PHYSICAL ACTIVITY MAINTENANCE AMONG INDIVIDUALS WITH STROKE

STRATGIES FOR PROMOTING PHYSICAL ACTIVITY MAINTENANCE AMONG INDIVIDUALS WITH STROKE

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Lay Abstract

Physical activity can help with recovery after stroke if it is maintained. This thesis examined ways to support stroke survivors with remaining active in their daily lives. The first study was a review of existing programs to investigate their effects on the physical activity levels of individuals with stroke. Findings from this study showed that current programs produced a small improvement in physical activity that was short-lived, and no program component was better than others at promoting activity maintenance. Insights from this review were used to design a new study that provides increased support to stroke survivors in steps to cater to individual needs. This study will investigate whether this program is practical, acceptable by stroke survivors and people delivering it, and helps to improve and maintain physical activity. Together, these studies provide directions for designing future programs, assessing activity maintenance, and propose the design for a novel study.

Abstract

Physical activity can have beneficial effects on post-stroke recovery, but only if it is maintained. Current evidence shows that physical activity levels of individuals with stroke do not meet recommended guidelines. This thesis investigated current programs and proposed a novel trial design to aid stroke survivors with maintaining their activity levels in free-living environments. The first study was a systematic review of the effects of current interventions in post-stroke recovery. The review reported no differences between intervention and control groups for *steps walked/day at 3-month* (standardized mean difference (SMD) 0.19; 95% CI -0.30 to 0.69; I^2 = 47%; GRADE rating: Very Low), *time spent in moderate-vigorous physical activity at 3-month* (SMD -0.03; 95% CI -0.73 to 0.68; I^2 = 52%; GRADE rating: Very Low), or *self-reported physical activity at the 6-month follow-up* (SMD 0.40; 95% CI -0.02 to 0.82; I^2 = 0%; GRADE rating: Very Low). However, the pooled estimate of the *self-reported physical activity at the 3-month follow-up* was above the line of no-effect (SMD 0.22; 95% confidence intervals, 0.01 to 0.42; I^2 = 0%; GRADE rating: Very Low). Intervention characteristics associated with physical activity maintenance could not be explored due to the low number of trials. Insights from this review were used to design an *Adaptive Treatment Strategy* where high-intensity interventions are sequentially tailored to participants following the identification of increased needs. A protocol of a proof-of-concept pilot *Sequential Multiple Assignment Randomized Trial* was outlined to assess trial *feasibility*, participants' *acceptability* with changes in interventions, participants' and staffs' *satisfaction* with the treatment strategy, and to provide *preliminary estimates of effect* of physical activity and self-efficacy for physical activity. Together, these two studies provide direction about intervention design, physical activity maintenance assessment, and proposes the design of a novel pilot SMART trial.

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List of Abbreviations

PA	Physical Activity
MVPA	Modera-vigorous physical activity
ATS	Adaptive Treatment Strategy
SMART	Sequential Multiple Assignment Randomized Trial
SD	Standard Deviation
CI	Confidence Interval
SMD	Standardized Mean Difference
HR	Hazard Ratio
OR	Odds Ratio
TEE	Total Energy Expenditure
TEF	Thermic Effect of Food
AEE	Activity-based Energy Expenditure
MET	Metabolic Equivalents
MET-min	Metabolic-equivalent minutes
ICC	Intraclass Correlation Coefficient
HAP-AAS	Human Activity Profile – Adjusted Activity Score
PADS	Physical Activity and Disability Survey
HPLP-II	Health Promoting Lifestyle Profile II
PASIPD	Physical Activity Scale for Individuals with Physical Disabilities
RCT	Randomized Controlled Trial
TIA	Transient Ischemic Attack
AHA	American Heart Association

Declaration of Achievement

This thesis was completed by the candidate and recognizes the contribution of Dr. Julie Richardson, Dr. Ada Tang, and Dr. Lehana Thabane in providing helpful insight into its preparation and in the research process. Emily Cino contributed to the study selection, data extraction, and quality assessment process of the literature review. Laura Banfield provided insight into the creation of the search terms.

Chapter 1

Introduction

Brief Introduction and Research Rationale

Stroke is the leading cause of adult disability and the third leading cause of mortality in Canada (1,2). Survivors of stroke often face physical and cognitive impairments, difficulty with performing activities of daily living, and difficulty engaging with their environment (3). Physical activity and exercise have been shown to have positive effects on post-stroke recovery (4–10). However, to date, no quantitative reviews have been published investigating the effects of current interventions in promoting physical activity maintenance among individuals with stroke. Since behavior change interventions involve a complex combination of techniques, such reviews (through an exploration of between-trial heterogeneity) can potentially identify promising strategies for promoting activity maintenance and inform the design of future trials (11).

Additionally, there are currently no trials with interventions designed specifically to promote long-term maintenance of physical activity (12,13). A potential way to promote activity maintenance is by tailoring interventions to participants through *adaptive treatment strategies* (ATSs), whereby higher-intensity treatments are sequentially provided based on participants' needs (14). However, ATSs and the *sequential multiple assignment randomized trials* (SMARTs) required to develop them (14) have not been investigated within the stroke rehabilitation literature. Thus, this thesis aimed to examine the effects of current stroke rehabilitation programs on physical activity maintenance and propose a novel pilot SMART for developing an ATS targeting activity maintenance among stroke survivors.

This thesis will provide an overview of stroke, physical activity, and the current and possible future strategies for promoting maintenance of physical activity. Three studies will be presented in this thesis: a systematic review protocol, the results from the systematic review and

meta-analysis, and a protocol for a proof-of-concept pilot SMART. Finally, the thesis will conclude with a discussion of the review results, pilot SMART, limitations, and future directions.

Characteristics of Stroke

A stroke occurs when blood vessels in the brain are either blocked (ischemic stroke) or ruptured (hemorrhagic stroke) that prevents oxygen and nutrient flow to brain tissues and causes cerebral infarctions (1). According to the American Heart Association, 38% of all strokes are ischemic, 10% are intracerebral hemorrhages, and 3% are subarachnoid hemorrhages (15). Symptoms of stroke are usually sudden and can include headaches, loss of coordination and balance, confusion, and weakness (paresis) or paralysis (plegia) often on one side of the body (1). These and subsequent physical, psychosocial, and cognitive sequelae can persist for a long time and impact a person's activities of daily living and quality of life (1).

Epidemiology of Stroke

According to the Global Burden of Disease study, stroke is the leading cause of mortality and disability in the world (16). Globally, there were 80 million stroke survivors, 13.7 million new cases, and 5.5 million deaths from stroke in 2016 (16). Within Canada, stroke is the leading cause of adult disability and the third leading cause of mortality, resulting in 62,000 new cases annually (1,2). There were 405,000 Canadians living with stroke in 2016 and this number is projected to increase to 726,000 survivors by 2038 (17). The prevalence of stroke also increases with age with the highest prevalence being among individuals $\geq$ 80 years (15). The prevalence of stroke is equal among males and females < 50 years, but higher among males in the 50 – 79 years age bracket (2). However, the prevalence of female stroke survivors is higher among individuals $\geq$ 80 years that can be attributed to the higher female life expectancy (2).

Risk factors

The risk factors for stroke include modifiable and non-modifiable risk factors, with modifiable risk factors explaining 90% of strokes and the burden from stroke (18,19). These modifiable risk factors include both metabolic and lifestyle factors. Metabolic risk factors include hypertension (OR, 2.56) (19), diabetes (HR, 1.73-2.27) (20), and obesity (OR, 1.57) (21), while behavioral risk factors include smoking (OR, 1.67) (19), physical inactivity (HR, 1.60) (22), heavy alcohol use (OR, 2.09) (21), and psychological factors such as stress and depression (OR, 2.20) (19). Non-modifiable risk factors include age (increase in two-fold risk per decade after age > 45years) (23), family history (15), and sex.

Physical Activity, Physical Fitness, and Exercise

Physical activity is "any bodily movement produced by the skeletal muscles that results in energy expenditure" (page 126) (24). Physical activity can be described based on intensity, duration, frequency, and/or mode (e.g. walking, cycling, gardening) and is broadly categorized into leisure-time, occupation-based, transportation-based, or domestic activities (25). In contrast to physical activity that is a behavior, physical fitness is a set of attributes (e.g. cardiorespiratory endurance, muscular endurance and strength, body composition, and flexibility) that an individual possesses or achieves (24). Exercise is "a subset of physical activity that is planned, structured, and repetitive and has a final or an intermediate objective [of] the improvement or maintenance of physical fitness" (24).

Due to the complex nature of physical activity behavior, there is no gold standard technique for measuring it (26). However, elevated energy expenditure above resting levels brought upon by physical activity can be used as a proxy measure (26). The total amount of

energy expended (TEE) from a human body is composed of resting energy expenditure (REE), the thermic effect of food consumed (TEF), and activity-related energy expenditure (AEE) (26):

$$TEE = REE + TEF + AEE$$

Resting energy expenditure (REE) is the amount of energy emitted by a fasted individual within a thermoneutral condition and can be influenced by age, sex, body size, and body composition (higher with increased proportion fat-free mass) (26,27). All three components of energy expenditure can be measured using indirect calorimetry, where the rate of oxygen consumed ($\dot{V}O_2$; $ml.kg^{-1}.min^{-1}$) and/or carbon dioxide produced ($\dot{V}CO_2$; $ml.kg^{-1}.min^{-1}$) from energy metabolism is monitored via metabolic carts (25). However, while this measurement procedure is well suited for laboratory settings, it is not feasible for assessing every day (free-living) activity (28). As such, the doubly labeled water technique (DLW) is considered the gold standard for measuring TEE within free-living environments (26). It involves the oral administration of stable isotopes of hydrogen (^2H) and oxygen (^{18}O) (29). The difference in the elimination rates between ^2H and ^{18}O (correlated with $\dot{V}CO_2$) is monitored through urine samples and subsequently used to measure TEE (29). The AEE can therefore be calculated according to the following equation, which assumes that the energy expended from food consumption (TEF) accounts for 10% of the total energy cost (30).

$$AEE = 0.9 \times TEE \times REE$$

Physical Activity Intensity

Increasing the intensity of physical activity increases the energy expended above resting levels (31). Therefore, physical activity intensity can be quantified in metabolic-equivalents (METs) that denote multiples of resting energy expenditure (32). One MET is the rate at which an individual expends energy (milliliters of O_2 consumed) while at rest relative to their mass

(kg), and is equivalent to 3.5 ml/O_2/kg/min by convention (32). For health research, a compendium was developed to categorize *absolute* intensities of physical activity as: light (<3 METs), moderate (3-6 METs), moderate-vigorous (>3 METs), and vigorous (>6 METs) (33).

While physical activity intensity is generally represented as an *absolute* measure outlined by the compendium (33), the differences in the overall physical fitness of individuals can affect their perceived level of exertion, resulting in different physiological stimuli (34). Hence, intensity can also be represented *relative* to an individual's cardiorespiratory fitness (% $\dot{V}O_2$ max) or rating of perceived exertion (25). However, absolute measures of physical activity intensity allow for the comparison of results across studies (35), and most national physical activity guidelines outline their recommendations according to this metric (36–38).

Physical Activity Measurement Instruments

Although there is no gold standard for measuring free-living physical activity, there are several field instruments currently in use. *Table 1* lists the common categories of physical activity measurement instruments along with their advantages and disadvantages.

Table 1: The advantages and disadvantages of free-living physical activity measurement instruments

Instrument Type	Description	Advantages	Disadvantages
Subjective Measures			
Self-reported Questionnaires	Questions prompt participants to recall components of their physical activity (e.g. duration, frequency, mode, and/or intensity) (39).	The measures are cost-effective and easy to administer (39), are useful for categorizing groups of individuals into discrete categories of physical activity intensity (40).	Questionnaires are subject to recall bias (40), less robust than objective measures in quantifying low and moderate intensity physical activity (39), and both over and underestimate physical activity assessed at the individual level (30,41). The validity of such questionnaires with DLW is inconsistent (42).
Self-report activity diary/logs	Participants are instructed to record components of physical activity (e.g. duration, frequency, mode, and/or intensity) in real-time (40).	These measures are less susceptible to recall bias than self-reported questionnaires and provide detailed real-time data (26,40).	Keeping such logs up to date is burdensome for participants, especially for individuals with cognitive dysfunction (26,40). If logs are not completed in real-time, they may be subject to recall bias (40).
Objective Measures			
Pedometers	Pedometers measure steps walked by recording the vertical acceleration of the hip beyond a chosen force threshold (26).	Pedometers are simple, low-cost, and capable of recording short durations of physical activity not captured by self-reported measures (40). Pedometers are sensitive to forward vertical motion in the form of running and moderate walking (26).	Pedometers cannot measure physical activity involving horizontal motions from upper body exercises (e.g. rowing) (40), cannot record the intensity, duration, or frequency of physical activity (40), and is inaccurate at slower walking speeds (<60m/min) (43).

Heart Rate Monitors	Heart rate monitors measure beats/minute using electrocardiography (chest-worn monitors) or by measuring blood flow through light refraction (26). Energy expenditure and physical activity intensity are estimated based on the assumption of a linear relationship between heart rate and $\dot{V}O_2$ (40).	These monitors can measure activities that do not require vertical trunk displacement (e.g. rowing or cycling) (40). Calibration procedures where heart rate is regressed with energy expended during submaximal exercise tests can be used to estimate relative intensities of physical activity (26).	The relationship between heart rate and VO_2 becomes non-linear below the flex heart rate (average of the highest heart rate when a person is standing and the lowest heart rate during the submaximal test) (44). Heart rate-VO_2 regression equations derived from submaximal test calibrations using one type of activity (e.g. walking or running) may not be accurate for other activities (44).
Armbands	These devices use heat flux, galvanic skin response, skin temperature, body temperature, and accelerometry to measure energy expenditure (40).	These devices are good for capturing energy expended from complex free-living movements that involve both ambulatory and non-ambulatory components (e.g. waking up grades while carrying heavy objects) (45).	Comparison with indirect calorimetry showed that these devices are not ideal for measuring energy expended from high-intensity activities (46).
Accelerometers	Estimates energy expenditure by recording acceleration counts within up to three planes (anteroposterior, mediolateral, and vertical) (26).	Tri-axial accelerometers demonstrate high criterion validity with DLW (26,40,47) and accurately capture large amounts of data about physical activity intensities resulting from both static (sitting/lying) and dynamic behaviors (26,40).	Accelerometers are expensive and require specialized hardware and software expertise to use (26,40). There currently are no standardized acceleration cut-off points to categorize absolute intensities of physical activity across devices that hampers between-study comparison of results (48).

Within each physical activity measurement instrument category, there are several instruments available with varying psychometric properties. Table 2 describes the physical activity measurement devices that have been represented in this thesis.

Table 2: Psychometric Properties of the Free-Living Physical Activity Measures

Self-report Measures		
Measures	Description	Psychometric Properties
Human Activity Profile – Adjusted Activity Score (HAP-AAS)	The HAP is a 94-item self-report measure that lists activities ranging from 1-10 METs. For each activity, participants indicate whether they are still doing, have stopped doing, or never did the activity (49). The maximum activity score (MAS) is the number of activities with the highest MET value that a participant is "still doing". The adjusted activity score (AAS) is calculated by subtracting the number of activities with lower MET values that participants "have stopped doing" from the MAS (49).	**Reliability** Test-retest reliability: ICC (3,1) was 0.95 for the HAP-AAS score in a sample of individuals with knee osteoarthritis (50). Internal Consistency: HAP-AAS demonstrated excellent internal consistency (α=0.91) when administered to community-dwelling older adults (51). **Validity** Criterion Validity: When assessed in a sample of community-dwelling older women (age>60years), the HAP-AAS score demonstrated significant correlations with the ActiGraph accelerometer for moderate-intensity activity/day (ρ=0.71) and energy expenditure (ρ=0.52) (49).
Physical Activity and Disability Survey (PADS)	The PADS was designed to reflect the potential activity performed by individuals with disabilities (52). It measures physical activity using six subscales: exercise, leisure-time physical activity, general activity, therapy, employment/schools, and wheelchair users (53). Responders	**Reliability** ICC(1,1) = 0.92 (53) **Validity**

	indicate the frequency and/or duration of time they allocate to each type of activity (53). The scoring system follows algorithms developed for each question, which are based on the time responders spend doing an activity and the intensity allocated to that activity (53).	Concurrent Validity: Low; the PADS questionnaire demonstrates wide 95% prediction bands compared with acceleration counts from the Actical accelerometer (53). Note: Both reliability and concurrent validity was evaluated in a sample of individuals with multiple sclerosis (53)
Health Promoting Lifestyle Profile II (HPLP-II)	The HPLP-II is a 52-item instrument that measures health-promoting behaviors on six subscales. The eight-item physical activity subscale enquires about responders' involvement with light, moderate, and/or vigorous activity that can be undertaken as a part of a planned and monitored program or as a part of daily/leisurely activity. Possible responses for each item are as follows: never = 1; sometimes = 2; often = 3; routinely =4 (54). The mean and standard deviation scores for each subscale can be calculated.	Internal Consistency: The physical activity subscale of the HPLP-II demonstrated excellent internal consistency (α=0.91) when measured in a sample of Taiwanese women (age; mean(SD) = 50.39(5.3)) (54).
Physical Activity Scale for Individuals with Physical Disabilities (PASIPD)	The PASIPD is a 13-item questionnaire that asks responders to recall the numbers of days and hours/day they participated in recreational, household, and occupational activities in the past seven days (55). The score is calculated by multiplying the average number of hours/day of an activity with the MET values associated with that activity to produce a MET-hours/day estimate (55).	**Reliability** Test-retest reliability: ρ = 0.77 (55) **Validity** Concurrent Validity: The PASIPD questionnaire was compared to the ActiGraph accelerometer worn at the hip for 7 days (ρ = 0.30) (55). Note: Test-retest reliability and concurrent validity were assessed in a sample of individuals with mixed chronic conditions (n=13 or 29% of participants had a stroke diagnosis) and using the 12-item Dutch version of the questionnaire (55).

Objective Measures		
GENEActiv accelerometer	Wrist-worn triaxial accelerometer that classifies free-living physical activity according to time spent in different intensities of activity (56).	**Validity** Criterion Validity: The GENEActiv accelerometer demonstrated excellent criterion validity with indirect calorimetry (r=0.86) (56). Concurrent Validity: The GENEActiv accelerometer demonstrated excellent concurrent validity with the ActiGraph accelerometer (r=0.92) (56). Note: Both types of validity were tested in a population of healthy adults (42≤age≤63 years)
Fit Bit One accelerometer	Wrist-worn triaxial accelerometer that measures steps walked and time spent in moderate-vigorous physical activity.	**Reliability** ICC ≥ 0.95 when measured in a population of healthy adults (mean(SD) age = 29.6 (5.7) years) (57). **Validity** Concurrent Validity: Fit Bit One demonstrated strong correlations with the Actical accelerometer with regards to steps walked per day (r>0.97) and light-intensity physical activity (r>0.91), but not for moderate-vigorous intensity physical activity (r<0.80) when evaluated in a sample of community-dwelling stroke survivors (mean (SD) ag e= 62.6 (9.3) years) (58).
StepWatch Activity Monitor	Contains an accelerometer and microprocessor to measure steps walked/day.	**Reliability** Excellent test-retest reliability (ICC: 0.93-0.989) for steps walked/day (59). **Validity**

		Concurrent validity: High correlation (r>0.89) with three-dimensional gait analysis for the number of steps walked (60) Note: Both the validity and reliability estimates were measured in a sample of community-dwelling stroke survivors ((mean (SD) age= 69.2 (12.6) years)
SenseWear Armband (SWA)	This device uses heat flux (heat emitted from the body), galvanic skin response (estimate of skin conductivity), skin temperature, and a bi-axial accelerometer to estimate energy expenditure (kcal/min).	**Reliability** Excellent reliability (ICC=0.97) when measured in a sample of healthy adults (18<age<45) (61) **Validity** The SWA demonstrated excellent concurrent validity with indirect calorimetry (ICC =0.72) when worn in the non-hemiplegic arm by community-dwelling stroke survivors (means (SD) age = 64.2 (10.4) years) (62).
Yamax Digiwalker SW-200 pedometer	Knee-mounted uniaxial pedometer measuring steps walked/day	**Reliability** ICC=0.73-0.95 (63) **Validity** Concurrent validity: Moderate to excellent correlations (ρ=0.95) between pedometer and manually counted steps (63) Note: Both reliability and validity estimates were based on a sample of community-dwelling stroke survivors (mean (SD) age = 60.40 (10.26) years)

ActiGraph GT3X	A tri-axial accelerometer that calculates steps walked/day and classifies free-living physical activity as time spent in different intensities of activity (64). Note: As described in chapter 3 of this thesis, the ActiGraph GT3X was planned to be worn on the ankle of the stroke survivors' unaffected side, which improves device acceptability and step count accuracy (65).	**Reliability** ICC (3,1) = 0.80 (95%CI: 0.63,0.90) when measuring steps walked/day in a sample of community-dwelling stroke survivors (65). Significant inter-instrument reliability (r>0.90) for single, 7-day, and 21-day measurements conducted in a sample of healthy adults (mean (SD) age = 31 (12.2)) (64). **Validity** Criterion validity: The ActiGraph GT3X demonstrated significant correlations (r=0.68) with DLW when measuring AEE in a sample of individuals with COPD (66).

ρ = spearmen's correlation coefficient; α = internal validity (cronbach's alpha); r = Pearson's correlation coefficient; ICC = Intraclass correlation coefficient; COPD = Chronic Obstructive Pulmonary Disease

As exemplified in Tables 1 and 2, there are different categories of physical activity measurements that vary in psychometric properties, measurement procedures, and the outcomes produced. In general, subjective questionnaires, while being inexpensive and easy to administer, have inconsistent validity, and are subject to bias. Self-report diaries, while being more accurate, are burdensome and often not feasible for long-term monitoring of physical activity. Among objective measures, accelerometers are the popular choice within trials because they are compact (26), generally accepted by individuals with stroke (65), and can continuously measure both the intensity and duration of physical activity (26,40).

Physical Activity After Stroke

Residual impairment, such as hemiparesis, spasticity, cognitive dysfunction, and aphasia following a stroke can make it difficult to engage in physical activity (3). The resultant sedentary lifestyle causes a decline in cardiorespiratory fitness, as the peak oxygen consumption ($\dot{V}O_2max$) of stroke survivors (67,68) is approximately in the 25^{th} percentile of healthy age- and sex-matched reference standards (69). Oftentimes, the $\dot{V}O_2max$ of stroke survivors scarcely passes the levels required for independent living ($\approx$15-18ml.kg^{-1}.min^{-1}) (68,70). Such findings are concomitant with the observation of persons 6-months post-stroke, where 39% of survivors have difficulties with self-care (bathing, dressing, grooming) (71). Longer periods of inactivity can reinforce cardiorespiratory fitness decline, which was confirmed by a randomized controlled trial in patients with chronic stroke where there was approximately ~10% decline in $\dot{V}O_2max$ among the lag-entry control group (72).

