology Series B: Psychological Sciences and Social Sciences*, 73(8), 1501–1513. doi:10.1093/geronb/gbx051
- Costello, E., Kafchinski, M., Vrazel, J., & Sullivan, P. (2011). Motivators, barriers, and beliefs regarding physical activity in an older adult population. *Journal of Geriatric Physical Therapy*, 34(3), 138–147. doi:10.1519/JPT.0b013e31820e0e71
- Craig, C. L., Marshall, A. L., Sjostrom, M., Bauman, A. E., Booth, M. L., Ainsworth, B. E., et al (2003). International physical activity questionnaire: 12-country reliability and

- validity. Medicine & Science in Sports & Exercise, 35(8), 1381–1395. doi:10.1249/01.MSS.0000078924.61453.FB
- Dunn, A. L., Marcus, B. H., Kampert, J. B., Garcia, M. E., Kohl, H. W., 3rd, & Blair, S. N. (1999). Comparison of lifestyle and structured interventions to increase physical activity and cardiorespiratory fitness: A randomized trial. *JAMA*, 281(4), 327–334.
- Eakin, J. M., & Mykhalovskiy, E. (2003). Reframing the evaluation of qualitative health research: Reflections on a review of appraisal guidelines in the health sciences. *Journal of Evaluation in Clinical Practice*, 9(2), 187–194.
- Eldridge, S. M., Chan, C. L., Campbell, M. J., Bond, C. M., Hopewell, S., Thabane, L., et al (2016). CONSORT 2010 statement: Extension to randomised pilot and feasibility trials. *BMJ*, *355*, i5239. doi:10.1136/bmj.i5239
- Elley, C. R., Kerse, N., Arroll, B., & Robinson, E. (2003). Effectiveness of counselling patients on physical activity in general practice: Cluster randomised controlled trial. *BMJ*, 326(7393), 793. doi:10.1136/bmj.326. 7393.793
- Fitzsimons, C. F., Baker, G., Gray, S. R., Nimmo, M. A., Mutrie, N., & Scottish Physical Activity Research Collaboration (2012). Does physical activity counselling enhance the effects of a pedometer-based intervention over the long-term: 12-month findings from the Walking for Wellbeing in the west study. *BMC Public Health*, 12, 206. doi:10.1186/1471-2458-12-206
- Fleig, L., McAllister, M. M., Chen, P., Iverson, J., Milne, K., McKay, H. A., et al (2016). Health behaviour change theory meets falls prevention: Feasibility of a habit-based balance and strength exercise intervention for older adults. *Psychology of Sport and Exercise*, 22, 114–122.
- Flocke, S. A., Crabtree, B. F., & Stange, K. C. (2007). Clinician reflections on promotion of healthy behaviors in primary care practice. *Health Policy*, 84(2–3), 277–283. doi:10.1016/j.healthpol.2007.04.003
- Fortier, M. S., Hogg, W., O'Sullivan, T. L., Blanchard, C., Sigal, R. J., Reid, R. D., et al (2011). Impact of integrating a physical activity counsellor into the primary health care team: physical activity and health outcomes of the Physical Activity Counselling randomized controlled trial. *Applied Physiology Nutrition and Metabolism*, 36(4), 503–514. doi:10.1139/h11-040
- Freedson, P. S., Melanson, E., & Sirard, J. (1998). Calibration of the Computer Science and Applications, Inc. accelerometer. *Medicine & Science in Sports & Exercise*, 30(5), 777–781.
- Gibbs, J. C., McArthur, C., Milligan, J., Clemson, L., Lee, L., Boscart, V. M., et al (2015). Measuring the implementation of a group-based Lifestyle-integrated Functional Exercise (Mi-LiFE) intervention delivered in primary care for older adults aged 75 years or older: A pilot

- feasibility study protocol. *Pilot and Feasibility Studies*, 1, 20. doi:10.1186/s40814-015-0016-0
- Glasgow, R. E., Vogt, T. M., & Boles, S. M. (1999). Evaluating the public health impact of health promotion interventions: The RE-AIM framework. *American Journal of Public Health*, 89(9), 1322–1327.