Reduction in cardiorespiratory fitness after a stroke occurs in part because skeletal muscles on the stroke-affected side experience atrophy, increase in intramuscular fat, reduction in capillaries per muscle fiber, and increase in more fatigable fast-twitch fibers (73). These

changes result in post-stroke fatigue (prevalent in 30-68% of stroke survivors) (74) and a two-fold higher energy cost for walking ($\dot{V}O_2$ per distance walked) compared to able-bodied individuals, thereby making it difficult to be active (75). While such impairments are an important barrier to physical activity, many survivors with low levels of impairment do not meet recommended activity guidelines (76,77). Such findings are indicative of ancillary personal and environmental factors that impact physical activity participation (See *Appendix B* for a description of the facilitators and barriers to physical activity experienced by stroke survivors). Finally, stroke does not occur in isolation but is also accommodated with other comorbidities that can inhibit participation in exercise programs (3). A cross-sectional study reported individuals who had recurrent strokes also had hypertension (75%), ischemic heart disease (37%), hyperlipidemia (56%), atrial fibrillation (29%), and diabetes mellites (24%) (78).

As such, in the time after stroke, there is an opportunity where aforementioned factors result in inactivity and physical activity intolerance, which in turn result in reduced physical fitness and decreased participation in daily life. Hence, supporting stroke survivors during this period to remain active is paramount for facilitating proper post-stroke recovery (3).

Benefits of Physical Activity in Stroke Recovery

Physical activity and exercise after stroke can improve balance and walking capacity (4), increase upper limb strength (SMD 0.98; 95% confidence interval (CI): 0.67 to 1.29) (5), improve cognitive function (SMD = 0.304, 95% CI: 0.14 to 0.47) (7), and attenuate depressive symptoms (SMD= −0.13 95%CI: −0.26 to 0.01) (6). Meta-analytic evidence also reported physical activity and exercise have positive effects on cardiovascular risk factors such as decreased systolic blood pressure, decreased fasting glucose levels, and increased high-density lipoproteins (8,9).

Physical Activity Recommendations and Current Literature

The American Heart Association (AHA) categorized physical activity and exercise recommendations based on three stages of post-stroke recovery (3). Within 24 hours following a stroke, physical activity goals were aimed at promoting early mobilization (e.g. via intermittent sitting or standing) and minimizing prolonged inactivity (3); however, the benefits of doing so remain uncertain (79–82). Once stable, exercise regimens, conducted within inpatient, community, or home-based settings, were recommended to regain or exceed pre-stroke levels of physical activity. These exercises emphasize progressive task difficulty, repetition, and functional practice, and involved cardiorespiratory and strength training to improve cardiorespiratory fitness, muscle strength, and functional mobility (3,83). At this stage, physical and occupational therapy was also recommended to improve motor recovery and skills, self-care, and occupational and leisure activities (45). The third set of goals were centered around helping stroke survivors develop and maintain strategies to meet the physical activity guidelines, prevent recurrent strokes, and improve and maintain physical function (3).

While there are quantitative reviews that explore the efficacy of strategies targeting the first two post-stroke stages (79,80,83), few reviews exist investigating long-term maintenance of physical activity. Given that behavioral change interventions involve a complex combination of different techniques, these reviews not only allow an investigation into the efficacy of current interventions but (through a meta-regression analysis) can also enable investigators to explore the potential of individual strategies with promoting activity maintenance (11). Such a synthesis of literature has been undertaken to investigate physical activity maintenance within several populations such as healthy adults (84,85), people with diabetes (86), people with obesity (87), and survivors of cancer (88). To our knowledge, currently, there are only narrative reviews

investigating physical activity maintenance among people with stroke (12,13). While such narrative syntheses provide valuable information, they contain the associated risk of assigning disproportionate weights to studies, which could bias the interpretation of the size, direction, consistency, and strength of evidence associated with the effect estimates (89). Thus, there is a need for synthesizing both narrative and quantitative evidence of trial-specific effect sizes pertaining to post-intervention physical activity maintenance.

Future Strategies for Promoting Physical Activity Maintenance

To promote physical activity maintenance, the AHA recommended customizing interventions for each participant (3). However, given the high costs associated with stroke, any proposed program would have to make efficient use of the limited resources available (17). One proposed method of tailoring interventions while also optimizing resource utilization is by using *adaptive treatment strategies* (ATSs) (14). These strategies initially assign low-intensity treatments (Stage 1) and sequentially tailor more intensive treatments (Stage 2) based on individual needs assessed using a *response measure* (14). This approach allows for a scaled and incremental intervention delivery method where resources are conserved in early stages and intensified as needed in later stages (14).

To develop high-quality ATSs, each decision rule (e.g. treatment type, response measure, response cut-off scores, and time spent in each stage) must be evidence-based, requiring the use of consecutive, expensive randomized controlled trials (14,90). Alternatively, a *sequential multiple assignment randomized trial* (SMART) design may be used to accelerate the development of high-quality ATSs and evaluate the timing, intervention sequence, and schemes for tailoring interventions through the use of randomized data (14,90). To date, the efficacy of ATSs or SMARTs has not been investigated among individuals with stroke.

Thesis Overview

This thesis was comprised of three studies exploring the physical activity maintenance among people with stroke. The first two studies were the protocol and results of a systematic review respectively, and the third study was a protocol for a proof-of-concept pilot SMART.

Study 1: Intervention Related Factors Associated with Physical Activity Maintenance Among Stroke Survivors: A Protocol for a Systematic Review, Meta-Analysis, and Meta-Regression

Study 2: Intervention Related Factors Associated with Physical Activity Maintenance Among Individuals with Stroke: A Systematic Review and Meta-Analysis

Objectives:

Primary: To investigate the effects of current interventions in promoting short- (3-months), moderate- (6-months), and long-term (≥12 months) physical activity maintenance among individuals with stroke.

Secondary: To investigate the intervention characteristics associated with short-, moderate-, and long-term physical activity maintenance among individuals with stroke.

Study 3: Developing an Adaptive Treatment Strategy Targeting Maintenance of Physical Activity after Stroke: A Pilot Sequential Multiple Assignment Randomized Trial (SMART)

Objectives: To investigate the *feasibility, acceptability, participant/staff satisfaction,* and to provide *preliminary estimates of effect* of a pilot SMART to develop an ATS for promoting physical activity maintenance among individuals with stroke.

Chapter 2

Intervention-Related Factors Associated with Physical Activity Maintenance Among Stroke Survivors

A Protocol for a Systematic Review, Meta-Analysis, and Meta-Regression

Masrur M, Richardson J, Tang A, Thabane L, Cino E. Intervention-related factors associated with physical activity maintenance among post-stroke patients: a protocol for a systematic review with meta-analysis and meta-regression. JBI Evid Synth. 2020;18(8):1738–50.

Abstract

Objective: The aim of this review is to **(1)** evaluate the effectiveness of current rehabilitation interventions in promoting short, moderate, and long-term physical activity maintenance among patients post-stroke, and **(2)** investigate the intervention characteristics associated with the promotion of physical activity maintenance among patients post-stroke.

Introduction: Physical activity and exercise can positively impact post-stroke recovery. However, few patients participate in the recommended levels of physical activity after stroke. To design better post-stroke programs, the characteristics of current interventions that promote physical activity maintenance need to be identified.

Inclusion Criteria: Randomized Controlled Trials including adults (age≥18) post-stroke, assessing physical activity via subjective or objective measures with a minimum of a three-month follow-up, and published in English will be included.

Methods: Literature search will be conducted using Medline, Embase, PsycINFO, CINAHL, SPORTDiscus, and Cochrane Central Register of Controlled Trials. The quality of the randomized trials will be assessed using the Cochrane risk of bias tool. Interventions will be coded using the Behavior Change Technique Taxonomy version 1. Standardized mean differences of physical activity between intervention and control groups will be calculated using study-specific measures and interpreted as small (<0.40), medium (0.40-0.70), or large (>0.70). Meta-analysis of effect sizes will be conducted for short (three months), moderate (six months), and long (≥12 months) term follow-ups. Univariable and multivariable random-effects meta-regression using intervention characteristics (setting, delivery method, delivery type, duration, outcome measure, and behavioral change techniques) will be conducted to identify predictors of physical activity maintenance.

Systematic Review Registration Number: CRD42019131056

Keywords: Stroke; Rehabilitation; Physical Activity; Maintenance; Intervention Factors

Introduction

Stroke is the second leading cause of mortality and the third leading cause of disability in the world, contributing to high individual and social burden(18). Physical activity and exercise can have positive implications for post-stroke recovery. Physical activity is "any bodily movement produced by the skeletal muscles that results in energy expenditure" (page 126), while exercise is "a subset of physical activity that is planned, structured, and repetitive and has a final or an intermediate objective [of] the improvement or maintenance of physical fitness" (page 128) (24). Physical activity and exercise after stroke can improve balance and walking capacity (4), increase upper and lower limb strength (5), improve cognitive function (7), and attenuate depressive symptoms (6). However, physical activity levels among stroke survivors do not meet the recommended guidelines (91). Therefore, improved post-stroke rehabilitation programs that promote physical activity maintenance need to be developed. To do so, the characteristics of current interventions that are efficacious in achieving such maintenance need to be identified.

Interventions to change behavior, such as physical activity, are complex and involve many interacting components. Hence, it is important to identify and compare the Behavioral Change Techniques (BCTs) underlying such interventions (92). Behavioral Change Techniques are defined as the irreducible, observable, and reproducible aspects of an intervention that redirect the causal processes of behavior to bring about a change (92). The Behavior Change Technique Taxonomy version 1 (BCTTv1), developed by Michie et al., groups 93 BCTs into 16 hierarchical clusters and provides a standardized method for identifying and comparing BCTs across trials (92).

Another factor to consider when assessing physical activity maintenance is the timepoints used to estimate it. Setting an *a-priori* timepoint is complicated given the lack of consensus that exists among researchers about how to define maintenance (93). For example, Rothman defines maintenance as the time when a specific behavior is automatically and effortlessly carried out (94). On the other hand, Kwasnicka et al. has suggested that behavior change is maintained when a new behavior becomes the dominant response – or has the highest probability of being carried out – across different times and contexts (95). It is difficult to adopt such conceptual definitions in reviews to compare maintenance effect sizes across trials. Instead, some reviewers have opted to calculate maintenance estimates at a pre-specified timepoint from the baseline (85). However, this definition can misconstrue maintenance estimates as it does not account for the variability of the intervention duration across trials. For example, if a review calculates maintenance effect sizes at six months post-baseline, it may encounter trials with an intervention period lasting for three months or six months. The first case assesses maintenance after a three-month follow-up, while the latter case assesses maintenance immediately following the end of the intervention. Such heterogeneity in intervention duration across trials can be addressed by adopting a post-intervention timepoint for evaluating maintenance. Previous reviews have classified short, moderate, and long-term PA maintenance at a post-intervention timepoint of three, six, and ≥12 months respectively (12,13).

A search of the JBI Database of Systematic Reviews and Implementation Reports, International Prospective Register of Systematic Reviews (PROSPERO), Embase, Medline, CINAHL, and the Cochrane Database of Systematic Reviews indicated that two previous reviews had narratively described the efficacy of the interventions in promoting PA maintenance among stroke survivors (12,13). While such narrative syntheses provide valuable information,

they contain the associated risk of assigning disproportionate weights to studies, which could bias the interpretation of the size, direction, consistency, and strength of evidence associated with effect estimates (89). Hence, it is preferable to combine both quantitative and narrative synthesis techniques to acquire a comprehensive judgment of intervention effects (89). However, neither of the previous reviews conducted a meta-analysis and justified this decision by citing the clinical diversity between trials (12,13). However, the inclusion of quasi-experimental trials, non-PA outcome measures, and/or participants without a stroke diagnosis (e.g. participants with Transient Ischemic Attacks (TIA)) in these reviews could have contributed to the high clinical heterogeneity perceived by the authors (12,13). Additionally, clinical and methodological diversity between trials manifests through statistical heterogeneity in the pooled estimates, which can be evaluated through statistical tests – as recommended by both the Cochrane Handbook for Systematic Reviews of Interventions and the JBI Reviewer's Manual (89,96). Hence, the decision of whether to conduct a meta-analysis or not could be made using objective statistical tests that are available for measuring between-study heterogeneity (89,96). Finally, even if high statistical heterogeneity exists between studies, an exploration of the sources of such diversity can provide valuable information regarding the key intervention factors associated with physical activity maintenance (89).

This review will aim to quantitatively synthesize the effectiveness of current interventions in promoting short, moderate, and long-term PA maintenance among patients following stroke. It will also aim to isolate the intervention characteristics that are associated with maintenance among stroke survivors.

Review Questions

Primary: To investigate the effectiveness of current interventions in promoting short (three months), moderate (six months), and long (≥12 months) term PA maintenance among patients post-stroke.

Secondary: To investigate the intervention characteristics associated with short, moderate, and long-term PA maintenance among patients post-stroke.

Methods

This systematic review protocol will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines (97). This protocol was registered with PROSPERO: CRD42019131056).

Inclusion Criteria

Participants: Studies with adults (age≥18 years) who have a confirmed diagnosis of stroke (ischemic or hemorrhagic) and not TIA will be included. If stroke participants are in a subgroup, then the analysis of that group needs to be conducted separately from the study population.

Interventions: Studies investigating post-stroke rehabilitation interventions that aim to address physical activity directly (for example, by incorporating self-monitoring strategies) or indirectly by influencing participants' functional outcomes (for example, by improving their gait or balance) will be included. Interventions can include but are not limited to, aerobic exercises, strength training, self-management education sessions, and behavioral interventions. Surgical, pharmaceutical or nutrition-based interventions will be excluded.

Comparator*:* The comparison group can include usual care, passive rehabilitation, programs that do not aim to increase physical activity, programs that do not promote physical activity maintenance or no intervention given.

Outcome Measure: Studies will be included if they use objective (e.g. accelerometers, pedometers, direct observation) or self-reported (e.g. logbooks, diaries, or questionnaires) physical activity outcome measures. Outcomes could include time spent in specified intensities of physical activity, energy expenditure from physical activity, percentage of participants meeting a trial-recommended level of physical activity, step count, or the number of transitions (e.g. sitting to standing). Studies will be excluded if they only report sedentary time, walking or exercise capacity, gait patterns, or the performance of activities of daily living.

Types of Studies: This review will include randomized controlled trials (RCTs) or cluster RCTs. Studies will be included if they have a follow-up period of at least three months post-intervention. No limitations are placed on the timing of the interventions.

Search Strategy

The search strategy will include medical subject headings and keywords for stroke, physical activity, RCTs, and follow-up. Terms for stroke will be adapted from the search strategy developed by the Cochrane Stroke Group. Appropriate physical activity search terms will be created by investigating the search strategies utilized in previously published reviews (12,13,85). Since this review will investigate short, moderate, and long-term PA maintenance, the follow-up terms will be created to capture the corresponding post-intervention timepoints (three, six, and ≥12 months follow-up). The title and abstracts of studies included in previous post-stroke intervention reviews will be searched to evaluate the accuracy of the follow-up terms used in this paper (12,13). All searches will be reviewed by a librarian from the Health Sciences Department of McMaster University. See *Appendix A* for a sample search conducted on Ovid Embase.

Information Sources

The following databases will be consulted for articles from their inception until July 2019: Ovid PsycINFO, Ovid Medline, Ovid EMBASE, EBSCO SPORTDiscus, EBSCO CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL). Grey literature will be searched using Google Scholar. The references of all included articles and relevant reviews will be hand searched.

Study Selection

All literature search results will be uploaded into Covidence (veritas health Innovation, Melbourne, Australia) and duplicates will be removed. Two independent reviewers (MM and EC) will screen titles and abstracts for selection. Full-text screening will also be conducted by the same reviewers. Reasons for full-text exclusion will be reported. Calibration exercises will be conducted at each selection stage. Discrepancies in judgment will be resolved via consultation with the third reviewer (JR). The search results will be reported according to the PRISMA guidelines in a flow diagram (97).

Assessment of Methodological Quality

The quality of individual studies will be assessed using Cochrane's risk of bias tool (97). The tool is divided into six domains: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. For each section within a domain, the independent reviewers (MM and EC) will assign a rating of high risk, low risk, or unclear risk (97). Discrepancies in judgment will be resolved through consultation with the third reviewer JR. This tool was chosen because it is compatible with both the meta-analysis software and the methodology used for evaluating the certainty of cumulative evidence.

Data Extraction

Data will be independently extracted by two reviewers (MM and EC) from the selected texts using the data extraction form included in *Appendix B.* Each reviewer will be trained on coding BCTs from the descriptions of trial interventions using modules from the BCT-Taxonomy Training website(98). Discrepancies in the extracted information will be addressed by consulting with a third reviewer (JR).

Data synthesis

Criteria of synthesis: The characteristics of each study (intervention, control, PA outcome measure, and BCTs used) will be summarized in tabular format. We anticipate these characteristics to vary between trials, and as such, we will use a random-effects model for the meta-analysis.

Unit of analysis issues: The primary unit of analysis will be per individual randomized. For cluster randomized control trials, we will extract the intra-cluster correlation coefficient (ICC) and modify the results according to the Cochrane guidelines (89). If an ICC is not present, the trial authors will be contacted or an ICC value from a similar trial will be used (89). In the case of studies with more than two intervention groups, similar groups will be combined or only two groups will be chosen to make a single pairwise comparison (89).

Measures of treatment effect: The standardized mean difference (SMD), with the two-sided 95% confidence interval (CI), between the intervention and control group will be used to estimate effect sizes for short, moderate, and long-term PA maintenance. The SMDs will be calculated using trial-specific PA outcome measures, and will be interpreted as small (<0.40), medium (0.40 – 0.70), or large (>0.70) (97). For dichotomous outcomes (e.g. percentage of people meeting a specified PA level) the log odds ratios (OR) will be calculated and converted to

SMDs using Cochrane guidelines (97). Physical activity effect sizes from an intention-to-treat analysis will be utilized if possible. If more than one physical activity measure is used in a trial, the authors will prioritize the measure that is validated and bear the most resemblance to the trial objective (e.g. if a trial investigates fitness walking, then we will prioritize brisk walking duration over steps taken).

Missing data*:* Trial authors will be contacted to obtain insufficient or missing information. Missing standard deviation values will be estimated from standard errors, confidence intervals, t values, and/or P values according to Cochrane guidelines (97).

Assessment of heterogeneity*:* We will assess statistical heterogeneity using the I^2 statistic (89,96). The level of heterogeneity will be judged according to the following criteria: Low (I^2: 0-40%), may be moderate (I^2: 30-60%), may be substantial (I^2: 50-90%), and considerable (I^2: 75-100%) (89).

Meta-Analysis: The PA maintenance estimates will be combined using Cochrane's RevMan 5.3.5 (Copenhagen: The Nordic Cochrane Centre, Cochrane) software for short (three months), moderate (six months), and long (≥12 months) term follow-ups. The SMDs from studies will be weighted according to the inverse variance method and combined according to the random-effects model (89,96). If substantial or considerable heterogeneity is present, a meta-regression will be undertaken to discover the sources of such heterogeneity.

Sensitivity Analysis: A sensitivity analysis will be conducted based on how the studies differed on the risk of bias assessment. However, since the blinding of participants and personnel delivering the interventions is rarely feasible for rehabilitation trials, performance bias will not be included in this analysis. According to Cochrane's guidelines, the results of the studies with high risk will be compared to ones with low or unclear risk (89).

Moderator Analysis: Univariable and multivariable random-effects meta-regression will be carried out to investigate the sources of heterogeneity and explore the intervention characteristics associated with short, moderate, and long-term physical activity maintenance. Intervention characteristics such as setting (community, university, primary care), delivery method (individual, group, or both), delivery type (in-person or remotely), duration in months (baseline to intervention-end), outcome measure (subjective vs objective), and BCTs will be included as explanatory variables. If there are not enough studies to conduct either the univariable or multivariable meta-regression, then we will narratively summarize the potential of the pre-specified intervention characteristics in promoting PA maintenance.

Variables significant ($p<0.10$) in the univariable regression will be retained and included in the multivariable analysis. Given that we expect moderate effect sizes, the multivariable regression will be conducted if a minimum of six studies per covariate is available (99). Cramer's V will be used to judge collinearity among the explanatory variables. In the case of collinearity, only one variable will be entered into the multivariable regression. Bootstrapping will be conducted to judge the reliability of the final model. If a multivariable regression cannot be performed, the significance of the explanatory variables will be evaluated at $p<0.05$ using univariable analysis. The STATA 15 (STATA Corp LLC, Texas, USA) software will be used for both the univariable and multivariable regression analysis.

Assessing Certainty in Findings

Meta bias: We will assess publication bias by using funnel plots and the Egger test if there are ≥10 studies. We will also subjectively comment on the overall outcome reporting bias by gauging how studies performed on the "selective outcome reporting" section of the Risk of Bias Tool.

Confidence in cumulative evidence: We will assess the certainty of evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology (100). A summary of findings (SoF) table will be created using GRADEPro GDT (McMaster University, ON, Canada). The outcomes within the SoF table will include the pooled short, moderate, and long-term PA maintenance estimates. The SoF will provide the following information where appropriate: within-study risk of bias, inconsistency of results, directness of evidence, precision of effect estimates, and publication bias.

Conflicts of Interest: The authors declare no conflicts of interest.

Chapter 3

Intervention-related Factors Associated with Physical Activity Maintenance Among Individuals with Stroke

A Systematic Review and Meta-Analysis

Abstract

Background: Physical activity can have beneficial effects on post-stroke recovery; however, many individuals with stroke do not maintain recommended levels of physical activity in their free-living environment.

Objectives: *Primary:* To investigate the effects of current rehabilitation interventions in promoting short (3-month), moderate (6-month), and long-term (≥12months) physical activity maintenance among individuals with stroke. *Secondary:* To investigate the intervention characteristics associated with the promotion of physical activity maintenance among individuals with stroke.

Data Sources: PsycINFO, Medline, EMBASE, SPORTDiscus, CINAHL, and the Cochrane Central Register of Controlled Trials were searched for studies published up to July 2019.

Study Selection: Randomized controlled trials that included adults ≥ 18 years post-stroke, assessed physical activity using subjective or objective measures at a minimum 3-month follow-up, and were published in English.

Data Extraction: Study data were extracted by two independent reviewers. Study quality was assessed using the Cochrane Risk of Bias Tool and interventions were coded using the Behavior Change Technique Taxonomy version 1.

Synthesis: Random-effects meta-analysis was performed by grouping effect sizes from similar physical activity outcomes at each timepoint. The certainty of evidence was assessed using GRADE.

Results: Seven articles were included. The effect sizes of steps walked/day at 3-months, time spent in moderate-vigorous physical activity at 3-months, and self-reported measures at 3- and 6-

months were pooled. Only self-reported physical activity at 3-months showed a difference between the intervention and control groups (standardized mean difference=0.22, 95% confidence interval, 0.01 to 0.42; I^2 = 0%; GRADE rating: very low). The intervention characteristics associated with physical activity maintenance could not be explored due to the low number of trials.

Conclusion: There was a small difference between intervention and control groups at the 3-month follow-up. Further behavioral change interventions with longer follow-ups and standardized outcome measures are required to evaluate activity maintenance.

PROSPERO Registration: CRD42019131056

Funding: None

Introduction

Stroke is the second leading cause of mortality and the third leading cause of disability in the world (16). Within Canada, there were 405,000 individuals living with stroke in 2016, costing the government $3.6 billion annually in healthcare and lost productivity (17,101). This number is projected to increase to 726,000 survivors by 2038 further increasing individual and social burden (17). As a further complication, the cumulative risk of recurrent stroke is also high following first-ever stroke: 26% at five years and 39% at 10 years (102). Physical activity (PA) and exercise can have positive impacts on post-stroke recovery. Physical activity is defined as "any bodily movement produced by the skeletal muscles that results in energy expenditure" (page 126), while exercise is a subgroup of PA that is planned, structured, and repetitive with the aim of improving and/or maintaining physical fitness (24).

Physical activity and exercise after stroke can improve balance and walking capacity (4), increase upper and lower limb strength (5), improve cognitive function (7), attenuate depressive symptoms (6), and can have positive effects on cardiovascular risk factors (8,9). However, it is doubtful whether individuals following a stroke meet the recommended PA guidelines (103). Therefore, improved rehabilitation programs need to be developed that help individuals remain active within free-living environments. To do so, *the efficacy of current stroke rehabilitation programs in promoting PA maintenance needs to be assessed, and the intervention characteristics associated with PA maintenance need to be identified.*

Interventions to change behaviors (such as PA) often involve a complex combination of components that make identification and between-study comparison of active ingredients difficult (92). Thus, it is important to employ a standardized taxonomy to code the active ingredients, or the Behavioural Change Techniques (BCTs), of such interventions (92). To

facilitate the classification of BCTs across trials, the Behavior Change Technique Taxonomy version 1 (BCTTv1) can be used, which defines 93 BCTs and groups them into 16 clusters (92). Since its introduction, the taxonomy has been used to identify the BCTs of interventions spanning a wide range of behaviors (104).

Another important factor is the timepoint used to estimate PA maintenance. Setting an *a-priori* timepoint is complicated due to the lack of consensus that exists among researchers concerning how to define maintenance of behavior (93). Some researchers define maintenance as the time when a behavior is *effortlessly* carried out (94), while others consider a newly-acquired behavior as maintained when it is *more likely* to be performed across times and contexts compared to old behaviors (95). However, it is difficult to adopt such conceptual definitions in reviews because most activity outcome measures do not report the automaticity or probability of performing PA (25).

Hence, some reviewers have opted to calculate maintenance at a pre-specified timepoint from baseline (85). However, this definition can misconstrue estimates as it does not account for the variability of the intervention duration across trials. For example, if a review calculates maintenance effect sizes at a timepoint set at six months post-baseline, it may encounter trials with an intervention period lasting for 3- months or 6-months. The trial with the 3-month intervention period would therefore assess maintenance after a 3-month follow-up, while the trial with the 6-month intervention period would assess maintenance immediately after the end of the intervention. Such heterogeneity in intervention durations can be addressed by assessing maintenance at a timepoint *following the end of the intervention period* (105). Thus, following previous reviews, we opted to classify short, moderate, and long-term PA maintenance at a *post-intervention follow-up* timepoint of three, six, and ≥12 months respectively (12,13).

A search of the International Prospective Register of Systematic Reviews (PROSPERO), Embase, Medline, CINAHL, SPORTDiscus, and the Cochrane Database of Systematic Reviews identified two previous reviews that had narratively described PA maintenance among stroke survivors (12,13). While such narrative syntheses provide valuable information, they contain the associated risk of assigning disproportionate weights to studies that could bias the size, direction, consistency, and strength of evidence (89). It is therefore preferable to combine both quantitative and narrative synthesis techniques to acquire a comprehensive judgment of intervention effects (89). Neither of the previous reviews conducted a meta-analysis and justified this decision by citing the clinical diversity between trials (12,13). However, the inclusion of quasi-experimental trials, non-PA outcome measures, and/or participants without a stroke diagnosis (e.g. participants with Transient Ischemic Attacks (TIA)) in these reviews could have contributed to the high clinical heterogeneity perceived by the authors (12,13). Finally, even if heterogeneity exists between studies, an exploration of the sources of such diversity can provide valuable information regarding the intervention characteristics that are associated with PA maintenance.

Hence, the objectives of the review are:

> *Primary:* To investigate the effects of current interventions in promoting short- (3-months), moderate- (6-months), and long-term (≥12 months) PA maintenance among individuals with stroke.
>
> *Secondary:* To investigate the intervention characteristics associated with short-, moderate-, and long-term PA maintenance among individuals with stroke.

Methods

This systematic review is reported according to the PRISMA guideline (106). It was registered with PROSPERO on May 5, 2019 (registration number: CRD42019131056) and the review protocol has been published (107).

Data Sources and Searches

The following databases were searched for articles from their inception until July 30, 2019: Ovid PsycINFO, Ovid Medline, Ovid EMBASE, EBSCO SPORTDiscus, EBSCO CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL). Grey literature was searched using Google Scholar. The references of all included articles and relevant reviews were also hand searched. The search strategy included medical subject headings and keywords for stroke, PA, RCTs, and follow-up. Terms for stroke were adapted from the Cochrane Stroke Group search strategy and appropriate PA terms were created using insights from previous reviews (12,13,85). Since this review investigated short, moderate, and long-term PA maintenance, search terms to capture three, six, and ≥12 months follow-up timepoints were created. The title and abstracts of studies included in previous reviews were searched to evaluate the accuracy of the follow-up terms used in this paper (12,13). All searches were reviewed by a librarian from the Health Sciences Department of McMaster University. A sample search strategy is included in the review protocol (107).

Study Selection

This review included randomized controlled trials (RCTs) or cluster RCTs that were published in English, recruited adults (age≥18 years) who had a confirmed diagnosis of stroke (ischemic or hemorrhagic), and a follow-up of at least 3 months. If study participants had more than one diagnosis, then the analysis for the participants with stroke had to be done separately.

The study intervention had to address PA directly (for example, by incorporating PA self-monitoring strategies) or indirectly by influencing participants' functional outcomes (for example, by improving their gait or balance). Surgical, pharmaceutical or nutrition-based interventions were excluded. Usual care, passive rehabilitation, programs that do not aim to increase PA, programs that do not promote PA maintenance, or no intervention provided was accepted as possible control groups. Studies also needed to include objective (e.g. accelerometers, pedometers, direct observation) or self-reported (e.g. logbooks, diaries, or questionnaires) PA outcome measures. Studies were excluded if they only reported sedentary time, walking or exercise capacity, gait patterns, or the performance of activities of daily living.

Risk of Bias

The quality of individual studies was assessed using the Cochrane risk of bias tool (89). Independent reviewers (MM and EC) assigned a rating of high risk, low risk, or unclear risk for each of the tool's six domains: selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias. Discrepancies in judgment were resolved through consultation with the third reviewer (JR).

Data Extraction and Quality Assessment

Literature search results were uploaded to the Covidence data management software and duplicates were removed. Two independent reviewers (MM and EC) conducted the title and abstract screening, full-text selection, and data extraction (data extraction form is included in the review protocol). Calibration exercises were conducted before each stage of the selection process; however, kappa statistics were not calculated to ascertain rater agreement as per Cochrane guidelines (89). Each reviewer was also trained on coding BCTs from the intervention

descriptions using modules from the BCT-Taxonomy Training website (98). Discrepancies in judgments were resolved via consultation with the third reviewer (JR).

Publication bias was assessed using the Egger test if ≥10 studies were available and certainty in the cumulative evidence was judged using GRADE (100).

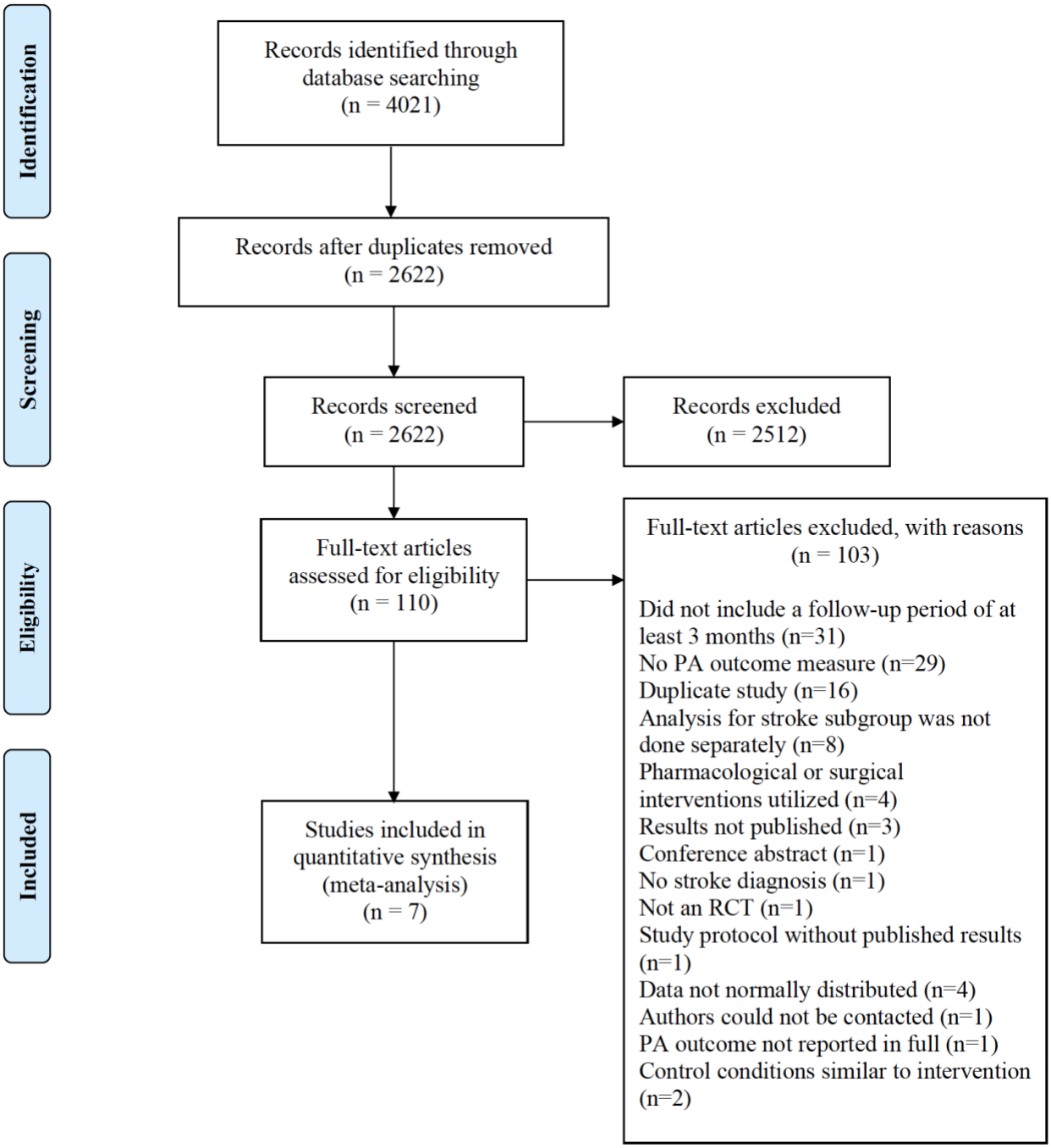
Data Synthesis and Analysis

The standardized mean difference (SMD) with 95% confidence intervals (CI) between the intervention and control group was used to estimate effect sizes for short, moderate, and long-term PA maintenance. These estimates were meta-analyzed using RevMan 5.3.5 (Copenhagen: The Nordic Cochrane Centre, Cochrane) and according to the random effects model and inverse variance weighting method (89). The effect sizes were interpreted as small (<0.40), medium (0.40 – 0.70), or large (>0.70) (89). Statistical heterogeneity was calculated using the I^2 statistic and judged according to the following criteria: low (I^2: 0-40%), may be moderate (I^2: 30-60%), may be substantial (I^2: 50-90%), and considerable (I^2: 75-100%) (89). Univariable and multivariable random-effects meta-regression analysis was attempted using STATA IC 15 (STATA Corp LLC, Texas, USA) to explore the association of pre-specified intervention characteristics (outlined in study protocol) with PA maintenance (107).

Results

The search strategy yielded 4021 trials and 11 studies met the inclusion criteria (108–117). However, two of those studies were excluded because their data were not normally distributed and could not be included in the meta-analysis (115,117). One study included the PA effect estimates in the form of a line graph and the authors could not be contacted to acquire written estimates (118). One study was also excluded because the authors reported PA estimates from the sports and leisure subscales of the Baecke physical activity questionnaire without combining the total score (116). In the end, data from seven trials (108–114) published between 2006 and 2018 were analyzed and pooled in the meta-analysis. *Figure 1* summarizes the selection process as a PRISMA flow diagram.

Figure 1: Prisma Flow Diagram



Participant Characteristics

Across the seven studies, there were 518 participants (intervention group, n=258; control group, n=260) with approximately 38% being female. Participants' age ranged from 56.7 years to 76.0 years. At baseline, four trials included participants between 1- and 4-months post-stroke and two trials included participants who were 40 to 70 months post-stroke. Outcomes measures corresponding to the activity/disability domain of the International Classification of Functioning, Disability, and Health were used to assess participants' limitations in activity (119). Four trials included participants with low to moderate limitations in activity: *Functional Independence Measure>100* (120); *Modified Rankin Scale<4* (119); *Berg Balance Scale>41* (121). However, three trials included participants with moderate to severe limitations in activity: *Barthel Index Score = 21-60* (122); *six-minute walk test distance<350m* (123). Participants did not demonstrate cognitive impairment (*Mini-Mental State Examination>24* (119) and *Abbreviated Mental Test Score>7* (124)) in all but two trials where cognitive outcomes were not reported.

The participant characteristics are summarized in *Table 1*.

Table 1: Participant Characteristics Table

Study ID, Country	Sample Size	Age (years)	Sex Female: n(%)	Time Since Stroke at Baseline (Months)	Activity & Disability Outcomes	Cognitive Function
Batchelor et al. (2012) Australia	Int: 71 Con: 85	Mean±SD Int: 70.8 ± 11.4 Con: 72.2 ± 9.9	Int: 26(36.60) Con: 31(36.47)	Mean±SD Int: 3.0 ± 1.6 Con: 3.1 ± 1.9	Functional Independence Measure (Mean±SD) Int: 107.7±14.6 Con: 106.8±18.3	Abbreviated Mental Test Score (Median(IQR)) Int: 9.0(2.0) Con: 9.0(2.0)
Dean et al. (2017) United Kingdom	Int: 23 Con: 22	Mean±SD Int: 70.0 ± 12 Con: 70.0 ± 10	Int: 7(30.23) Con: 8(36.36)	<3 Months Post-Stroke (n(%)) Int: 1(4) Con: 0(0) At >3 Months Post-Stroke (n(%)) Int: 22(96) Con: 22(100)	Simplified Modified Rankin Scale Score<4 (n(%)) Int: 22(100) Con: 23(100)	Mini-Mental State Examination Score (Mean±SD) Int: 27.5(2.54) Con: 27.9(3.01)
Kanai et al. (2018) Japan	Int: 23 Con: 25	Median (IQR) Int: 74.0(62.0 – 76.0) Con: 67.0(56.5 – 69.5)	Int: 15(65.22) Con: 15(60.00)	Median (IQR) Int: 4.1 (3.5 – 4.5) Con: 3.9 (3.7 – 4.2)	Berg Balance Scale Score (Median (IQR)) Int: 56.0(55.0-56.0) Con: 56.0(54.5-56.0)	Multiple Mini-Mental State Score≥23
Mudge et al. (2009) New Zealand	Int: 31 Con: 27	Mean (range) Int: 76.0(39.0-89.0)	Int: 12(31.0) Con: 14(52.0)	Median(range) Int: 39.96(7.2-15.96) Con: 69.96(6.0-224.40)	Six Minute Walk Test Distance (m) (Mean±SD) Int: 263±110	Not available

		Con: 71.0(44.0-86.0)			Con: 201±99	
Olney et al. (2006) Canada	Int: 37 Con: 35	Mean±SD Int: 63.5(12.0) Con: 65.8(11.6)	Int: 14(37.6) Con: 13(37.1)	Mean±SD Int: 4.1(4.4) Con: 3.4(3.9)	Six Minute Walk Test Distance (m) (Mean±SD) Int: 262.8±129.6 Con: 273.6±122.4	Not available
Vanroy et al. (2017) Belgium	Int: 33 Con: 26	Median (IQR) Int: 66.7(8.8) Con: 63.8(11.8)	Int: 13(39.4) Con: 8 (30.8)	Mean±SD Int: 50.5(19.8) Con: 48.5(19.2)	Barthel Index (Median (IQR)) Int: 30(15-70) Con: 32.5(15-65)	Mini-Mental State Examination (Median (IQR)) Int: 26.5(24-28.5) Con: 28(27-28)
Wan et al. (2016) China	Int: 40 Con: 40	Mean±SD Int: 60.24(12.57) Con: 59.07(12.36)	Int: 10(25.0) Con: 13(32.5)	Participants enrolled one month after experiencing a stroke	Modified Rankin Scale Score<4 (n(%)) Int: 80(100) Con: 78(100)	Not available

Int = Intervention Group; Con = Control Group; SD = Standard Deviation; IQR = Interquartile Range

Interventions

Intervention programs used a combination of exercise programs (upper and/or lower extremity exercises; supervised and/or home-based exercises), aerobic-training, self-monitoring strategies, and individualized consultations with staff to improve participants' PA levels. One trial included only periodic telephone-based contacts as an intervention following hospital discharge (114). These programs were delivered by healthcare professionals (nurses, physiotherapists, occupational therapists) or personal trainers, and not multidisciplinary teams. The average duration of these interventions was 11 weeks, with program lengths ranging from 1.7 to 32 weeks. The BCTs used in each trial's intervention design are included in *Appendix C.* Five studies (108,110,111,113,114) compared interventions with inactive controls (e.g. usual care, educational sessions/brochures, passive rehabilitation, social bonding) and two trials (109,112) included control conditions with exercise components.

Follow-up

Four (109,110,113,114) trials included only a 3-month follow-up. One trial (108) included a 6-month follow-up and two trials (111,112) included a 9-month follow-up in addition to a 3-month follow-up. Trials with the 9-month follow-up were used to evaluate moderate (6-month) PA maintenance because long-term PA maintenance was defined as having a ≥12-month follow-up. None of the identified trials included a long-term (≥12 months) follow-up.

Physical Activity Outcome Measures

Two trials (108,109) used only objective measures, three trials (112–114) used only self-reported measures, and two trials (110,111) used both objective and self-reported measures to evaluate participants' PA levels. The objective PA measures included accelerometers (108,109), pedometers (111), and activity monitors (110,111) that were used to evaluate the steps

walked/day (109–111), time spent in MVPA (min/day) (108,109), and energy expenditure (kcal/24hours) (111). The self-reported PA measures included the Human Activity Profile (Adjusted Activity Score) (112,114), Physical Activity and Disability Scale (110), Health-Promoting Lifestyle Profile II (114), and the Physical Activity Scale for Individuals with Physical Disabilities (111).

The study characteristics are summarized in *Table 2*.

Table 2: Characteristics of Included Studies

Study ID, Country	Intervention Condition	Intervention Deliverer	Intervention Duration	Control Condition	Follow-up Duration	Physical Activity Outcome Measurements
Batchelor et al. (2012) Australia	Tailored home-based exercise program, self-monitoring with recording sheets, fall risk minimization education and booklet, injury risk minimization strategies	Physiotherapist	32 weeks	Usual care, fall prevention booklet	4 months	Human Activity Profile - Adjusted Activity Score
Dean et al. (2017) United Kingdom	Functional strengthening exercises, balance and coordination activities, functional mobility tasks, individualized home-based program, individualized consultations with trainer	Personal Trainers	12 weeks	Usual care, exercise advice booklet	3 months 6 months	Average minutes spent/day in total, light, moderate, vigorous, and moderate-vigorous physical activity measured using a wrist-worn accelerometer
Kanai et al. (2018) Japan	Supervised exercise program, self-monitoring using accelerometer, individualized consultations with physical therapist	Physical Therapist	1.7 weeks	Inpatient rehabilitation program	3 months	Average steps walked/day measured using Fit Bit One accelerometer Time spent in MVPA (min/day) measured using Fit Bit One accelerometer
Mudge et al. (2009)	Graded circuit exercise program composed of gait or standing balance activity, lower extremity muscle strengthening, and stretching	Principal Investigator	4 weeks	Social bonding and stroke management educational sessions	3 months	Average steps walked/day measured using the StepWatch Activity Monitor

New Zealand		Physiotherapy Students				Physical Activity and Disability Scale
Olney et al. (2006) Canada	Supervised tailored exercise sessions composed of aerobic and strength training	Unspecified	10 weeks	Supervised exercise sessions (1 week) + Verbal/written instructions	3.5 months 9.5 months	Human Activity Profile-Adjusted Activity Score
Vanroy et al. (2017) Belgium	Aerobic training (cycling) and educational sessions on stroke risk factors and active living	Unspecified	12 weeks	Passive mobilization therapy for the paretic hip and knee	3 months 9 months	Number of steps walked/day measured using a pedometer (Yamax Digiwalker SW-200) Physical Activity Scale for Individuals with Physical Disabilities Energy Expenditure (kcal/24hours) measured using an activity monitor (SenseWear Pro2)
Wan et al. (2016) China	Phone-based consultations (goal setting, problem-solving, and social support), educational brochures on stroke risk factors	Nurse	4 weeks	Educational Brochure on stroke risk factors	3 months	Physical activity subscale of Health Promoting Lifestyle Profile II

MVPA = Moderate to Vigorous Physical Activity; min = minutes

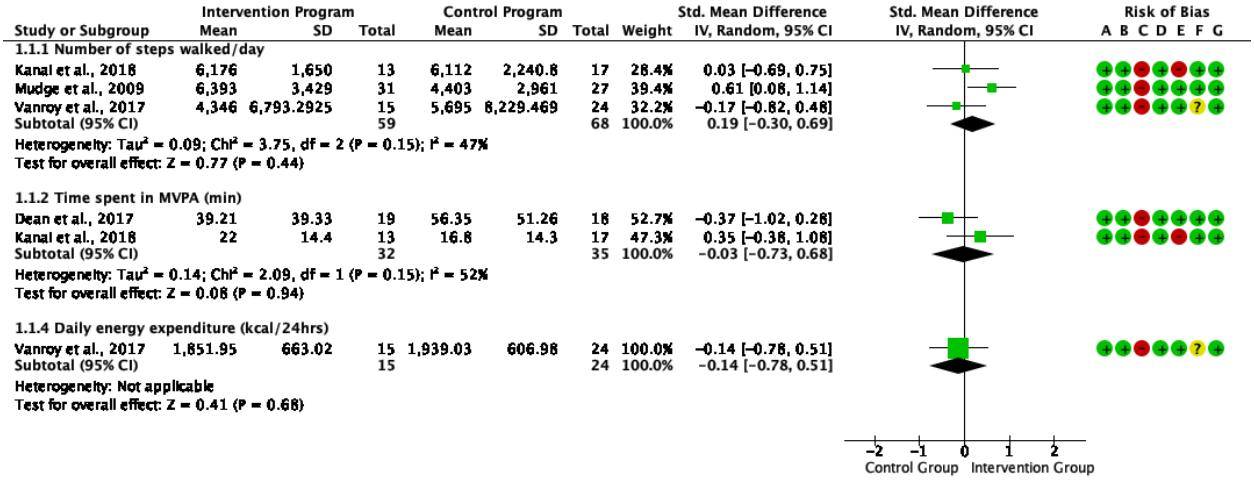
Assessment of Risk of Bias

Within-study risk of bias differed with follow-up time; therefore, visual representation of risk of bias summary was included with the forest plots of each subgroup at 3- and 6-month follow-up (*Figure 2 and Figure 3*). All seven trials were judged to have a high risk of bias for the category "blinding of participants and personnel". The risk of bias from incomplete outcome data increased (from low to high risk) for two trials (108,112) from 3- to 6-month follow-up due to increased participant attrition. Summary of the risk of bias judgments are included in *Appendix D*.