- Graneheim, U. H., & Lundman, B. (2004). Qualitative content analysis in nursing research: Concepts, procedures and measures to achieve trustworthiness. *Nurse Education Today*, 24(2), 105–112. doi:10.1016/j.nedt.2003.10.001
- Guralnik, J. M., Simonsick, E. M., Ferrucci, L., Glynn, R. J., Berkman, L. F., Blazer, D. G., et al (1994). A short physical performance battery assessing lower extremity function: Association with self-reported disability and prediction of mortality and nursing home admission. *Journal of Gerontology*, 49(2), M85–94.
- Harden, S. M., Smith, M. L., Ory, M. G., Smith-Ray, R. L., Estabrooks, P. A., & Glasgow, R. E. (2018). RE-AIM in clinical, community, and corporate settings: Perspectives, strategies, and recommendations to enhance public health impact. Front Public Health, 6, 71. doi:10.3389/ fpubh.2018.00071
- Iliffe, S., Kendrick, D., Morris, R., Masud, T., Gage, H., Skelton, D., et al (2014). Multicentre cluster randomised trial comparing a community group exercise programme and home-based exercise with usual care for people aged 65 years and over in primary care. *Health Technology Assessment*, 18(49), vii–xxvii, 1–105. doi:10.3310/hta18490
- Janssen, I. (2012). Health care costs of physical inactivity in Canadian adults. Applied Physiology Nutrition and Metabolism, 37(4), 803–806. doi:10.1139/h2012-061
- Katz, A., Lambert-Lanning, A., Miller, A., Kaminsky, B., & Enns, J. (2012). Delivery of preventive care: The national Canadian Family Physician Cancer and Chronic Disease Prevention Survey. *Canadian Family Physician*, 58(1), e62–69.
- Kind, P., Dolan, P., Gudex, C., & Williams, A. (1998). Variations in population health status: Results from a United Kingdom national questionnaire survey. *BMJ*, *316*(7133), 736–741.
- Knight, E., & Petrella, R. J. (2014). Prescribing physical activity for healthy aging: Longitudinal follow-up and mixed method analysis of a primary care intervention. *The Physician and Sportsmedicine*, 42(4), 30–38. doi:10.3810/psm.2014.11.2089
- Lawton, B. A., Rose, S. B., Elley, C. R., Dowell, A. C., Fenton, A., & Moyes, S. A. (2008). Exercise on prescription for women aged 40–74 recruited through primary care: Two year randomised controlled trial. *BMJ*, 337, a2509. doi:10.1136/bmj.a2509
- Lee, L., Patel, T., Costa, A., Bryce, E., Hillier, L. M., Slonim, K., et al (2017). Screening for frailty in primary care: Accuracy of gait speed and hand-grip strength. *Canadian Family Physician*, 63(1), e51–e57.

- Life Study Investigators, Pahor, M., Blair, S. N., Espeland, M., Fielding, R., Gill, T. M., et al (2006). Effects of a physical activity intervention on measures of physical performance: Results of the lifestyle interventions and independence for Elders Pilot (LIFE-P) study. *Journals of Gerontology Series A: Biological and Medical Sciences*, 61(11), 1157–1165.
- Martin, J. T., Wolf, A., Moore, J. L., Rolenz, E., DiNinno, A., & Reneker, J. C. (2013). The effectiveness of physical therapist-administered group-based exercise on fall prevention: A systematic review of randomized controlled trials. *Journal of Geriatric Physical Therapy*, 36(4), 182–193. doi:10.1519/JPT.0b013e3182816045
- Merom, D., Pye, V., Macniven, R., van der Ploeg, H., Milat, A., Sherrington, C., et al (2012). Prevalence and correlates of participation in fall prevention exercise/physical activity by older adults. *Preventive Medicine*, *55*(6), 613–617. doi:10.1016/j.ypmed.2012.10.001
- Michie, S., West, R., Campbell, R., Brown, J., & Gainforth, H. (2014). *ABC of behaviour change theories* (2nd ed.). Sutton, United Kingdom: Silverback Publishing.