Meta-Analysis

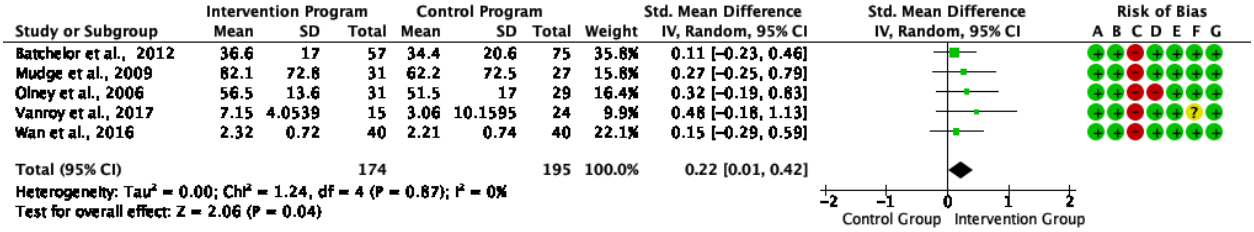
This review meta-analyzed the PA effect sizes for objective and self-reported PA separately at 3- and 6-month follow-up (*Figure 2-5*). The following PA outcomes were only assessed in one trial and therefore could not be pooled: total energy expenditure (kcal/24 hours) at 3-and 6-month follow-up, steps walked/day at 6-month follow-up, time (min) spent in MVPA at 6-month follow-up. There were no differences between intervention and control groups for the steps walked/day at the 3-month (SMD 0.19; 95% CI -0.30 to 0.69; I^2 = 47%; GRADE rating: Very Low), time spent in MPVA at the 3-month (SMD -0.03; 95% CI -0.73 to 0.68; I^2 = 52%; GRADE rating: Very Low), or self-reported PA at the 6-month follow-up (SMD 0.40; 95% CI -0.02 to 0.82; I^2 = 0%; GRADE rating: Very Low). Only the pooled estimate of the self-reported measures at the 3-month follow-up was above the line of no-effect (SMD 0.22; 95% CI 0.01 to 0.42; I^2 = 0%; GRADE rating: Very Low). The certainty of cumulative evidence is outlined in the summary of findings table (*Table 4*).

31Figure 2: Number of steps walked, time spent in MVPA, and daily energy expenditure at three-month follow-up assessed using objectives measures



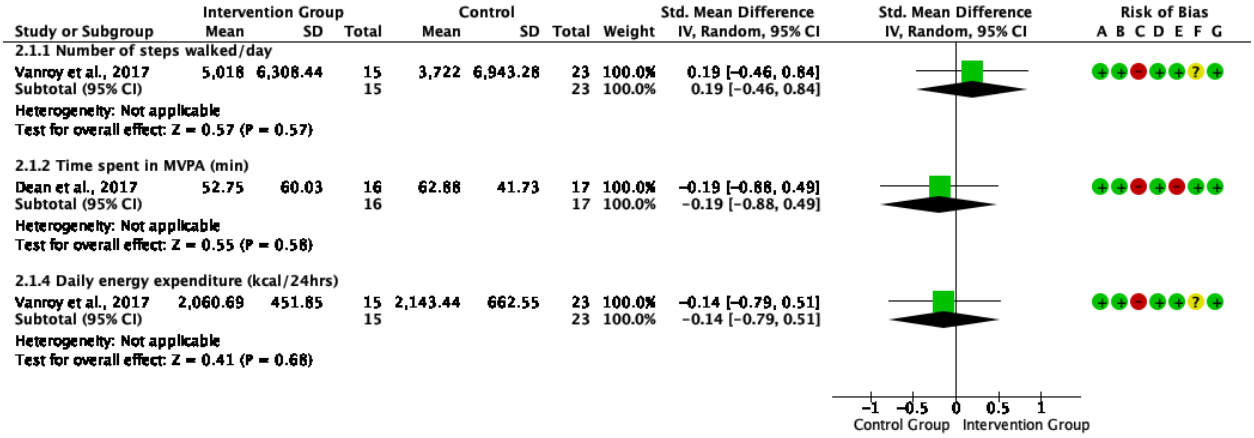
Risk of bias legend
(A) Allocation concealment (selection bias)
(B) Random sequence generation (selection bias)
(C) Blinding of participants and personnel (performance bias): Objective Measures
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias): 3 Month Follow-up
(F) Selective reporting (reporting bias)
(G) Other bias

Figure 3: Self-reported physical activity at three-month follow-up



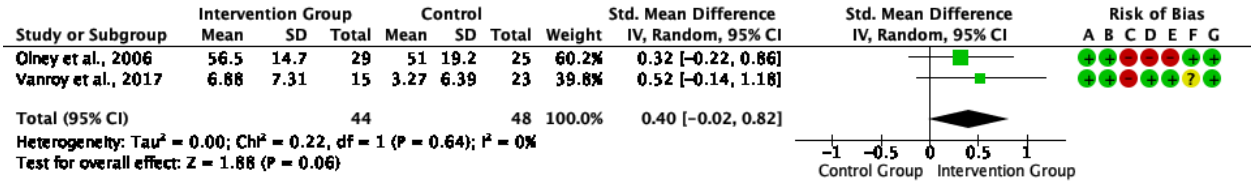
Risk of bias legend
(A) Allocation concealment (selection bias)
(B) Random sequence generation (selection bias)
(C) Blinding of participants and personnel (performance bias): Self-report Measures
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias): 3 Month Follow-up
(F) Selective reporting (reporting bias)
(G) Other bias

1Figure 4: Number of steps walked, time spent in MVPA, and daily energy expenditure at six-month follow-up assessed using objectives measures



Risk of bias legend
(A) Allocation concealment (selection bias)
(B) Random sequence generation (selection bias)
(C) Blinding of participants and personnel (performance bias): Objective Measures
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias): 6 Month Follow-up
(F) Selective reporting (reporting bias)
(G) Other bias

Figure 5: Self-reported physical activity at six-month follow-up



Risk of bias legend
(A) Allocation concealment (selection bias)
(B) Random sequence generation (selection bias)
(C) Blinding of participants and personnel (performance bias): Self-report Measures
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias): 6 Month Follow-up
(F) Selective reporting (reporting bias)
(G) Other bias

Table 4: Summary of findings table of pooled physical activity outcomes at the three- and six-month follow-up

Certainty assessment							№ of patients		Effect	Certainty
№ of studies	**Study design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other**	**intervention**	**control**	**Absolute (95% CI)**	
Number of steps walked per Day at three-month follow-up (assessed with: Accelerometer or Pedometer)										
4	randomized controlled trials	serious [a]	not serious	serious [b]	serious [c]	none	58	68	SMD **0.19 SD higher** (0.3 lower to 0.69 higher)	⨁◯◯◯ VERY LOW
Time Spent in MVPA at Three Month Follow-up (assessed with: Accelerometer)										
2	randomized controlled trials	serious [a]	not serious	serious [d]	serious [c]	none	32	35	SMD **0.03 SD lower** (0.73 lower to 0.68 higher)	⨁◯◯◯ VERY LOW
Self-report Measures at Three Month Follow-up (assessed with: HAP-AAS, PADS, PASIPD, HPLP II)										
6	randomized controlled trials	serious [a]	not serious	serious [b]	serious [c]	none	174	195	SMD **0.22 SD higher** (0.01 higher to 0.42 higher)	⨁◯◯◯ VERY LOW

Certainty assessment							№ of patients		Effect	Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other	intervention	control	Absolute (95% CI)	
Self-reported PA measures at Six Month Follow-up (assessed with: PASIPD/HAP-AAS)										
2	randomized controlled trials	serious [a]	not serious	serious [b]	serious [c]	none	44	48	SMD **0.4 SD higher** (0.02 lower to 0.82 higher)	⨁◯◯◯ VERY LOW

CI: Confidence interval; **SMD:** Standardized mean difference

Explanations

a. Possible bias from lack of blinding of participants and personnel

b. Participants in three trials had moderate to severe limitations in activity.

c. There were <400 participants for outcome comparison.

d. Variability in control group treatments.

Sensitivity Analysis

We could not compare the pooled effect estimates of studies with high vs low risk of bias (as outlined in the study protocol) because the trials within each PA outcome had a similar risk of bias profile (107). However, we did not account for the differences in control groups (exercise-based vs. inactive). Thus, we conducted a post-hoc sensitivity analysis – as permissible by the Cochrane Handbook (89) – by pooling the results of trials with only inactive control groups. After removing the two trials that contained exercise-based control groups (109,112), only the effect sizes from the steps walked/day (n=2 trials) and self-reported measures (n=4 trials) at the 3-month follow-up timepoint could be pooled. There were no significant differences (p>0.90) in the pooled effect sizes of the original meta-analysis and sensitivity analysis (*Figures 6 and 7*).

Figure 6: Meta-analysis of the number of steps walked/day at 3-month follow-up using combined vs. inactive controls

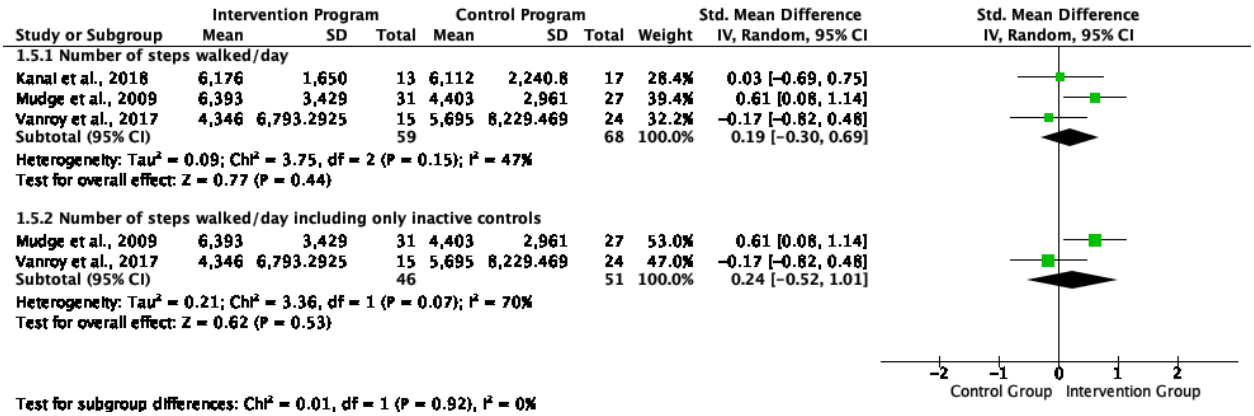
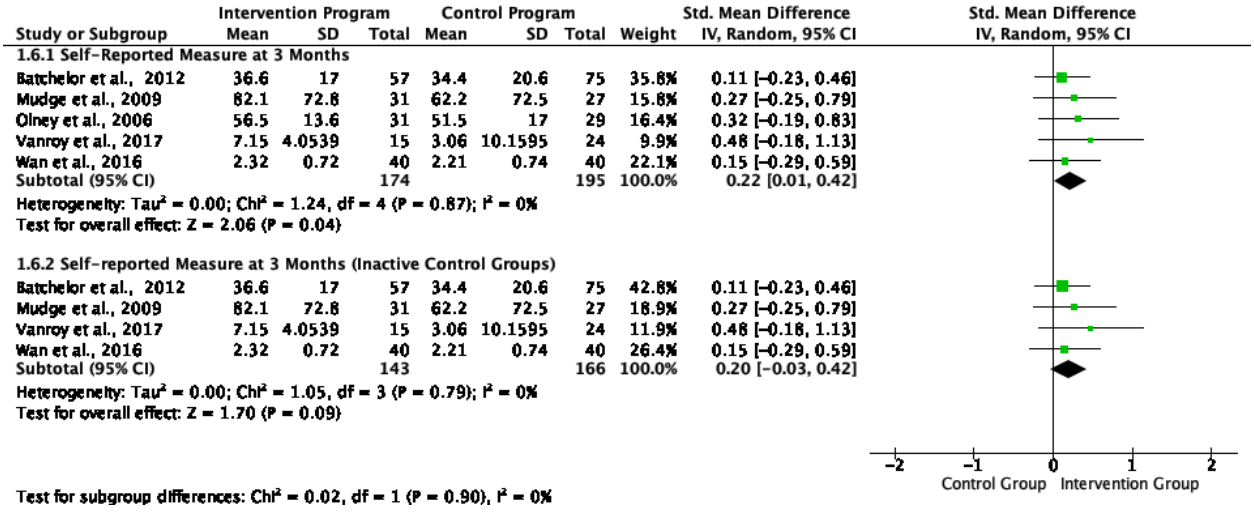


Figure 7: Meta-analysis of self-reported physical activity at 3-month follow-up using combined vs. inactive controls



Meta-regression

We could not conduct a meta-regression because the low number of trials in each of the PA outcomes meant that there would be a high risk for both false positive and false negative findings (89). Additionally, trials within each PA outcome subgroups had effect estimates close to each other, had overlapping 95% CIs, and had similar intervention characteristics. Thus, we also could not systematically identify and summarize the relative effects of the pre-specified intervention characteristics in promoting PA maintenance.

Discussion

This was the first review to meta-analyze the effects of current stroke rehabilitation programs in short (3 months) and moderate (6 months) PA maintenance according to: *steps walked/day, time spent in MVPA, daily energy expenditure, and self-reported PA.* Only self-reported PA at 3-month follow-up demonstrated a non-zero pooled effect size. A post-hoc

sensitivity analysis with inactive versus exercise-based control groups did not demonstrate significant changes in the pooled estimates for the affected PA outcomes: *steps walked/day and self-reported PA at the 3-month follow-up.* With regards to the secondary aim, we were unable to explore the intervention characteristics associated with PA maintenance due to the low number of trials, close effect estimates, overlapping confidence intervals, and similarities in trial design.

Strengths

This review used a robust methodology with a peer-reviewed protocol (107) to reduce between-study heterogeneity, minimize bias, and add additional insights to the current stroke rehabilitation literature. Two independent reviewers coded the trial interventions using a standardized, validated, and widely used taxonomy of behavioral change techniques (BCTTv1) to describe interventions (92). A previous review by Morris et al. (2014) grouped interventions into two broad categories: *tailored counseling* and *tailored supervised exercises* (92). However, by doing so, details of the often complex and multifaceted behavior change interventions could have been lost. For example, categorizing interventions that used "monitoring of PA goals" and "motivational interviewing" into the broad group of *tailored counseling* combines two different BCTs (92). The first technique entails participants "self-monitoring" themselves while the second technique provides "social support" to improve PA levels (12). These different techniques could contribute to varying effect estimates that a broad categorization would not be able to distinguish. By using a standardized and validated taxonomy, this review provided nuanced documentation of BCTs currently being employed in stroke rehabilitation programs (92).

Additionally, in contrast to the previous reviews, this paper used strict inclusion criteria to reduce between-study heterogeneity. For example, we only included trials that recruited

participants with a confirmed stroke diagnosis while previous reviews also included individuals with TIA (12,13). Unlike stroke, TIA does not produce residual disability that can markedly influence how participants approach PA after discharge from hospital or outpatient rehabilitation programs. Additionally, the previous reviews included non-PA outcome measures (e.g., six-minute walk test, Frenchay Activities Index, 10m walk test, etc.) that could have contributed to greater perceived between-study heterogeneity (12,13). In contrast, this review only included validated objective and self-reported PA outcomes measures and also grouped similar PA outcomes in the meta-analysis. The use of SMDs to calculate effect sizes and the random-effects model to pool the results further accounted for heterogeneity in outcome measures and population characteristics respectively (89).

Comparison of Results with Previous Reviews

The results of this paper differed in some respects from previous reviews. For example, Morris et al. (2014) identified *tailored supervised exercises* and Moore et al. (2018) reported nine BCTs as intervention characteristics with the potential to promote PA maintenance (12,13). However, both reviews employed a narrative synthesis of trial results that possesses the risk of selectively over or underweighting effect estimates (89). Our analysis showed that the current literature does not afford the statistical power to explore whether some intervention characteristics are more efficacious than others in promoting post-stroke PA maintenance.

These insights have important implications for future trial design as it discourages the reliance on pre-specified BCTs. Instead, per the advice from Michie et al. (2011), it encourages the consideration of all BCTs, with the selection of appropriate ones being driven by the needs of participants and/or trial feasibility (125). This type of intervention design language was implemented in the pilot trial by Dean et al. (2018) that chose BCTs based on consultations with

participants (108). Intervention design frameworks such as the *Behavior Change Wheel* can also facilitate the selection of BCTs based on a ***systematic evaluation*** of the target behavior, the mechanisms of behavior change, and feasibility constraints of a trial (126). With a more developed body of literature, future reviewers can be better equipped to both narratively and quantitatively evaluate the intervention characteristics associated with PA maintenance.

Similar to previous reviews, the number of eligible trials identified decreased with increasing follow-up time (13). Three of the included trials had 6-month follow-up assessments, but no trials with long-term follow-up (≥12 months) were identified. While there are no established guidelines for assessing behavior change maintenance, some researchers have purported that a minimum 6-month follow-up is required based on the tenets of the Transtheoretical Model of behavior change (85,127,128). Several factors may have led to the unavailability of longer follow-ups in these trials including: a lack of pre-established protocols for the follow-up period, high participant attrition rates, loss of study infrastructure after the end of a trial, or inability to acquire funding for the follow-up period (129). Thus, it is recommended that such challenges be addressed when developing future trial protocols to include longer follow-ups (minimum of 6-months) to properly assess activity maintenance.

With regards to outcome measures, trials used various objective and self-reported measures to investigate different dimensions of PA. The grouping of trials with similar outcomes in this review decreased the number of trials within each pooled estimate. Thus, utilizing a standardized physical activity outcome across trials would allow effect estimates to be pooled within one group, thereby improving the precision of meta-analyzed results and increasing the statistical power for future meta-regression analysis. When choosing outcome measures, it is important to consider that most guidelines frame physical activity recommendations using energy

expenditure (*metabolic equivalent minutes*) or time (*minutes*) spent in MVPA over 7 days (36–38,130). However, only two trials identified in this review reported physical activity as time spent in MVPA/day. Heterogeneous outcomes that do not correspond to guideline metrics (*steps walked/day; daily total energy expenditure*) make it difficult to assess whether participants are meeting adequate duration and intensity of physical activity and complicate between-study comparison of results (131–133).

Another important consideration is whether to use self-reported questionnaires or objective measures to assess physical activity. Most of the trials included in this review used self-reported questionnaires that may be attributed to the measures' low cost and ease of administration (26,39,40). However, self-reported questionnaires are subject to recall and social desirability bias, less accurate than objective measures for quantifying MVPA (especially at an individual level), and participants' responses are influenced by the wording used in the questionnaires (25,26,40,41). Contrarily, the use of objective measures (e.g. accelerometers) has been increasing due to their compact size, ability to capture large amounts of data, general acceptability by individuals with stroke, and accuracy with measuring MVPA (25,26,40). Thus, reporting physical activity as energy expenditure from, or time spent in, MVPA measured using objective measures (e.g. accelerometers) is recommended.

Study Limitations

The main limitation of this review was the low number of trials that were included in the analysis due to our stringent inclusion criteria. The lack of trials prevented us from conducting a meta-regression and evaluating the relative efficacies of intervention characteristics in promoting PA maintenance. Additionally, three of the seven trials included participants with moderate to severe limitations in activity. Since we did not have access to the patient-level data, it was not possible to conduct a sensitivity analysis based on this participant characteristic.

Conclusion

The benefits of PA post-stroke have been well established. As such, rehabilitation programs need to be developed with the aim of both improving and maintaining participants' PA levels. This review yielded important insights into the current state of the post-stroke rehabilitation literature with regards to PA maintenance. The results of this review demonstrated that interventions achieved a small effect size (using self-reported measures) for a short period following the end of an intervention. Additionally, due to the low number of trials investigating post-intervention PA of participants, we were unable to investigate the relative efficacies of intervention characteristics with promoting PA maintenance. However, our study results provide direction for authors of future trials to explore design features within interventions that are congruent with their participants' needs, including an emphasis on adhering to standardized outcome measures and longer follow-ups.

Chapter 4

Developing an Adaptive Treatment Strategy Targeting Maintenance of Physical Activity After Stroke: A Pilot Sequential Multiple Assignment Randomized Trial

Submitted for funding to the Heart & Stroke Foundation's Grand-in-Aid program and the Canadian Institutes of Health Research Competition Fall 2020

Abstract

Introduction: Physical activity can positively affect post-stroke recovery; however, the activity levels of stroke survivors do not meet the recommended guidelines. Tailoring interventions can promote free-living activity maintenance; however, previous stroke rehabilitation trials have not investigated *adaptive treatment strategies* (ATSs) where high-intensity interventions are sequentially tailored following the identification of increased needs. Such ATSs are developed and evaluated through *sequential multiple assignment randomized trials* (SMARTs).

Objectives: This paper outlines the protocol for investigating the *feasibility*, *acceptability*, *participant/staff satisfaction*, and to provide *preliminary estimates of effect* of a pilot SMART to develop an ATS for promoting physical activity maintenance among individuals with stroke.

Methods: *Study Design:* This is a proof-of-concept, assessor-blinded pilot SMART with 1:1 allocation ratio. *Interventions & Randomization:* Forty-two participants will be randomized to receive low-intensity interventions (*Stage 1; one month*) and will sequentially be randomized to receive higher-intensity interventions (*Stage 2; two months*) based on whether they require more support to meet physical activity guidelines. *Eligibility:* Stroke survivors (age $\geq$ 18 years) who can ambulate 10m without assistive devices and tolerate 60 minutes of activity with rest intervals. *Outcomes:* Primary outcome includes the *feasibility* (recruitment, attrition, adherence, treatment fidelity, adverse events) of carrying out a SMART. Secondary outcomes include participants' *acceptability* with intervention change, participants' and staffs' *satisfaction* with the program, accelerometry-measured *physical activity*, and self-reported *self-efficacy*. *Analysis*: Outcomes will be assessed at baseline, end of Stage 1 and 2, and 6-months follow-up (*Stage 3*). Descriptive statistics and between-group differences with 95% confidence intervals will be used to analyze primary and secondary outcomes.

Discussion: This is the first pilot SMART intended for developing and evaluating an ATS for promoting physical activity maintenance among stroke survivors. Results of this trial may inform the development of future full-scale trials where more personalized effective treatments are assigned, thereby enhancing client-centered care.

Introduction

Stroke is a second leading cause of mortality and disability in the world (16). Within Canada, 405,000 individuals were living with stroke in 2016, which is projected to increase to 726,000 survivors by 2038 (17). Physical activity is defined as "any bodily movement produced by the skeletal muscles that results in energy expenditure", while exercise is a subgroup of physical activity that is planned, structured, and repetitive with the aim of improving and/or maintaining physical fitness (24). The importance of physical activity in post-stroke recovery is well established. Physical activity and exercise after stroke can improve balance and walking capacity (4), increase upper limb strength (134), improve cognitive function (7), and attenuate depressive symptoms (6). Meta-analytic evidence also reported physical activity and exercise having positive effects on cardiovascular risk factors such as decreased systolic blood pressure, decreased fasting glucose levels, and increased high-density lipoproteins (8,9).

While the importance of physical activity is predicated in most stroke-based rehabilitation programs, very few trials design interventions with the aim of promoting activity maintenance among stroke survivors (12,13) (Chapter 2). This gap in the literature is important to address because decreased activity levels lead to a decline in cardiorespiratory fitness, which compounds the negative impacts on functional capacity and psychological wellbeing post-stroke (3). Both the American Heart and American Stroke Associations have identified investigating long-term physical activity maintenance as an important goal for future post-stroke rehabilitation research (3). These recommendations also emphasized tailoring programs to the unique needs of individuals to facilitate increased activity maintenance (3). However, with the reported annual cost associated with stroke amounting to $3.6 billion within Canada, any proposed program would have to make efficient use of the resources available (101). One way to achieve tailoring

of interventions while also optimizing resource utilization is by using Adaptive Treatment Strategies (14).

Adaptive Treatment Strategies

Adaptive Treatment Strategies (ATSs) individualize treatments by a sequence of decision rules that specify whether, how, when, and based on what measures should the intensity, dosage, type, and/or delivery of interventions be changed during the course of care (14). In general, ATSs start with low-intensity treatments (*Stage 1 interventions*) thereby conserving available resources (14). Participants' response to these initial treatments is ascertained at a pre-specified time and by a pre-specified cut-off score of a selected measure (*response measure*) (14). Participants above the cut-off score (responders) continue with the initial treatments, while participants below the cut-off score (non-responders) are provided with more intensive treatments (*Stage 2 interventions*) to support them with achieving the desired response (14). To develop a high-quality ATS, each decision rule (e.g. treatment type, response measure, response cut-off scores, and time spent in each stage) needs to be evidence-based, which require the use of consecutive expensive randomized controlled trials (14). To accelerate the development of ATSs, a Sequential Multiple Assignments Randomized Trial (SMART) design can be used (14).

Full-Scale and Pilot SMART

The central aim of a SMART is to produce a sequence of treatments that can be tailored to the target participants; that is, to create optimized ATSs (14). A SMART allows researchers to evaluate the timing, response measure, intervention sequence, and schemes for tailoring interventions through the use of randomized data (14). Within a SMART, participants are generally first randomized to one of two low-intensity Stage 1 interventions (14). Upon determining the response of participants to the initial treatment options, non-responders are

randomized to receive one of two higher-intensity Stage 2 interventions (14). Due to the novelty of the SMARTs and its departure from the general randomized controlled trial designs, it is imperative to conduct a pilot SMART to demonstrate the feasibility and acceptability of carrying out a full-scale trial (14,90). This protocol outlines the methodology for conducting a proof-of-concept pilot SMART for promoting free-living physical activity maintenance among stroke survivors.

Conceptual Framework for Intervention Design

To our knowledge, most interventions to change behavior involve a complex combination of different behavior change techniques (BCTs), and evidence regarding the potential of existing programs for promoting physical activity maintenance remain uncertain (12,13). Hence, to create the ATS intervention sequence, we used the Behavior Change Wheel (BCW) that outlines eight standardized steps for selecting BCTs based on a systematic evaluation of behavioral targets, needs of the population, and feasibility constraints (126). All BCTs from Michie et al.'s (2013) Behavior Change Technique Taxonomy version 1 were considered and the most appropriate ones were selected using the BCW (*Appendix D* provides a detailed description of this selection process) (92,126). The selected BCTs fit with two behavior change theories: **Control Theory**, which purports that a feedback loop of goal setting, self-monitoring, receiving feedback, and reviewing goals is central to behavior change (135), and **Social Cognitive Theory**, which identifies self-efficacy as the causal determinant of behavior change and outlines how it is influenced through mastery of experiences (successfully accomplishing tasks), social modeling (observing others performing a task), verbal persuasion (providing encouragement), and improved psychophysiological states (136).

Intervention Sequence

Stage 1 interventions were composed of the FIT for FUNCTION and *FIT for FUNCTION+* Level *1* programs. **FIT for FUNCTION** is a community-based wellness program created from the LiveWell partnership between YMCA, Hamilton Health Sciences, and McMaster University (137). It is composed of group and individual exercise classes and educational sessions aimed at improving community reintegration of stroke survivors (137). While the program does not include behavioral change interventions for free-living physical activity maintenance, attending the group sessions could provide sufficient motivation for individuals who possess high functional capacity, pre-stroke physical activity history, and positive beliefs about the benefits of physical activity (138). Additionally, since FIT for FUNCTION is an established program within the Hamilton area, it represents a *low-resource* intervention suitable for Stage 1.

***FIT for FUNCTION+* Level 1** adds *low-resources* intensive components from the Control Theory (goal setting and self-monitoring) to the existing FIT for FUNCTION program (135). In a review of current behavior change maintenance theories, Kwasnicka et al. (2016) identified self-monitoring as an important factor for maintaining a behavior past initiation (95). In a review by Michie et al. (2009), self-monitoring was shown to have the strongest association with post-intervention physical activity among healthy adults when compared to all other BCTs (139). Murray et al. (2017) also reported self-monitoring being associated with physical activity maintenance among healthy adults, while Samdal et al. (2017) reported both self-monitoring and goal setting being associated with PA maintenance among obese adults (11,140). Thus, *FIT for FUNCTION+* Level 1 was composed of the following BCTs: *goal setting, action planning, and self-monitoring*.

Stage 2 interventions were composed of the *FIT for FUNCTION+* Level 2 and *FIT for FUNCTION+* Level 3 programs. ***FIT for FUNCTION+* Level 2** enhanced the application of the Control Theory by including feedback and review of behavioral goals to the existing FIT for FUNCTION program (135). This intervention design corresponds with findings from Michie et al. (2009), which reported that combining self-monitoring with one or more components of Control Theory produced a greater post-intervention physical activity effect size (139). We propose that participants who require additional support beyond Stage 1 would benefit from a comprehensive intervention targeting all components of the Control Theory feedback loop. Thus, *FIT for FUNCTION+* Level 2 comprised of the following BCTs: *goal setting, action planning, self-monitoring, behavioral feedback, and review of behavioral goals*.

***FIT for FUNCTION+* Level 3** provides participants with increased support by incorporating BCTs targeted at improving self-efficacy for physical activity to the existing FIT for FUNCTION program as per the Social Cognitive Theory (136). The self-efficacy construct has been used to design a wide array of successful behavior change interventions including physical activity (141). Both Kwasnicka et al. (2016) and Rothman et al. (2004) also identified self-efficacy as an important factor for facilitating individuals' transition from behavioral initiation to maintenance (95,142). Thus, *FIT for FUNCTION+* Level 3 will include the following BCTs: *information about health consequences, problem-solving, social support, graded tasks, instruction on how to perform the behavior, and demonstration of the behavior*.

Defining the Response Measure

We defined *response* to Stage 1 interventions as meeting 500 metabolic equivalent minutes (MET-min) of energy expenditure from moderate-vigorous physical activity (MVPA) in the last 7 days. One MET is the ratio of the rate of energy expenditure while performing an

activity compared to the rate of energy expended at rest (3.5ml O_2/min/kg) (26). However, since physical activity is performed in variable intensities and duration, the MET-min can be used to standardize energy expenditure to time (26). This response measure, which roughly corresponds to performing 150 minutes of moderate or 75 minutes of vigorous-intensity physical activity per week, aligns with physical activity guidelines for adults and older adults, including people with stroke (36–38,130). It is important to note the response measure is *not an indication of the effectiveness of Stage 1 interventions*, but rather a way to *reduce participant heterogeneity and tailor the interventions to participant characteristics* (14).

Objectives

This proof-of-concept pilot SMART will be conducted to answer the following questions.

1. What is the **feasibility** (recruitment, attrition, treatment fidelity, and occurrence of adverse events) of conducting a SMART?

   Criteria for determining success of feasibility are as follows:

   - *Recruitment: 2 participants/month (based on target sample size n=42 over projected 21 months of recruitment),*
   - *Attrition: <20% over course of the study,*
   - *Adherence: >80% participants complete >80% of intervention sessions; >80% participants with ≥4 days of valid accelerometry data,*
   - *Fidelity: >80% intervention sessions delivered as intended*
   - *Adverse events: no major injuries or adverse events related to study*

2. What is participants' **acceptability** of a possible change in intervention at Stage 2 if they do not respond to Stage 1 interventions?

We anticipate that >80% of participants will rate their acceptability as "positive" or "very positive" and their agreement as "yes" or "definitely yes" with undergoing a change in treatments during Stage 2 if they do not respond to Stage 1 interventions.

3. Will participants and therapists be **satisfied** with receiving and delivering ATSs respectively?
   We believe that >80% of participants and therapists will provide a "high satisfaction" rating with the adaptive treatment strategies included in this SMART.
4. What are **preliminary estimates of effect** of the ATS on physical activity and self-efficacy for physical activity?
   We anticipate that the interventions will improve physical activity levels and participants' self-efficacy for physical activity.

Methods

Study Setting

The group exercise classes, individual exercise sessions, and the self-management sessions for *FIT for FUNCTION* will be held at the Downtown Hamilton YMCA. The group exercise sessions will maintain a class size of 12 with a staff to participant ratio of 1:4 (137). All BCTs of the *FIT for FUNCTION+* interventions, except self-monitoring, will be delivered virtually (phone or video conferencing) by the research staff as it would alleviate time and scheduling constraints associated with in-person delivery.

Eligibility Criteria

We will adopt the eligibility criteria of the FIT for FUNCTION trial (137). Participants will be eligible if they are 18 years old, experienced ischemic or hemorrhagic stroke, able to ambulate 10 m without assistive devices, can tolerate 60 minutes of activity with rest intervals, are not currently engaged in active rehabilitation, able to independently follow instructions, and

able to communicate in English. Participants will be excluded if they only experienced a transient ischemic attack or if they have communication challenges (e.g. global aphasia) that would prevent them from participating in the educational components of either the *FIT for FUNCTION* program or the *FIT for FUNCTION+* behavioral interventions. Potential participants will be initially screened by the Lead Research Coordinator for eligibility by telephone, followed by secondary in-person eligibility screening during baseline. Per standard procedure of *FIT for FUNCTION* signed medical clearance will be required to participate.

Recruitment

Participants will be recruited from: (1) inpatient acute care, inpatient rehabilitation, outpatient rehabilitation, and stroke prevention clinics at Hamilton Health Sciences; (2) family physicians who were previously informed of FIT for FUNCTION; (3) stroke recovery chapters, media community announcements, and YMCA website. Participants who are scheduled to participate in the FIT for FUNCTION program within the Hamilton area will also be contacted.

Randomization & Allocation Sequence

This is a proof-of-concept, assessor-blinded pilot study that will use a SMART design. Before Stage 1, participants will be randomized (1:1 allocation) to receive FIT for FUNCTION or *FIT for FUNCTION+* Level 1. Before Stage 2, non-responders of Stage 1 interventions will be randomized (1:1 allocation) to receive the higher intensity *FIT for FUNCTION+* Level 2 or *FIT for FUNCTION+* level 3. In both stages, the participants will be the unit of randomization. The randomization sequence will be computer-generated by a statistician at the Methods Center of McMaster University. The Lead Research Coordinator will contact the Methods Centre to receive the group allocation after attaining participant consent and completing the baseline assessments to ensure allocation concealment.

Study Timeline

This study has four assessment timepoints: baseline (**T0**) for demographic and baseline characteristics, end of Stage 1 (**T1**; 1 month after baseline) for response measure, end of Stage 2 (**T2**; end of intervention period; 3 months after baseline) and Stage 3 (**T3**; end of the 6- month follow-up period; 9 months after baseline). *Table 1* summarizes the timeline for interventions and assessments.

Table 1 Schedule of enrollment, assessment, and interventions

	Timepoint					
	Pre-T0	**T0**	Post-T0	**T1**	**T2**	**T3**
Enrollment						
Eligibility Screening	X	X				
Informed Consent		X				
Allocation			X			
Interventions						
FIT for FUNCTION				◆—	—◆	
Intervention A				◆—		
Intervention B					◆—	
Intervention C					◆—	
Baseline Assessments						
Demographic information		X				
National Institutes of Health Stroke Scale		X				
Chedoke-McMaster Stroke Assessment		X				
Montreal Cognitive Assessment		X				
Centre for Epidemiological Studies Depression		X				
Physical Activity Measures						
Accelerometry		X		X	X	X
Self-reported physical activity		X		X	X	X
Self-efficacy for physical activity		X		X	X	X
Feasibility Measures						
Recruitment	X	X				
Attrition and adherence				X	X	X
Treatment fidelity				X	X	
Adverse events				X	X	X
Acceptability Measures						
Perception of intervention change		X		X	X	
Satisfaction					X	
Exit phone interview					X	

Blinding

Due to the nature of the interventions and how they are delivered, it will not be possible to blind either the participants or the staff delivering the interventions. However, all feasibility and acceptability measures, other than self-report measures and accelerometry data, will be collected by an assessor blinded to group allocation. Participants will be reminded to hide their study group identity from the assessor, and any instances of unblinding will be recorded. .

Study Staff

The exercise sessions of the *FIT for FUNCTION* program will be delivered by a kinesiologist trained to work with individuals with stroke, while the self-management and education components will be delivered by a trained YMCA staff member (137). All other interventions will be delivered by a stroke rehabilitation physiotherapist. The physiotherapist will be trained on how to deliver the *FIT for FUNCTION+* behavioral interventions by the research staff before the baseline assessments and a refresher will be provided before Stage 2 interventions begin.

Interventions

FIT for FUNCTION program consists of group (60 min; twice/week) and individual (60 min; once/week) exercise sessions. The kinesiologist-led group exercise sessions are composed of: warm-up (10 min), task-oriented strengthening and cardiovascular conditioning (20 min), and mobility and balance (20 min) training. Participants are given access to the YMCA equipment and facilities for the individual exercise sessions. The program also includes eight self-management and education sessions (once/week) delivered by a trained YMCA staff member. Further program details are included in the published study protocol (137).

***FIT for FUNCTION+* Level 1** is a *low-resource* intensive program that applies components of Control Theory to FIT for FUNCTION (135). Participants will participate in FIT for FUNCTION and will also be prompted to negotiate a free-living physical activity **goal** (150 minutes of MVPA/week) with the physiotherapist, that corresponds to the response measure, or if required, approximates the response measure. The physiotherapist will also be prompted to set goal-specific **action plans** to specify the intensity, duration, and frequency with which to perform physical activity each day. Participants will be provided with a FitBit™ activity tracker to **self-monitor** their behavior. While the Fitbit™ is known to underreport time spent in MVPA compared to research-grade accelerometers, it is still recommended for promoting behavior change through self-monitoring (58).

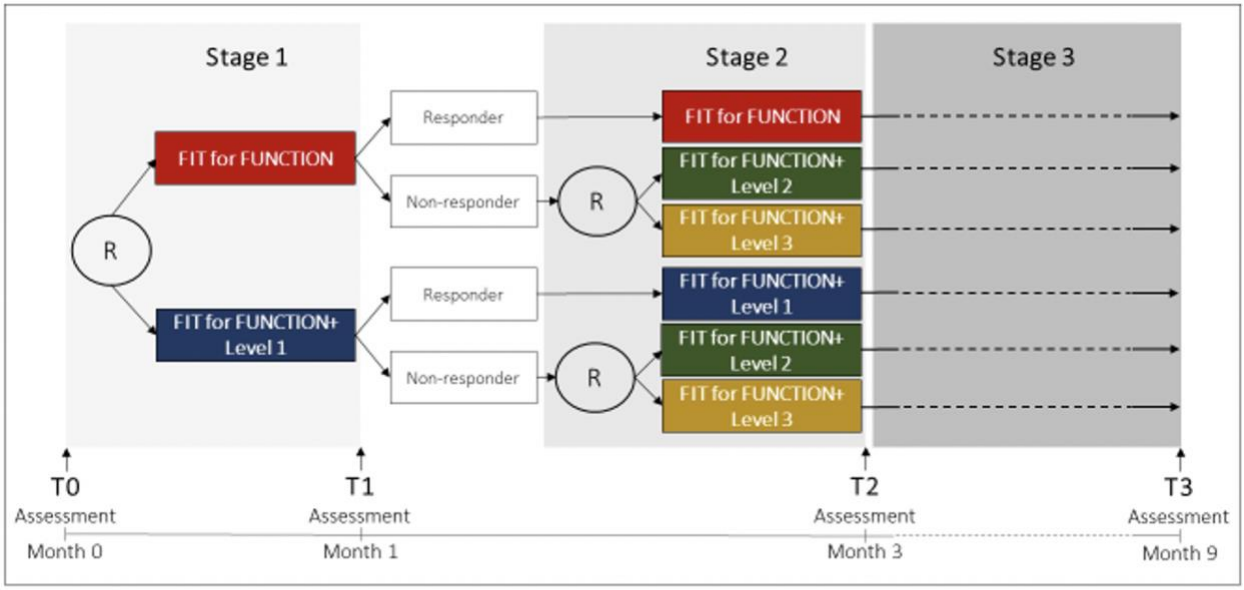
***FIT for FUNCTION+* Level 2** enhances the support provided to participants by combining additional components of the Control Theory(140). Participants will continue with FIT for FUNCTION and will also receive **feedback** from the physiotherapist about their physical activity during Stage 1 (trajectories of MVPA min/day and week). Based on this feedback, physical activity **goals** and **action plans** will be **reviewed** and renegotiated once at the *beginning of Stage 2* and again *after 4 weeks* to corresponds with, or approximate, the response measure. Participants will also continue to use the Fitbit™ to **self-monitor** MVPA. Participants will receive final feedback about their activity levels *at the end of Stage 2*.

***FIT for FUNCTION+* Level 3** provides increased support by incorporating behavioral change techniques targeted at improving self-efficacy for physical activity (136). Participants will continue with FIT for FUNCTION and receive support from the physiotherapist for setting incrementally larger **goals** biweekly (**graded tasks**) corresponding to the response measure. At the *beginning of Stage 2*, participants can discuss their beliefs about physical activity, receive

evidence-based **information** about the benefits of physical activity on stroke recovery, and **problem-solve** to reduce barriers that prevent physical activity participation with the physiotherapist. The physiotherapist will provide **instructions** and **demonstrate** ways to intensify daily activities (e.g. walking) to moderate-vigorous levels and explore sources of **social support** for physical activity engagement (e.g. caregivers). A check-in session with the physiotherapist *midway through Stage 2* will allow participants to review progress and develop new solutions as needed. The physiotherapist will also provide **social support** and general encouragement *throughout Stage 2* that is not contingent on meeting MVPA goals.

Refer to *Figure 1* for the Study Flow Chart.

Figure 1 Study Flow Diagram



Interventions	Description
FIT for FUNCTION	Group & individual exercise sessions + self-management sessions
FIT for FUNCTION+ Level 1	FIT for FUNCTION + goal setting + action planning + self-monitoring
FIT for FUNCTION+ Level 2	FIT for FUNCTION + goal setting + action planning + self-monitoring + feedback + review of behavioral goals
FIR for FUNCTION+ Level 3	FIT for FUNCTION + graded tasks (biweekly goal setting) + problem solving + instructions on how to performing the behavior + demonstration of behavior + social support

Baseline Measures

Demographic characteristics including age, sex, gender identity, details of stroke (type, date, location), employment, partner status, living arrangements (e.g. co-residents, caregiver support), caregiving and household roles, and education will be collected at **T0**. Additionally, participants' stroke severity (NIH Stroke Scale), stage of stroke recovery (Chedoke McMaster Stroke Assessment), cognitive impairment (Montreal Cognitive Assessment (MoCA)), and presence of depressive symptoms (Centre for Epidemiologic Studies Depression Scale) will be assessed to characterize the sample.

Response Measure

Response to Stage 1 interventions will be measured using the ActiGraph GT3X-BTLE (ActiGraph LLC, Pensacola FL, USA), which is a compact (46 x 33 x 15 mm), lightweight (19g), and water-resistant tri-axial accelerometer with a 30-100Hz sampling rate and dynamic range of ±8 gravitation units (65). The accelerometer will be worn on the unaffected side ankle during waking hours for seven consecutive days (65). Accelerometry data will be collected at all timepoints (**T0-T3)** and will only be considered valid if there are 4 days (10 hours/day; at least one weekend day) of time spent wearing the device (143). Accelerometry-derived activity counts will be converted into energy expenditure (MET-min) using its proprietary algorithm (ActiLife 6, Pensacola FL, USA) (144).

Feasibility Measures

Recruitment will be assessed by recording the number of participants who: 1) expressed interest in the study, 2) were deemed eligible during phone screening, 3) declined to participate (and reasons for doing so), 4) were eligible at the baseline evaluation, and 5) withdrew consent after baseline assessment (and reasons of doing so).

Attrition and adherence will be quantified throughout the study period (**T1-T3**) by recording: 1) The number of participants who dropped out of each intervention arm (and reasons for doing so), 2) physiotherapist-documented adherence to study protocol (e.g. number of missed sessions, with reasons), and 3) the number of participants where response measure could not be determined (<4 valid days of valid accelerometry data) with reasons for the abbreviated wear time.