- Morey, M. C., Dubbert, P. M., Doyle, M. E., MacAller, H., Crowley, G. M., Kuchibhatla, M., et al (2003). From supervised to unsupervised exercise: Factors associated with exercise adherence. *Journal of Aging and Physical Activity*, 11(3), 351–368.
- Pahor, M., Guralnik, J. M., Ambrosius, W. T., Blair, S., Bonds, D. E., Church, T. S., et al (2014). Effect of structured physical activity on prevention of major mobility disability in older adults: The LIFE study randomized clinical trial. *JAMA*, 311(23), 2387–2396. doi:10.1001/jama.2014.5616
- Pavey, T. G., Taylor, A. H., Fox, K. R., Hillsdon, M., Anokye, N., Campbell, J. L., et al (2011). Effect of exercise referral schemes in primary care on physical activity and improving health outcomes: Systematic review and metaanalysis. *BMJ*, 343, d6462. doi:10.1136/bmj.d6462
- Pinto, B. M., Goldstein, M. G., Ashba, J., Sciamanna, C. N., & Jette, A. (2005). Randomized controlled trial of physical activity counseling for older primary care patients. *American Journal of Preventive Medicine*, 29(4), 247–255. doi:10.1016/j.amepre.2005.06.016
- Rosser, W. W., Colwill, J. M., Kasperski, J., & Wilson, L. (2010). Patient-centered medical homes in Ontario. *New England Journal of Medicine*, 362(3), e7. doi:10.1056/NEJMp0911519
- Sherrington, C., Michaleff, Z. A., Fairhall, N., Paul, S. S., Tiedemann, A., Whitney, J., et al (2016). Exercise to prevent falls in older adults: An updated systematic review and meta-analysis. *British Journal of Sports Medicine*.51(24), 1750–1758. doi:10.1136/bjsports-2016-096547
- Shier, V., Trieu, E., & Ganz, D. A. (2016). Implementing exercise programs to prevent falls: Systematic descriptive review. *Injury Epidemiology*, *3*, 16. doi:10.1186/s40621-016-0081-8

- Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L. P., et al (2010). A tutorial on pilot studies: The what, why and how. *BMC Medical Research Methodology*, 10, 1. doi:10.1186/1471-2288-10-1
- Topolski, T. D., LoGerfo, J., Patrick, D. L., Williams, B., Walwick, J., & Patrick, M. B. (2006). The Rapid Assessment of Physical Activity (RAPA) among older adults. *Preventing Chronic Disease*, 3(4), A118.
- Troiano, R. P., Berrigan, D., Dodd, K. W., Masse, L. C., Tilert, T., & McDowell, M. (2008). Physical activity in the United States measured by accelerometer. *Medicine & Science in Sports & Exercise*, 40(1), 181–188. doi:10.1249/mss.0b013e31815a51b3
- Warburton, D. E., Nicol, C. W., & Bredin, S. S. (2006). Health benefits of physical activity: The evidence. *CMAJ*, 174(6), 801–809. doi:10.1503/cmaj.051351
- Weber, M., Belala, N., Clemson, L., Boulton, E., Hawley-Hague, H., Becker, C., & Schwenk, M. (2018). Feasibility and effectiveness of intervention programmes integrating functional exercise into daily life of older adults: A systematic review. *Gerontology*, 64(2), 172–187. doi:10.1159/000479965
- Yarnall, K. S., Pollak, K. I., Ostbye, T., Krause, K. M., & Michener, J. L. (2003). Primary care: Is there enough time for prevention? *American Journal of Public Health*, 93(4), 635–641.