Treatment Fidelity will be assessed at **T1 and T2**. Audiotapes physiotherapist-participant interactions will be reviewed by an independent assessor using a standardized checklist (*Appendix E*) to record whether behavior change techniques associated with each treatment arm were accurately delivered as intended.

Adverse events experienced by the participants throughout the study period (**T0-T3**), including but not limited to muscle stiffness, soreness, injuries, or falls, will be recorded.

Acceptability Measures

Participants' acceptability with a change in interventions at Stage 2 will be ascertained at **T0, T1, and T2**. A 2-item questionnaire, adapted from Gunlicks-Stoessel et al.(2011), will ask participants to rate on a 5-point Likert scale their feelings (-2 = "very negative", +2 = "very positive") and agreement (-2 = "definitely no", +2 = "definitely yes") with the change (145). At **T0**, all participants will be asked to complete the questionnaires, while at **T1 and T2**, only participants receiving the more intensive Stage 2 interventions (*FIT for FUNCTION+* Level 2-3) will complete the questionnaire.

Satisfaction Measure

Participants' and staffs' **satisfaction** with the program will be assessed at **T2** using the 8-item Client Satisfaction Questionnaire (CSQ-8), which classifies satisfaction with the program as

low (CSQ; 8-20), medium (CSQ; 21-26), or high (CSQ 27-32) (146). The CSQ-8 is a self-report instrument that has excellent internal consistency (Cronbach's alpha = 0.93) (147) and has been used in previous pilot SMARTs (145,148).

Exit phone interviews will also be conducted and audio recorded with each participant at **T2**. The interview will contain open-ended questions about the acceptability of the SMART design and ATSs and will explore how self-efficacy and physical activity affects physical activity engagements.

Self-efficacy Measure

Self-efficacy for physical activity will be assessed at all timepoints **T0-T3** using a single question adapted from the *FIT for FUNCTION* program that asks participants to rate their confidence, on a 10-point Likert-scale (1="not confident", 10="very confident"), with performing 150 minutes of MVPA/week (137).

Data Analysis

This is a proof-of-concept pilot trial; therefore, formal hypothesis testing of effectiveness will not be undertaken. Instead, descriptive statistics will be used to summarize *feasibility, acceptability, satisfaction,* and to *provide preliminary estimates of effect*. Between-group differences (with 95% CI) for physical activity, self-efficacy scores, and percentage of people meeting the response measure through **T0-T3** will be reported. *Table 2* summarizes the objectives along with the criteria for success, hypotheses, and methods of analysis.

Table 2 Summary table of study objectives with associated criteria for success, hypotheses, and methods of analysis

Objectives	Criteria/Hypothesis	Outcomes	Analysis
Feasibility of conducting full-scale SMART			
Recruitment	2 participants/month over 21 months; target sample size n=42	Recruitment rate	Descriptive statistics (%) of eligible participants recruited, attrition, adherence, fidelity, and valid accelerometry data Reasons for declining to participate, drop-outs, missing data will be noted Occurrence of adverse events will be recorded
Attrition	<20% attrition over the study period	Attrition rate	
Adherence	>80% of participants completing interventions	Adherence rate	
	>80% of participants with ≥4 days of accelerometry data	ActiGraph accelerometer	
Fidelity	>80% of interventions sessions delivered as intended	Fidelity checklist	
Adverse Events	No major injuries or adverse events	Recorded adverse events	
Acceptability with the change of interventions at Stage 2			
Acceptability	>80% of participants accepting and agreeing with intervention change	Self-reported acceptability questionnaire	Descriptive statistics (%) of sessions delivered as intended
Satisfaction with treatment sequence			
Client and Staff Satisfaction	>80% of participants and staff reporting "high satisfaction"	CSQ-8 questionnaire	Descriptive statistics (%) of participants and staff reporting "high satisfaction"
Preliminary estimates of effect			
Physical activity	Increase in physical activity levels	ActiGraph accelerometer	Descriptive statistics: % of responders; Mean (SD) of energy expenditure and self-efficacy scores for each intervention arm Between-group differences (95% CI) in physical activity, self-efficacy, and responders through T0-T3
Self-Efficacy	Increase in self-efficacy levels	Self-efficacy Questionnaire	

Data Collection and Management

Participant data will be inserted into REDCap, which is a secure web-based data management software. All enrolled participants will be assigned a unique study ID, and the information linking their ID to their personal details will be kept at a Methods Center at McMaster University. Access to REDCap will be restricted to the blinded assessors, principal investigators, and the research coordinator. Any data that is transferred between the data collectors and study staff will be done so using password encrypted flash drives. Participant data will be retained for 7-10 years at the McMaster School of Rehabilitation Science.

Sample Size

The sample size for this pilot trial was calculated with the aim of gauging the feasibility and acceptability of the project and according to the guidelines proposed by Almirall et al. (2012)(90). We estimate that a minimum of three participants is required at each of the non-response subgroups (*FIT for FUNCTION+* Level 2 and 3) to investigate the feasibility and acceptability aims of this trial. Considering a 90% probability of meeting that subgroup sample and expecting an initial non-response rate of 55%, the trial would require 38 participants. Taking into account a 10% attrition rate from **T0**-**T3**, we would require a sample size of 42 participants.

Discussion

To our knowledge, this study is the first attempt at a pilot SMART for developing an ATS for promoting long-term physical activity maintenance among stroke survivors. The initial Stage 1 interventions have been designed to make use of existing community-based resources (FIT for FUNCTION program) (3), while also introducing easy-to-implement BCTs (*FIT for FUNCTION+* Level 1) to represent *low-resource* intensive treatments. An evidence-based response measure was also implemented to divert *high-resource* intensive treatments (*FIT for*

FUNCTION+ Level 2-3) to stroke survivors who need them. Thus, the treatment sequence tested in this trial and potentially fine-tuned in future full-scale SMARTs may effectively tailor interventions to stroke survivors while also making efficient use of available resources.

Another innovative factor of this trial is that the interventions have been designed with the focus of promoting free-living physical activity maintenance, which has not been attempted in previous post-stroke recovery programs (12,13). The interventions also have a strong theoretical basis as the BCW was used to *systematically* identify factors influencing activity maintenance, the needs of stroke survivors, and potential feasibility constraints (126). These interventions also represent two behavioral change theories (Control Theory and Social Cognitive Theory) that have been previously used in interventions promoting physical activity initiation and maintenance (95,139,140,149). Trial-end interviews are also planned to fine-tune all aspects of this trial based on participants' satisfaction and acceptability with the program.

Since the proposed ATS will be implemented within communities, we have adopted the FIT for FUNCTION program's broad eligibility criteria as it represents a wide spectrum of individuals living with stroke within the community (137). Thus, if this trial and the future full-scale SMART demonstrates positive results, there will be strong evidence for the implementation of the ATS to a heterogeneous population of stroke survivors residing within communities. A key strength of this trial is that it leverages the existing innovative LiveWell partnership spanning community, academic, and healthcare centers, which will ensure trial results are disseminated within communities, provincially, and nationally (137). In addition, YMCA is a national body available in provinces across Canada. Hence, this partnership provides an existing framework for conducting future full-scale multicentre SMARTs if this pilot trial yields positive results.

Chapter 5

Discussion

Summary of Findings

The overall objective of this thesis was to investigate intervention strategies for promoting physical activity maintenance among people with stroke. The benefits of physical activity after stroke are well documented (4–10), however, there are currently no quantitative reviews exploring the efficacy of post-stroke rehabilitation interventions in promoting activity maintenance (12,13). Since behavioral change interventions are complex (92), such reviews also allow for the comparison of intervention characteristics that can inform the development of future trials (11). Additionally, tailoring interventions to individuals have been identified as a promising way to promote activity maintenance among individuals with stroke (3). However, prior to the work in this thesis, tailoring schemes that sequentially assign higher-intensity interventions based on individual needs (*adaptive treatment strategies* (ATSs)), developed and evaluated through *sequential multiple assignment randomized trials* (SMARTs), have not been investigated in this population (14,90).

The first two studies addressing this work are:

Study 1: Intervention Related Factors Associated with Physical Activity Maintenance Among Stroke Survivors: A Protocol for a Systematic Review with Meta-Analysis and Meta-Regression

and

Study 2: Intervention Related Factors Associated with Physical Activity Maintenance Among Individuals with Survivors: A Systematic Review and Meta-Analysis

The objective of this review was: *Primary:* to investigate the effects of current interventions in promoting short- (3-months), moderate- (6-months), and long-term (≥12 months) physical activity maintenance among individuals with stroke, and *Secondary:* to explore

the intervention characteristics associated with short, moderate, and long-term physical activity maintenance among people with stroke. The results of this study reported that there was a small difference in self-reported physical activity at 3-month follow-up between intervention and control groups. Further, the review highlighted the absence of statistical power in the current stroke rehabilitation literature to explore intervention characteristics (*through meta-regression analysis*) associated with physical activity maintenance.

Study 3: Developing an Adaptive Treatment Strategy Targeting Maintenance of Physical Activity after Stroke: Protocol for a Pilot Sequential Multiple Assignment Randomized Trial

The third paper outlined the protocol for investigating the *feasibility*, *acceptability*, *participant/staff satisfaction*, and to provide *preliminary estimates of effect* of a pilot SMART to develop an ATS for promoting physical activity maintenance among individuals with stroke.

Limitations of the Current Post-Stroke Rehabilitation Literature

The systematic review results indicated that there was a small difference in self-reported physical activity at 3-month follow-up between intervention and control groups. However, few trials with small sample sizes were available for the pooled estimates and the quality of the cumulative evidence was "very low". These results are indicative of the limitations of the post-stroke rehabilitation literature for assessing activity maintenance.

There was a paucity of trials with adequate follow-up timepoints to properly assess physical activity maintenance. Short-term maintenance was defined in this review using a 3-month follow-up timepoint because it is reflective of the design of most stroke rehabilitation trials (12,13) and corresponds with the methodology of previous reviews (12,13,88). However, there are no established guidelines for assessing behavior change maintenance, and some

researchers have purported that a minimum 6-month follow-up is required based on the tenets of the Transtheoretical Model of behavior change (85,127,128). Only three trials included in our review had a 6-month follow-up, and the effect estimates from only two of those trials were pooled in the self-reported measures subgroup. Additionally, there were no eligible trials with long-term (≥12 months) follow-up identified. Several factors may have led to the unavailability of longer follow-ups in these trials including: a lack of pre-established protocols for the follow-up period, high participant attrition rates, loss of study infrastructure after the end of a trial, or inability to acquire funding for the follow-up period (129). *Thus, it is recommended that such challenges be addressed when developing future trial protocols to include longer follow-ups (minimum of 6-months) to properly assess activity maintenance* (129,150).

The subgrouping of effect estimates based on outcome type (steps walked/day, time spent in MVPA, daily energy expenditure, and self-reported outcomes) reduced the number of trials that were available for each subgroup at the 3- and 6-month timepoints. Utilizing a standardized physical activity outcome across trials would allow effect estimates to be pooled within one subgroup, thereby improving the precision of meta-analyzed results and increasing the statistical power for future meta-regression analysis. When choosing a physical activity outcome, it is important to consider that the evidence tying the benefits of physical activity to the reduction of cardiovascular disease risk factors focus on activities conducted at a moderate-vigorous intensity (MET>3) (151,152). Additionally, national and international physical activity guidelines, including activity recommendations for individuals with stroke, recommend obtaining 500 MET-min of energy expenditure (or 150 minutes of MVPA) over 7 days (36–38,130). However, there were few trials identified in this review (two at 3-month follow-up; one at 6-month follow-up) that reported physical activity as time spent in MVPA/day. Heterogeneous outcomes that do not

correspond with guideline metrics (*steps walked/day; daily total energy expenditure*) make it difficult to assess whether participants are meeting adequate duration and intensity of physical activity and complicate between-study comparison of results (131–133).

Another important consideration is whether to use self-reported questionnaires or objective measures to assess physical activity. Most of the trials included in this review used self-reported measures – a trend that corresponds with the results of other reviews (13,132). The use of self-reported questionnaires in these trials may be attributed to their low cost and ease of administration (26,39,40). However, self-reported questionnaires are subject to recall and social desirability bias, less accurate than objective measures for quantifying MVPA (especially at an individual level), and participants' responses are influenced by the wording used in the questionnaires (25,26,40,41). Contrarily, the use of objective measures (e.g. accelerometers) has been increasing due to their small size, ability to capture large amounts of data, general acceptability, and accuracy with measuring MVPA (25,26,40). *Thus, reporting physical activity as energy expenditure from, or time spent in, MVPA measured using objective measures (e.g. accelerometers) is recommended.*

Designing Interventions for Physical Activity Maintenance

The systematic review results highlighted that the current stroke rehabilitation literature does not afford the statistical power to explore the potential of existing *behavioral change techniques* for promoting physical activity maintenance. Hence, it is important to consider how to choose appropriate behavioral change techniques to design future interventions. One approach is to base the design of interventions on established theories since they outline the causal pathways and constructs of behavioral change (104). However, many theories do not specify how to target such constructs (153) causing researchers to make assumptions on how to design

interventions that have yet to be validated (141,153). Additionally, there are several theories (e.g. theory of planned behavior, transtheoretical model, social cognitive theory, etc.) currently available that propose distinct causal pathways for behavioral change (153). Hence, before deciding on the theory-based strategy, it is paramount to conduct a thorough analysis of the behavioral targets, the potential ways of promoting behavioral change, and the feasibility of selected strategies (126,141).

As such, the SMART interventions were developed using the Behavioral Change Wheel that outlines eight steps for ***systematically evaluating*** behavioral targets (*based on the COM-B model*), choosing behavioral change techniques, and assessing feasibility constraints (126). The behavioral change techniques that were chosen from following this systematic framework were representative of two theories – The Social Cognitive Theory and the Control Theory – which have previously demonstrated the potential for promoting maintenance of behavior change (95,139,142). *Hence, given the infancy of post-stroke physical activity maintenance literature, the use of such frameworks is recommended as they allow for the systematic evaluation and implementation of behavior change techniques.*

Strengths

The systematic review possessed key strengths that added additional insights about physical activity maintenance to the post-stroke rehabilitation literature. The review used a robust methodology with a peer-reviewed protocol (107) to reduce between-study heterogeneity, minimize bias, and provide accurate insights. Two independent reviewers coded the trial interventions using a standardized, validated, and widely used taxonomy of behavioral change techniques to provide explicit descriptions of existing interventions (92). Additionally, strict inclusion criteria along with appropriate models (*random-effects*) for pooling data were adopted

to minimize and account for between-study heterogeneity. Further, the review only included trials with validated physical activity measures that were grouped according to the similarity of outcomes to provide accurate between-trial comparisons. Such design features allowed the quantitative pooling and accurate weighting (*inverse variance*) of effect estimates that had not been attempted in previous reviews (12,13).

The pilot SMART protocol is also a novel addition to the post-stroke literature as it is the first trial designed to evaluate the potential of ATSs for promoting long-term physical activity maintenance – an important component of the post-stroke continuum of care (92). The intervention and response measure for this trial was carefully designed to offer *existing and easy-to-implement* treatments to stroke survivors, and sequentially tailor more *resource-intensive* treatments to those requiring additional support for meeting activity guidelines (14). The interventions were systematically developed through a rigorous examination of behavioral targets, needs of the population, and feasibility constraints (See *Appendix E*) (126), and through detailed consultations with experts on stroke, exercise, and self-management (JR and AT). Additionally, these interventions are the first to be designed with a focus on post-intervention activity maintenance (12,13) and represent constructs from two theories (Control Theory and Social Cognitive Theory) that have been widely used in behavioral change interventions (95,139,142).

Furthermore, the trial includes broad eligibility criteria that will provide strong evidence for the implementation of the proposed treatments to a wide spectrum of community-dwelling individuals living with stroke if the results are positive (137). It will also leverage innovative partnerships between community, academic centers, and healthcare organizations (LiveWell) to recruit participants, disseminate results, and establish infrastructures for future full-scale

SMARTs (137). Thus, the strengths and insights of the systematic review, and rigor and potential of the SMART trial provide key contributions to the current post-stroke rehabilitation literature.

Limitations

We acknowledge the limitations of both studies in this thesis. The systematic review was limited by a lack of studies that impacted the precision of pooled estimates and prevented the pre-planned meta-regression analysis. Additionally, we could not systematically isolate and comment on the potential of individual intervention characteristics for promoting activity maintenance due to the similarities between trials, the proximity of the effect estimates within subgroups, and the overlap of confidence intervals. However, these findings highlighted limitations of the current literature (e.g. lack of adequate follow-up, non-standardized outcome measures) and provided insights for future intervention design.

Although the design of the pilot SMART is limited by the inability to blind participants and staff to group allocation, all outcome measures (except self-report and accelerometry data) will be collected by assessors blinded to group allocation to minimize bias. Additionally, participants will be asked to conceal their group assignment, and instances of unblinding will be recorded.

Clinical Significance

Participation in physical activity becomes complicated after a stroke due to the residual impairments experienced by stroke survivors (3). However, many community-dwelling stroke survivors, despite having mild impairments, do not meet the recommended physical activity guidelines (76,77). Some possible reasons for this observation are that long-term physical activity participation is facilitated by: confidence in skill level amidst perceived impairments from stroke (138,154,155), access to knowledge about how and where to exercise (156,157),

access to transportation (156), support from family and health care professionals' (138,154,155), perceptions of the benefits of physical activity(138), and positive emotions (lack of fear and embarrassment) (138,155). Hence, addressing this complex combination of personal and environmental influences, in addition to the motor and cognitive impairments from stroke, are paramount to ensuring long-term activity maintenance (3).

However, limitations of the current literature (e.g. inadequate follow-up, non-standardized outcome measures) can prevent an accurate assessment of existing interventions and compromise the development of future programs. This is an important gap to address because, without adequate support, stroke survivors may continue with a sedentary lifestyle that would compound deleterious impacts on functional capacity and psychological wellbeing, ultimately resulting in a reduced quality of life (3). Thus, trials such as the pilot SMART that have been developed with a focus on promoting activity maintenance represent an important direction for post-stroke recovery programs. The results of this SMART can lead to the development of treatment sequences (ATSs) that are fluid, flexible, and can be tailored to the individuals' needs, thereby enhancing client-centered care (14).

Future Directions

Evidence regarding the beneficial effects of physical activity in post-stroke recovery is emerging, and an increasing emphasis is being placed on promoting activity maintenance (90). However, to investigate how to best promote physical activity maintenance, future trials need to include longer follow-ups in their design (128). Additionally, these trials should use standardized outcomes (e.g. MVPA min/day, MET-min/day) that are assessed using objective measures (e.g accelerometers) to correspond with physical activity guidelines. Finally, future trials should follow standardized frameworks, such as the Behavior Change Wheel, to design interventions

based on systematically identifying the needs of stroke survivors and trial-specific feasibility constraints (126).

Results of the pilot SMART, including interviews with participants, will be used to fine-tune the proposed ATS if required. Further, the response measure outlined in the SMART protocol represents an *intermediate tailoring variable* because it is included in the middle of a program to inform subsequent tailoring of interventions (14). Further evidence from future full-scale SMARTs can inform the development of *baseline tailoring variables* that allocate appropriate interventions to participants at the beginning of a program, thereby further tailoring support to individuals (14).

Conclusion

Physical activity has beneficial effects for post-stroke recovery but is only optimized if a consistent activity level, according to published guidelines, is maintained. This thesis outlined the first review that quantitatively assessed the effects of current stroke rehabilitation programs in promoting physical activity maintenance and explored promising intervention characteristics to promote activity maintenance. The review reported a small improvement in self-reported physical activity at 3-month follow-up, outlined limitations in the current literature and provided directions to inform the design of future studies for assessing physical activity maintenance. Additionally, the thesis outlined the protocol of a pilot trial, including a novel SMART design, to develop and evaluate an intervention strategy that sequentially tailors support to individuals. Insights from these two studies can help investigators to properly examine and effectively operationalize intervention strategies to promote long-term maintenance of physical activity among stroke survivors.

References

1. Stroke in Canada: Highlights from the Canadian Chronic Disease Survaillence System [Internet]. 2013. Available from: https://www.canada.ca/en/public-health/services/publications/diseases-conditions/stroke-canada-fact-sheet.html
2. 2019 Report on Heart, Stroke and Vascular Cognitive Impairment. 2019.
3. Billinger SA, Arena R, Bernhardt J, Eng JJ, Franklin BA, Johnson CM, et al. Physical activity and exercise recommendations for stroke survivors: A statement for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2014;45(8):2532–53.
4. Minjeong A, Shaughnessy M. The effects of exercise-based rehabilitation on balance and gait for stroke patients: a systematic review. J Neurosci Nurs. 2011;43(6).
5. Dorsch S, Ada L, Alloggia D. Progressive resistance training increases strength after stroke but this may not carry over to activity: a systematic review. J Physiother. 2018;64(2):84–90.
6. Eng JJ, Reime B. Exercise for depressive symptoms in stroke patients: A systematic review and meta-analysis. Clin Rehabil. 2014;28(8):731–9.
7. Oberlin LE, Waiwood AM, Cumming TB, Marsland AL, Bernhardt J, Erickson KI. Effects of physical activity on poststroke cognitive function a meta-analysis of randomized controlled trials. Stroke. 2017;48(11):3093–100.
8. D'Isabella NT, Shkredova DA, Richardson JA, Tang A. Effects of exercise on cardiovascular risk factors following stroke or transient ischemic attack: a systematic review and meta-analysis. Clin Rehabil. 2017;31(12):1561–72.
9. Brouwer R, Wondergem R, Otten C, Pisters MF. Effect of aerobic training on vascular and metabolic risk factors for recurrent stroke: a meta-analysis. Disabil Rehabil. 2019;0(0):1–8.
10. Saunders D, Sanderson M, Hayes S, Johnson L, Kramer S, Carter D, et al. Physical fitness training for stroke patients. Cochrane Database Syst Rev. 2020;(3).
11. Murray JM, Brennan SF, French DP, Patterson CC, Kee F, Hunter RF. Effectiveness of physical activity interventions in achieving behaviour change maintenance in young and middle aged adults: A systematic review and meta-analysis. Soc Sci Med. 2017;192(1):125–33.
12. Morris JH, Macgillivray S, McFarlane S. Interventions to promote long-term participation in physical activity after stroke: A systematic review of the literature. Arch Phys Med Rehabil. 2014;95(5):956–67.
13. Moore SA, Hrisos N, Flynn D, Errington L, Price C, Avery L. How should long-term free-living physical activity be targeted after stroke? A systematic review and narrative synthesis. Int J Behav Nutr Phys Act. 2018;15(1).

14. Almirall D, Nahum-Shani I, Sherwood NE, Murphy SA. Introduction to SMART designs for the development of adaptive interventions: with application to weight loss research. Transl Behav Med. 2014;4(3):260–74.

15. Callaway CW, Carson AP, Chamberlain AM, Chang AR, Knutson KL, Lewis TT, et al. Heart Disease and Stroke Statistics — 2020 Update A Report From the American Heart Association. 2020. 139–596 p.

16. GBD Stroke Collaborators. Global, regional, and national burden of stroke, 1990 – 2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet Neurol. 2019;18:439–58.

17. Krueger H, Koot J, Hall RE, Callaghan CO, Bayley M, Corbett D. Prevalence of Individuals Experiencing the Effects of Stroke in Canada: Trends and Projections. Stroke. 2015;46:2226–31.

18. Feigin VL, Roth GA, Naghavi M, Parmar P, Krishnamurthi R, Chugh S, et al. Global burden of stroke and risk factors in 188 countries , during 1990 – 2013 : a systematic analysis for the Global Burden of Disease Study 2013. Lancet Neurol. 2016;15(9):913–24.

19. Donnell MJO, Chin SL, Rangarajan S, Xavier D, Liu L, Zhang H, et al. Global and regional eff ects of potentially modifi able risk factors associated with acute stroke in 32 countries (INTERSTROKE): a case-control study. Lancet [Internet]. 388(10046):761–75. Available from: http://dx.doi.org/10.1016/S0140-6736(16)30506-2

20. Emerging Risk Factors Collaboration. Diabetes mellitus, fasting blood glucose concentration, and risk of vascular disease : a collaborative meta-analysis of 102 prospective studies. Lancet. 2010;375(1):2215–22.

21. Mitchell AB, Cole JW, Mcardle PF, Cheng Y, Ryan KA, Sparks MJ, et al. Obesity Increases Risk of Ischemic Stroke in Young Adults Andrew. 2016;46(6):1690–2.

22. Willey J, Moon Y, Sacco R, Greenlee H, Diaz K, Wright C. Physical inactivity is a strong risk factor for stroke in the oldest old: findings from a multi-ethnic population (the Northern Manhattan Study). 2018;12(2):197–200.

23. Kelly-Hayes M. Influence of Age and Health Behaviors on Stroke Risk: Lessons from Longitudinal Studies. J Am Geriatr Soc. 2011;58:325–8.

24. Caspersen CJ, Powell KE, Christenson GM, Public S, Reports H, Apr M, et al. Physical Activity, Exercise, and Physical Fitness: Definitions and Distinctions for Health-Related Research. 1985;100(2):126–31.

25. Strath SJ, Kaminsky LA, Ainsworth BE, Ekelund U, Freedson PS, Gary RA, et al. Guide to the assessment of physical activity: Clinical and research applications: A scientific statement from the American Heart association. Circulation. 2013;128(20):2259–79.

26. Hills AP, Mokhtar N, Byrne NM. Assessment of Physical Activity and Energy Expenditure: An Overview of Objective Measures. Front Nutr. 2014;1(June):1–16.

27. Piers LS, Soares MJ, Mccormack LM, O'Dea K. Is there evidence for an age-related reduction in metabolic rate? J Appl Physiol. 1998;85(6):2196–204.

28. Leonard WR. Laboratory and field methods for measuring human energy expenditure. Am J Hum Biol. 2012;24(3):372–84.

29. Speakman JR. The history and theory of the doubly labeled water technique. Am J Clin Nutr. 1998;68(4).

30. Westerterp KR. Assessment of physical activity: A critical appraisal. Eur J Appl Physiol. 2009;105(6):823–8.

31. Howley ET. Type of activity: Resistance, aerobic and leisure versus occupational physical activity. Med Sci Sports Exerc. 2001;33(6 SUPPL.).

32. Ceesay M, Prentice M, Day C, Scott W. The use of heart rate monitoring in the estimation of energy expenditure : a validation study using indirect whole-body calorimetry. 1989;61:175–86.

33. Ainsworth BE, Haskell WL, Whitt MC, Irwin ML, Swartz AM, Strath SJ, et al. Compendium of physical activities: An update of activity codes and MET intensities. Med Sci Sports Exerc. 2000;32(498–503).

34. Chowdhury AK, Tjondronegoro D, Chandran V, Zhang J, Trost SG. Prediction of relative physical activity intensity using multimodal sensing of physiological data. Sensors (Switzerland). 2019;19(20):1–14.

35. Miller N, Srath S, Swartz A, Cashin S. Estimating Absolute and Relative Physical Activity Intensity Across Age via Accelerometry in Adults. J Aging Phys Act. 2010;18(2):158–70.

36. Davies DSC, Atherton F, McBride M, Calderwood C. UK Chief Medical Officers ' Physical Activity Guidelines [Internet]. Department of Health and Social Care, UK. 2019. Available from: https://www.gov.uk/government/publications/physical-activity-guidelines-uk-chief-medical-officers-report

37. Early W, Obesity C, Initiative P, Start H, Taken S, Activity P, et al. Physical Activity Guidelines for Americans. 2018.

38. Canadian Physical Activity Guidelines [Internet]. 2017. Available from: www.csep.ca/guidelines

39. Prince SA, Adamo KB, Hamel ME, Hardt J, Connor Gorber S, Tremblay M. A comparison of direct versus self-report measures for assessing physical activity in adults: A systematic review. Int J Behav Nutr Phys Act. 2008;5.

40. Sylvia LG, Bernstein EE, Hubbard JL, Keating L, Anderson EJ. Practical guide to measuring physical activity. J Acad Nutr Diet. 2014;114(2):199–208.

41. Cleland C, Ferguson S, Ellis G, Hunter RF. Validity of the International Physical Activity Questionnaire (IPAQ) for assessing moderate-to-vigorous physical activity and sedentary behaviour of older adults in the United Kingdom. BMC Med Res Methodol. 2018;18(1):1–12.

42. Dowd KP, Szeklicki R, Minetto MA, Murphy MH, Polito A, Ghigo E, et al. A systematic

literature review of reviews on techniques for physical activity measurement in adults: A DEDIPAC study. Int J Behav Nutr Phys Act. 2018;15(1).

43. Abel MG, Peritore N, Shapiro R, Mullineaux DR, Rodriguez K, Hannon JC. A comprehensive evaluation of motion sensor step-counting error. Appl Physiol Nutr Metab. 2011;36(1):166–70.

44. Stubbs RJ, Hughes DA, Johnstone AM, Whybrow S, Horgan GW, King N, et al. Rate and extent of compensatory changes in energy intake and expenditure in response to altered exercise and diet composition in humans. Am J Physiol - Regul Integr Comp Physiol. 2004;286(2 55-2):350–8.

45. Johannsen DL, Calabro MA, Stewart J, Franke W, Rood JC, Welk GJ. Accuracy of armband monitors for measuring daily energy expenditure in healthy adults. Med Sci Sports Exerc. 2010;42(11):2134–40.

46. Drenowatz C, Eisenmann JC. Validation of the SenseWear Armband at high intensity exercise. Eur J Appl Physiol. 2011;111(5):883–7.

47. White T, Westgate K, Hollidge S, Venables M, Olivier P, Wareham N, et al. Estimating energy expenditure from wrist and thigh accelerometry in free-living adults: a doubly labelled water study. Int J Obes. 2019;43(11):2333–42.

48. Corder K, Van Sluijs EMF, Wright A, Whincup P, Wareham NJ, Ekelund U. Is it possible to assess free-living physical activity and energy expenditure in young people by self-report? Am J Clin Nutr. 2009;89(3):862–70.

49. Bastone A de C, Moreira B de S, Vieira RA, Kirkwood RN, Dias JMD, Dias RC. Validation of the Human Activity Profile Questionnaire as a Measure of Physical Activity Levels in Older Community-Dwelling Women. J Aging Phys Act. 2014;22(3):348–56.

50. Bennell KL, Hinman RS, Crossley KM, Metcalf BR, Buchbinder R, Green S, et al. Is the Human Activity Profile a useful measure in people with knee osteoarthritis? J Rehabil Res Dev. 2004;41(4):621–9.

51. Souza DC, Wegner F, Costa LCM, Chiavegato LD, Lunardi AC. Measurement properties of the Human Activity Profile questionnaire in hospitalized patients. Brazilian J Phys Ther. 2017;21(3):153–8.

52. Rimmer JH, Rubin SS, Braddock D, Hedman G. Physical activity patterns of African-American women with physical disabilities. Med Sci Sports Exerc. 1999;31(4):613–8.

53. Kayes NM, McPherson KM, Taylor D, Schluter PJ, Wilson BJK, Kolt GS. The Physical Activity and Disability Survey (PADS): Reliability, validity and acceptability in people with multiple sclerosis. Clin Rehabil. 2007;21(7):628–39.

54. Meihan L, Chung-Ngok W. Validation of the psychometric properties of the health-promoting lifestyle profile in a sample of Taiwanese women. Qual Life Res. 2011;20(4):523–8.

55. van der Ploeg HP, Streppel KRM, van der Beek AJ, van der Woude LHV, Vollenbroek-Hutten M, van Mechelen W. The Physical Activity Scale for Individuals with Physical

Disabilities: test-retest reliability and comparison with an accelerometer. J Phys Act Health. 2007;4(1):96–100.

56. Esliger DW, Rowlands A V., Hurst TL, Catt M, Murray P, Eston RG. Validation of the GENEA accelerometer. Med Sci Sports Exerc. 2011;43(6):1085–93.

57. Evenson KR, Goto MM, Furberg RD. Systematic review of the validity and reliability of consumer-wearable activity trackers. Int J Behav Nutr Phys Act. 2015;12(1).

58. Hui J, Heyden R, Bao T, Accettone N, Catherine, Richardson J, et al. Validity of the fitbit one for measuring activity in community-dwelling stroke survivors. Physiother Canada. 2018;70(1):81–9.

59. Mudge S, Stott SN. Test-retest reliability of the StepWatch Activity Monitor outputs in individuals with chronic stroke. Clin Rehabil. 2008;22(10–11):871–7.

60. Mudge S, Stott NS, Walt SE. Criterion Validity of the StepWatch Activity Monitor as a Measure of Walking Activity in Patients After Stroke. Arch Phys Med Rehabil. 2007;88(12):1710–5.

61. Brazeau AS, Karelis AD, Mignault D, Lacroix MJ, Prud'homme D, Rémi RL. Test-retest reliability of a portable monitor to assess energy expenditure. Appl Physiol Nutr Metab. 2011;36(3):339–43.

62. Manns PJ, Haennel RG. SenseWear armband and stroke: Validity of energy expenditure and step count measurement during walking. Stroke Res Treat. 2012;2012.

63. Vanroy C, Vissers D, Cras P, Beyne S, Feys H, Vanlandewijck Y, et al. Physical activity monitoring in stroke: SenseWear Pro2 Activity accelerometer versus Yamax Digi-Walker SW-200 Pedometer. Disabil Rehabil. 2014;36(20):1695–703.

64. Aadland E, Ylvisåker E. Reliability of the actigraph GT3X+ accelerometer in adults under free-living conditions. PLoS One. 2015;10(8):1–10.

65. Campos C, DePaul VG, Knorr S, Wong JS, Mansfield A, Patterson KK. Validity of the ActiGraph activity monitor for individuals who walk slowly post-stroke. Top Stroke Rehabil. 2018;25(4):295–304.

66. Gore S, Blackwood J, Guyette M, Alsalaheen B. Validity and Reliability of Accelerometers in Patients With COPD: A SYSTEMATIC REVIEW. J Cardiopulm Rehabil Prev. 2018;38(3):147–58.

67. Pang MYC, Eng JJ, Dawson AS, McKay HA, Harris JE. A community-based fitness and mobility exercise program for older adults with chronic stroke: A randomized, controlled trial. J Am Geriatr Soc. 2005;53(10):1667–74.

68. Macko RF, Ivey FM, Forrester LW, Hanley D, Sorkin JD, Katzel LI, et al. Treadmill exercise rehabilitation improves ambulatory function and cardiovascular fitness in patients with chronic stroke: A randomized, controlled trial. Stroke. 2005;36(10):2206–11.

69. Kaminsky LA, Arena R, Myers J. Reference standards for cardiorespiratory fitness measured with cardiopulmonary exercise testing data from the fitness registry and the

importance of exercise national database. Mayo Clin Proc. 2015;90(11):1515–23.

70. Shephard RJ. Maximal oxygen intake and independence in old age. Br J Sports Med. 2009;43(5):342–6.

71. Mayo NE, Wood-Dauphinee S, Côté R, Durcan L, Carlton J. Activity, participation, and quality of life 6 months poststroke. Arch Phys Med Rehabil. 2002;83(8):1035–42.

72. Rimmer JH, Riley B, Creviston T, Nicola T. Exercise training in a predominantly African-American group of stroke survivors. Med Sci Sports Exerc. 2000;32(12):1990–6.

73. Billinger SA, Coughenour E, MacKay-Lyons MJ, Ivey FM. Reduced cardiorespiratory fitness after stroke: Biological consequences and exercise-induced adaptations. Stroke Res Treat. 2012;2012.

74. Duncan F, Kutlubaev MA, Dennis MS, Greig C, Mead GE. Fatigue after stroke: A systematic review of associations with impaired physical fitness. Int J Stroke. 2012;7(2):157–62.

75. Danielsson A, Willén C, Sunnerhagen KS. Measurement of Energy Cost by the Physiological Cost Index in Walking After Stroke. Arch Phys Med Rehabil. 2007;88(10):1298–303.

76. Rand D, Eng JJ, Tang PF, Jeng JS, Hung C. How active are people with stroke?: use of accelerometers to assess physical activity. Stroke. 2009;40(1):163–8.

77. Hornnes N, Larsen K, Boysen G. Little change of modifiable risk factors 1 year after stroke: A pilot study. Int J Stroke. 2010;5(3):157–62.

78. Leoo T, Lindgren A, Petersson J, Von Arbin M. Risk factors and treatment at recurrent stroke onset: Results from the recurrent stroke quality and epidemiology (RESQUE) study. Cerebrovasc Dis. 2008;25(3):254–60.

79. VA/DoD Clinical Practice Guideline for the Management of Stroke Rehabilitation. 2019.

80. Li Z, Zhang X, Wang K, Wen J. Effects of Early Mobilization after Acute Stroke: A Meta-Analysis of Randomized Control Trials. J Stroke Cerebrovasc Dis. 2018;27(5):1326–37.

81. Luft AR, Kesselring J. Critique of A Very Early Rehabilitation Trial (AVERT). Stroke. 2016;47(1):291–2.

82. Langhorne P, Wu O, Rodgers H, Ashburn A, Bernhardt J. A very early rehabilitation trial after stroke (AVERT): a Phase III, multicentre, randomised controlled trial. Health Technol Assess (Rockv). 2017;21(54):1–119.

83. Stoller O, de Bruin ED, Knols RH, Hunt KJ. Effects of cardiovascular exercise early after stroke: systematic review and meta-analysis. BMC Neurol [Internet]. 2012;12(1):1. Available from: BMC Neurology

84. Howlett N, Trivedi D, Troop NA, Chater AM. Are physical activity interventions for healthy inactive adults effective in promoting behavior change and maintenance, and which behavior change techniques are effective? A systematic review and meta-analysis.

Transl Behav Med. 2019;9(1):147–57.

85. Murray JM, Brennan SF, French DP, Patterson CC, Kee F, Hunter RF, et al. Effectiveness of physical activity interventions in achieving behaviour change maintenance in young and middle aged adults: A systematic review and meta-analysis. Soc Sci Med [Internet]. 2017;192:125–33. Available from: https://doi.org/10.1016/j.socscimed.2017.09.021

86. Cradock KA, ÓLaighin G, Finucane FM, Gainforth HL, Quinlan LR, Ginis KAM. Behaviour change techniques targeting both diet and physical activity in type 2 diabetes: A systematic review and meta-analysis. Int J Behav Nutr Phys Act. 2017;14(1).

87. Gourlan MJ, Trouilloud DO, Sarrazin PG. Interventions promoting physical activity among obese populations: A meta-analysis considering global effect, long-term maintenance, physical activity indicators and dose characteristics. Obes Rev. 2011;12(7):633–45.

88. Grimmett C, Corbett T, Brunet J, Shepherd J, Pinto BM, May CR, et al. Systematic review and meta-analysis of maintenance of physical activity behaviour change in cancer survivors. Int J Behav Nutr Phys Act. 2019;16(1):1–20.

89. Higgins, Julian PT and Green S. Cochrane Handbook for Systematic Reviews of Interventions | Cochrane Training. Handbook. 2011.

90. Almirall D, Compton S, Gunlicks-Stoessel M, Duan N, Murphy S. Designing a Pilot Sequential Multiple Assignment Randomized Trial for Developing an Adaptive Treatment Strategy. Stat Med. 2012;31(17):1887–902.

91. Fini NA, Holland AE, Keating J, Simek J, Bernhardt J. How is physical activity monitored in people following stroke? Disabil Rehabil. 2015;37(19):1717–31.

92. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: Building an international consensus for the reporting of behavior change interventions. Ann Behav Med. 2013;46(1):81–95.

93. Ory M, Smith M, Mier N, Wernicke M. The Science of Sustaining Health Behavior Change: The Health Maintenance Consortium. Am J Health Behav. 2010;34(6):647–59.

94. Rothman AJ. Toward a Theory-Based Analysis of Behavioal Maintenance. Heal Psychol. 2000;19(1):64–9.

95. Kwasnicka D, Dombrowski SU, White M, Sniehotta F. Theoretical explanations for maintenance of behaviour change: a systematic review of behaviour theories. Health Psychol Rev. 2016;10(3):277–96.

96. Tufanaru C, Munn Z, Aromataris E, Campbell J HL. Chapter 3: Systematic reviews of effectiveness. In: Aromataris E, Munn Z (Editors). Joanna Briggs Inst Rev Man. 2017;

97. Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, et al. Preferred reporting items for systematic review and meta-analysis protocols (prisma-p) 2015: Elaboration and explanation. BMJ. 2015;349(December 2014):1–25.

98. BCT Taxonomy Training [Internet]. [cited 2019 Jul 18]. Available from: https://www.bct-taxonomy.com/about

99. Fu R, Gartlehner G, Grant M, Shamliyan T, Sedrakyan A, Wilt TJ, et al. Conducting quantitative synthesis when comparing medical interventions: AHRQ and the Effective Health Care Program. Journal of Clinical Epidemiology. 2011.

100. Schünemann H, Brożek J, Guyatt G, Oxman A. GRADE handbook for grading quality of evidence and strength of recommendations. The GRADE Working Group. 2013.

101. Public Health Agency of Canada. Tracking heart disease and stroke in Canada [Internet]. Public Health Agency of Canada. Edmonton, AB; 2011. Available from: http://www.phac-aspc.gc.ca/publicat/2009/cvd-avc/pdf/cvd-avs-2009-eng.pdf

102. Mohan KM, Wolfe CDA, Rudd AG, Heuschmann PU, Kolominsky-Rabas PL, Grieve AP. Risk and cumulative risk of stroke recurrence: A systematic review and meta-analysis. Stroke. 2011;42(5):1489–94.

103. Fini NA, Holland AE, Keating J, Simek J, Bernhardt J. How physically active are people following stroke? Systematic review and quantitative synthesis. Phys Ther. 2017;97(7):707–17.

104. Michie S, Carey RN, Johnston M, Rothman AJ, De Bruin M, Kelly MP, et al. From theory-inspired to theory-based interventions: A protocol for developing and testing a methodology for linking behaviour change techniques to theoretical mechanisms of action. Ann Behav Med. 2018;52(6):501–12.

105. Seymour RB, Hughes SL, Ory MG, Elliot DL, Kirby KC, Migneault J, et al. A lexicon for measuring maintenance of behavior change. Am J Health Behav. 2010;34(6):660–8.

106. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ. 2009;339.

107. Masrur M, Richardson J, Tang A, Thabane L, Cino E. Intervention-related factors associated with physical activity maintenance among post-stroke patients: a protocol for a systematic review with meta-analysis and meta-regression. JBI Evid Synth. 2020;18(8):1738–50.

108. Dean SG, Poltawski L, Forster A, Taylor RS, Spencer A, James M, et al. Community-based rehabilitation training after stroke: Results of a pilot randomised controlled trial (ReTrain) investigating acceptability and feasibility. BMJ Open. 2018;8(2):1–13.

109. Kanai M, Izawa KP, Nozoe M, Kubo H, Kobayashi M, Onishi A, et al. Long-Term Effect of Promoting In-Hospital Physical Activity on Postdischarge Patients with Mild Ischemic Stroke. Clin Rehabil. 2019;28(8):1047–56.

110. Mudge S, Barber PA, Stott NS. Circuit-Based Rehabilitation Improves Gait Endurance but Not Usual Walking Activity in Chronic Stroke: A Randomized Controlled Trial. Arch Phys Med Rehabil. 2009;90(12):1989–96.

111. Vanroy C, Feys H, Swinnen A, Vanlandewijck Y, Truijen S, Vissers D, et al. Does a

cycling program combined with education and followed by coaching promote physical activity in subacute stroke patients? A randomized controlled trial. Disabil Rehabil. 2019;98(4):413–21.

112. Olney SJ, Nymark J, Brouwer B, Culham E, Day A, Heard J, et al. A randomized controlled trial of supervised versus unsupervised exercise programs for ambulatory stroke survivors. Stroke. 2006;37(2):476–81.

113. Batchelor FA, Hill KD, Mackintosh SF, Said CM, Whitehead CH, Gardner MM, et al. Effects of a multifactorial falls prevention program for people with stroke returning home after rehabilitation: A randomized controlled trial. Arch Phys Med Rehabil. 2012;93(9):1648–55.

114. Wan LH, Zhang XP, You LM, Ruan HF, Chen SX, Mo MM, et al. The efficacy of a comprehensive reminder system to improve health behaviors and blood pressure control in hypertensive ischemic stroke patients. J Stroke Cerebrovasc Dis. 2018;25(9):2259–70.

115. Vahlberg B, Cederholm T, Lindmark B, Zetterberg L, Hellström K. Short-term and long-term effects of a progressive resistance and balance exercise program in individuals with chronic stroke: a randomized controlled trial. Disabil Rehabil. 2017;39(16):1615–22.

116. Marquardt MK, Oettingen G, Gollwitzer PM, Sheeran P, Liepert J. Mental contrasting with implementation intentions (MCII) improves physical activity and weight loss among stroke survivors over one year. Rehabil Psychol. 2017;62(4):580–90.

117. Mayo NE, Anderson S, Barclay R, Cameron JI, Desrosiers J, Eng JJ, et al. Getting on with the rest of your life following stroke: a randomized trial of a complex intervention aimed at enhancing life participation post stroke. Clin Rehabil. 2015;29(12):1198–211.

118. Severinsen K, Jakobsen JK, Pedersen AR, Overgaard K, Andersen H. Effects of resistance training and aerobic training on ambulation in chronic stroke. Am J Phys Med Rehabil. 2014;93(1):29–42.

119. Salter K, Campbell N, Richardson M, Mehta S, Jutai J, Zettler L, et al. Outcome Measures in Stroke Rehabilitation. In: Evidence-Based Review of Stroke Rehabilitation [Internet]. Heart and Stroke Foundation; 2013. Available from: http://www.ebrsr.com/evidence-review

120. Uniform Data System for Medical Rehabilitacion. The FIM ® Instrument: Its Background, Structure, and Usefulness. UDSMR. Buffalo; 2012.

121. Berg K, Wood-Dauphinee S, Williams JI, Gayton D. Measuring balance in the elderly: Preliminary development of an instrument. Physiother Canada. 1989;41(6):304–11.

122. Shah S, Vanclay F, Cooper B. Improving the sensitivity of the Barthel Index for stroke rehabilitation. J Clin Epidemiol. 1989;42(8):703–9.

123. Enright PL, McBurnie MA, Bittner V, Tracy RP, McNamara R, Arnold A, et al. The 6-min walk test: A quick measure of functional status in elderly adults. Chest. 2003;123(2):387–98.

124. Hodkinson HM. Evaluation of a mental test score for assessment of mental impairment in

the elderly. Age Ageing. 1972;

125. Michie S, Stralen MM van, West R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Arch Dermatol. 2011;121(7):929–30.

126. Michie S, Atkins L, West R. The Behaviour Change Wheel: A Guide to Designing Interventions. London: Silverback Publishing; 2014. 1–46 p.

127. Howlett N, Trivedi D, Troop NA, Chater AM, Id S. Are physical activity interventions for healthy inactive adults effective in promoting behavior change and maintenance, and which behavior change techniques are effective? A systematic review and meta-analysis. Transl Behav Med. 2019;9(1):147–57.

128. Prochaska JO, Di Clemente CC. Transtheoretical therapy: Toward a more integrative model of change. Psychotherapy. 1982;19(3):276–88.

129. Drye L, Casper A, Sternberg A, Holbrook J, Jenkins G. The transitioning from trials to extended follow-up studies. Clin Trials. 2014;11(6):635–47.

130. Rudd T. National clinical guideline for stroke: Intercollegiate Stroke Working Party. Clin Med (Northfield Il). 2016;17(2).

131. Silfee VJ, Haughton CF, Jake-Schoffman DE, Lopez-Cepero A, May CN, Sreedhara M, et al. Objective measurement of physical activity outcomes in lifestyle interventions among adults: A systematic review. Prev Med Reports. 2018;11(May):74–80.

132. Johnson S, Regnaux JP, Marck A, Berthelot G, Ungureanu J, Toussaint JF. Understanding how outcomes are measured in workplace physical activity interventions: A scoping review. BMC Public Health. 2018;18(1):1–12.

133. Tudor-locke C, Craig CL, Brown WJ, Clemes SA, Cocker K De, Giles-corti B, et al. How Many Steps/day are Enough? For Adults. Int J Behav Nutr Phys Act. 2011;8(79):1–17.

134. Harris JE, Eng JJ. Strength training improves upper-limb function in individuals with stroke: A meta-analysis. Stroke. 2010;41(1):136–40.

135. Carver C, Scheier M. Control Theory: A Useful Conceptual Framework for Personality-Social, Clinical, and Health Psychology Charles. Psychol Bull. 1982;92(1):111–35.

136. Bandura A. SOCIAL COGNITIVE THEORY: An Agentic Perspective. Annu Rev Psychol. 2001;52:1–26.

137. Richardson J, Tang A, Guyatt G, Thabane L, Xie F, Sahlas D, et al. FIT for FUNCTION: Study protocol for a randomized controlled trial. Trials. 2018 Jan 15;19(1).

138. Morris JH, Oliver T, Kroll T, Joice S, Williams B. Physical activity participation in community dwelling stroke survivors: synergy and dissonance between motivation and capability. A qualitative study. Physiotherapy. 2017;103(3):311–21.

139. Michie S, Abraham C, Whittington C, McAteer J. Effective Techniques in Healthy Eating and Physical Activity Interventions: A Meta-Regression. Heal Psychol. 2009;28(6):690–701.

140. Samdal GB, Eide GE, Barth T, Williams G, Meland E. Effective behaviour change techniques for physical activity and healthy eating in overweight and obese adults; systematic review and meta-regression analyses. Int J Behav Nutr Phys Act. 2017;14(1):1–14.

141. Michie S, Abraham C. Interventions to Change Health Behaviours: Evidence-Based or Evidence-Inspired? Psychol Heal. 2004;19:29.

142. Rothman AJ, Baldwin AS, Hertel AW, Fuglestad PT. Self-regulation and behavior change : Disentangling behavioral initiation and behavioral maintenance. Handb Self-Regulation Res Theory, Appl. 2011;(January 2016):106–22.

143. Lee IM, Shiroma EJ, Evenson KR, Kamada M, LaCroix AZ, Buring JE. Accelerometer-measured physical activity and sedentary behavior in relation to all-cause mortality: The women's health study. Circulation. 2018;137(2):203–5.

144. Lee JY, Kwon SY, Kim WS, Hahn SJ, Park J, Paik NJ. Feasibility, reliability, and validity of using accelerometers to measure physical activities of patients with stroke during inpatient rehabilitation. PLoS One [Internet]. 2018;13(12):1–13. Available from: http://dx.doi.org/10.1371/journal.pone.0209607

145. Gunlicks-Stoessel M, Nufson L, Westervelt A, Almirall D, Murphy S. A Pilot SMART for Developing an Adaptive Treatment Strategy for Adolescent Depression. J Clin Child Adolesc Psychol. 2011;45(June):314–8.

146. Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: Development of a general scale. Eval Program Plann. 1979;2(3):197–207.

147. Attkisson CC, Zwick R. The client satisfaction questionnaire. Psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann. 1982;5(3):233–7.

148. Pistorello J, Jobes DA, Compton SN, Locey NS, Walloch JC, Gallop R, et al. Developing Adaptive Treatment Strategies to Address Suicidal Risk in College Students: A Pilot Sequential, Multiple Assignment, Randomized Trial (SMART). Arch Suicide Res. 2018;22(4):644–64.

149. Stacey FG, James EL, Chapman K, Courneya KS, Lubans DR. A systematic review and meta-analysis of social cognitive theory-based physical activity and/or nutrition behavior change interventions for cancer survivors. J Cancer Surviv. 2015;9(2):305–38.

150. Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios LP, et al. A tutorial on pilot studies: The what, why and how. BMC Med Res Methodol. 2010;10:1–10.

151. Glazer NL, Lyass A, Esliger DW, Blease SJ, Freedson PS, Massaro JM, et al. Sustained and Shorter Bouts of Physical Activity are Related to Cardiovascular Health. Med Sci Sports Exerc. 2013;45(1):109–15.

152. Walker, S N; Sechrist, K R; Pender NJ. Promoting Healthy Lifestyle characteristics - Walker 1987.pdf. Vol. 36, The Health-Promoting Lifestyle Profile: development a d psychometric characteristics. 1987. p. 76–81.

153. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From Theory to Intervention : Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques. 2008;57(4):660–80.

154. Jurkiewicz MT, Marzolini S, Oh P. Adherence to a home-based exercise program for individuals after stroke. Top Stroke Rehabil. 2011;18(3):277–84.

155. Nicholson S, Sniehotta FF, Van Wijck F, Greig CA, Johnston M, Mcmurdo MET, et al. A systematic review of perceived barriers and motivators to physical activity after stroke. Int J Stroke. 2013;8(5):357–64.

156. Rimmer JH, Wang E, Smith D. Barriers associated with exercise and community access for individuals with stroke. J Rehabil Res Dev. 2008;45(2):315–22.

157. Lisa A. Simpson, Janice J. Eng AET. Exercise perceptions among people with stroke: Barriers and facilitators to participation. Int J Ther Rehabil. 2011;18(9):530.

158. Moore SA, Hallsworth K, Plötz T, Ford GA, Rochester L, Trenell MI. Physical Activity, Sedentary Behaviour and Metabolic Control following Stroke: A Cross-Sectional and Longitudinal Study. PLoS One. 2013;8(1).

159. Abraham C, Michie S. A Taxonomy of Behavior Change Techniques Used in Interventions. Heal Psychol. 2008;27(3):379–87.

Appendix

Appendix A Ovid Embase Search Strategy

#	Searches	Results
1	exp exercise/	316961
2	exercis*.mp.	494068
3	exp physical activity/	385815
4	physical activity.mp.	192030
5	fitness/	35757
6	physical fitness.mp.	11997
7	running/	27211
8	run*.mp.	258993
9	walking/	63750
10	walk*.mp.	179424
11	swimming/	20956
12	swim*.mp.	51024
13	(gym adj2 member*).mp.	88
14	gardening/	1493
15	physical education/	10707
16	dancing/	4410
17	danc*.mp.	9838
18	sport/	48119
19	sport*.mp.	135869
20	yoga/	6769
21	yoga.mp.	8424
22	recreation/	18165
23	(fitness adj3 (regime* or program* or class* or cent*)).mp.	2769
24	recreation.mp.	22177
25	motor activity/	43157
26	cardiorespiratory fitness/	3933
27	cardiorespiratory fitness.mp.	7009

28	aerobic capacity/	11231
29	aerobic capacity.mp.	14005
30	(physical adj5 (fit* or train* or activ* or endur*)).mp.	225682
31	(exercis* adj5 (fit* or train* or activ* or endur* or class)).mp.	77583
32	((leisure or fitness) adj5 (centre* or center* or facilit*)).mp.	1493
33	aquafitness.mp.	4
34	aquatics.mp.	155
35	jogging/	1959
36	jog*.mp.	3687
37	pilates/	578
38	cycling/	11360
39	(bike* or biking).mp.	3635
40	rollerblading.mp.	39
41	roller blading.mp.	9
42	roller skating/	28
43	exertion*.mp.	30185
44	resistance training/	15772
45	resistance training.mp.	18808
46	weight lifting/	4777
47	high intensity interval training/	1522
48	("use" adj3 stair*).mp.	277
49	((spinning or spin) adj2 class*).mp.	131
50	treadmill ergometry/ or treadmill/ or treadmill test/ or treadmill exercise/	31746
51	treadmill.mp.	46526
52	Tai Chi/	2700
53	tai chi.mp. or Tai Chi/	3056
54	nordic walking/	251
55	or/1-54	1316409
56	cerebrovascular disease/	52768
57	basal ganglion hemorrhage/	567
58	cerebral artery disease/	4190

59	cerebrovascular accident/	187339
60	stroke/	127046
61	Vertebrobasilar Insufficiency/	2647
62	stroke patient/ or stroke unit/	30846
63	exp carotid artery disease/	63240
64	exp Brain Hemorrhage/	129685
65	brain infarction/ or brain stem infarction/ or cerebellum infarction/	52419
66	exp Brain Ischemia/	172314
67	exp intracranial aneurysm/	31874
68	cerebellum injury/	1893
69	carotid endarterectomy/	17466
70	paradoxical embolism/	1776
71	(stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc* or cva* or apoplex* or isch?emi* attack* or neurologic* deficit* or SAH or AVM).tw.	478436
72	((brain* or cerebr* or cerebell* or cortical or vertebrobasilar or hemispher* or intracran* or intracerebral or infratentorial or supratentorial or MCA or anterior circulation or posterior circulation or basal ganglia) adj5 (isch?emi* or infarct* or thrombo* or emboli* or occlus* or hypox* or vasospasm or obstruction or vasculopathy)).tw.	164344
73	((lacunar or cortical) adj5 infarct*).tw.	7099
74	((brain* or cerebr* or cerebell* or intracerebral or intracran* or parenchymal or intraventricular or infratentorial or supratentorial or basal gangli* or subarachnoid or putaminal or putamen or posterior fossa) adj5 (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)).tw.	98091
75	((brain or cerebral or intracranial or communicating or giant or basilar or vertebral artery or berry or saccular or ruptured) adj5 aneurysm*).tw.	41957
76	((brain or intracranial or basal ganglia or lenticulostriate) adj5 (vascular adj5 (disease* or disorder or accident or injur* or trauma* or insult or event))).tw.	1929
77	((isch?emic or apoplectic) adj5 (event or events or insult or attack*)).tw.	42605
78	((cerebral vein or cerebral venous or sinus or sagittal) adj5 thrombo*).tw.	9121
79	(CVDST or CVT).tw.	2550

80	((intracranial or cerebral art* or basilar art* or vertebral art* or vertebrobasilar or vertebral basilar) adj5 (stenosis or isch?emia or insufficiency or arteriosclero* or atherosclero* or occlus*)).tw.	32559
81	or/56-80	841258
82	55 and 81	50204
83	randomized controlled trial/	559606
84	(Random* Contro* Tria* or rct).mp.	791402
85	83 or 84	791402
86	follow up.mp. or follow up/	1827752
87	3 month*.mp.	308683
88	three month*.mp.	86673
89	6 month*.mp.	450436
90	six month*.mp.	110170
91	12 month*.mp.	292959
92	twelve month*.mp.	12004
93	1 year.mp.	285109
94	1 yr.mp.	13427
95	((following or post) adj2 discharge).mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word]	18369
96	15 month*.mp.	34997
97	fifteen month*.mp.	1163
98	24 month*.mp.	92215
99	twenty four month*.mp.	1063
100	or/86-99	2766460
101	85 and 100	218836
102	82 and 101	1902

Appendix B Data Extraction Form

Initials:		Date:
1. Article identifiers		
Country:	Author:	Year:

2. Eligibility	
☐RCT or cluster RCT	☐At least 3-months follow-up
☐Intervention: Intended increase participant PA	☐Age ≥18 yrs. ☐English language
☐Post-Stroke Patients	

3. Study details		
Country:		
Source of funding	☐Government	☐ Other :
	☐Foundation:	☐Not reported
	☐ Industry:	
Study Design:	☐Randomized Parallel Group	☐ Quasi-randomized Parallel Group
	☐Cross over	☐ Cluster-randomized
Clinical trial registration database and #:		☐Not reported
Research Question/Purpose:		

4. Participants
Disease(s) (if non-stroke):
Inclusion Criteria:

Exclusion Criteria:
Recruitment Setting ☐ Hospital (Inpatient) ☐ Specialty Clinic (Outpatient) ☐ Unclear ☐ Primary care ☐ Community setting: ☐ Institution: ☐Other:

Baseline Characteristics		Intervention		Comparison #1		Comparison #2	
Time since stroke (SD)							
Mean age (SD)							
Stroke Severity							
Sample Size	Total n=	n=		n=		n=	
Gender		Males	Females	Males	Females	Males	Females
		☐# ☐%	☐# ☐%	☐# ☐%	☐# ☐%	☐# ☐%	☐# ☐%

Baseline Characteristics cont.	Intervention	Comparison #1	Comparison #2
BMI			
PA level			
Other:			
Other:			

5. Intervention
Training/characteristics of the deliverer
Hypothesized effect of intervention (as stated by author) ☐Not reported

Mode of Delivery	
☐Face to face group	☐Written material (booklets, books, etc.)
☐Face to face individual	☐Apps
☐ Telephone	☐Online Program:
☐Video/DVD/ CD-ROM	☐Other:
Content ☐Exercise	☐Behavioral Intervention
Description:	Description:
	BCT (Cluster + BCT):
Length (weeks)	
Frequency (sessions per week)	
Duration of sessions hours/minutes	
Quantity (length x frequency x duration) hours	

6. Comparison/Control	
Training/characteristics of the deliverer	
Hypothesized effect of intervention (as stated by author)	☐Not reported
Mode of Delivery	
☐Face to face group	☐Written material (booklets, books, etc.)
☐Face to face individual	☐Apps
☐ Telephone	☐Online Program:
☐Video/DVD/ CD-ROM	☐Other:

Content	☐Exercise Description:	☐Behavioral Intervention Description: BCT (Cluster + BCT):
Length (weeks)		
Frequency (sessions per week)		
Duration of sessions	hours/minutes	
Quantity (length x frequency x duration)	hours	

Outcome Measures			
A. Name			
☐Primary Outcome ☐Secondary Outcome ☐ Tertiary Outcome ☐Unclear			
Type: ☐Patient-reported ☐Objective ☐Combination ☐Other			
Description			
☐ Categorical ☐ Continuous	Min Units_____	Max	Maximum score = best ☐ worst ☐

9. Results
Any significant differences in demographics, health-related characteristics or baseline outcome measures? No ☐ ☐ Yes – If yes, please explain:
Sample size calculation included? Yes ☐ No ☐ Were the statistical methods for the primary outcome measure(s) appropriate? Yes ☐ No ☐ Were the statistical methods for the secondary outcome measures appropriate Yes ☐ No ☐ Was an intention-to-treat analysis performed for the primary outcome(s)? Yes ☐ No ☐

Was an intention-to-treat analysis performed for the secondary outcome(s)? Yes ☐ No ☐

Was the ICC reported for cluster randomized trials? Yes ☐ No ☐

Was adherence to the intervention quantified? Yes ☐ No ☐

If yes, note adherence rates in each group if known:

Was there other information about the acceptability of the intervention? Yes ☐ No ☐

NOTES:

Were outcomes assessed separately for each group? Yes ☐ No ☐

Were any adverse events or side effects reported? Yes ☐ No ☐

If yes, please complete this table:

Adverse event	Total N (%)	N (%) in Control Group	N (%) in Intervention Group	Total N (%) attributed to Intervention

Were reasons for participants lost to follow-up reported?

Were reasons similar between groups?

Lost to follow-up	Total N (%)	N (%) in Control Group	N (%) in Intervention Group	

10. Data Extraction				
Measure	Intervention		Comparison 1	
	n	Mean (SD); SE; CI; P Value	n	Mean (SD); SE; CI; P-Value

Appendix C Behavioral change techniques used in interventions

Study ID, Country	BCTs Used in Intervention
Batchelor et al. (2012) Australia	Action Planning Self-monitoring of behavior Feedback on behavior Demonstration of behavior Behavioral practice and rehearsal Instruction on how to perform the behavior Social Support (unspecified) Graded Tasks Information about Health consequences Credible source Generalization of a target behavior
Dean et al. (2017) United Kingdom	Goal Setting Problem Solving Action Planning Review Behavioural Goals Self-Monitoring of Behaviour Social Support (unspecified) Instructions on how to perform a behavior Demonstration of Behaviour Behavioral practice/rehearsal Material Incentive (behavior) Graded Tasks
Kanai et al. (2018) Japan	Self-monitoring of behavior Goal setting (behavior) Action planning Review behavior goals Social reward Graded tasks Feedback on behavior Credible Source Information about health consequences
Mudge et al. (2009) New Zealand	Instruction on how to perform the behavior Behavioral practice/rehearsal Demonstration of the behavior Graded tasks
Olney et al. (2006) Canada	Instruction on how to perform the behavior Behavioral practice/rehearsal Demonstration of behavior Review behavior goals Action Planning Biofeedback
Vanroy et al. (2017)	Instruction on how to perform a behavior

Belgium	Behavioral practice/rehearsal Demonstration of the behavior Information about health consequences Action Planning
Wan et al. (2016) China	Goal setting (behavior) Action planning Credible source Information about health consequences Feedback on behavior Problem-solving Social support Instruction on how to perform the behavior

Appendix D Summary of Risk of Bias Judgements

Batchelor et al. (2012)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"participants were allocated into either the control group or the intervention group (1:1 allocation ratio, simple randomization) using a computer-generated random allocation sequence ..."	Low risk
Allocation concealment (selection bias)	"Staff independent of the study undertook sequence and concealment. The envelopes containing the allocation will be stored in one location and participants will be assigned in order of completed baseline assessment."	Low risk
Blinding of participants and personnel (performance bias)	"... participants were not blind to group allocation ..." Comment: The study authors did not specify whether the staff delivering the interventions were blinded to group allocation.	High Risk
Blinding of outcome (detection bias)	"The physiotherapists conducting baseline and the follow-up assessment were blind to group allocation."	Low Risk
Incomplete outcome data (attrition bias) – 3 Month Follow-up	Comment: The number of participants missing at the three-month follow-up was 7(10.93%) and control 5(6.25%) for the intervention and control group respectively. The reasons for loss to follow-up were similar between the intervention and control groups.	Low Risk
Selective reporting (reporting bias)	Comment: The trial was registered and a protocol for the trial was published. Both the registry and the protocol contained outcomes that were subsequently reported in the original trial manuscript.	Low risk
Other Bias	None to report	Low risk

Dean et al. (2017)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"Participants will be allocated 1:1 to either intervention or control arms using a web-based randomization service supported by the Peninsula Clinical Trials Unit (PenCTU). We	Low Risk

	will use minimization procedures to ensure balance between groups on two variables: time since stroke (≤3 vs >3 months), since spontaneous recovery might be more likely among those whose stroke was relatively recent, and level of functional disability (modified Rankin Scale (mRS) score ≤2 vs >2), since this may limit the extent and nature of training possible for a participant."	
Allocation concealment (selection bias)	"Once the remote randomization service has registered and randomized the participant, allocation will be made known to the trial manager, who will not be involved in assessing patient outcomes. Following randomization, the trial manager will contact participants to inform them of group allocation."	Low Risk
Blinding of participants and personnel (performance bias)	"Participants, personal trainers providing the intervention, and researchers conducting the process and economic evaluation cannot be blinded to allocation."	High Risk
Blinding of outcome measure (detection bias)	"... [O]utcomes will be assessed by an independent assessor blinded to group allocation. Participants, who have been informed of their allocation, will be reminded to hide their allocation from the assessor. Any incidents of unblinding will be recorded, and the assessor will be asked to record their guess of participant allocation after undertaking the assessments. Following recommended strategies to maintain and assess blinding, the outcomes assessor will not be based at the research center."	Low Risk
Incomplete outcome data (attrition bias) – 3 Month Follow-up	Comment: The number of participants missing at the three-month follow-up was 4(17.00%) and 4(18.00%) for the intervention and control group respectively. The reasons for loss to follow-up were similar in both groups.	Low Risk
Incomplete outcome data (attrition bias) – 6 Month Follow-up	Comment: The number of participants missing at the six-month follow-up was 7(30.00%) and 5(23.00%) for the intervention and control group respectively. These attrition rates are not within acceptable ranges even though reasons for loss to follow-up were similar in both groups.	High Risk
Selective reporting (reporting bias)	Comment: All outcomes in protocol and the register were reported in the final paper.	Low Risk

Other Bias	Comment: None to report	Low Risk

Kanai et al. (2018)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"An independent person who was not involved in enrollment or outcome assessment performed the randomization using a computer-generated 1:1 allocation sequence and permuted block size of 2." Comment: A clear description of the randomization was provided in the original transcript	Low Risk
Allocation concealment (selection bias)	"Participants were randomly assigned to the intervention group or the control group by ... [an] ... independent person. The sequence was concealed until intervention."	Low Risk
Blinding of participants and personnel (performance bias)	"This study did not blind physical therapists as to which patients were in the intervention group or control group." Comment: The authors did not specify whether participants were blinded to group allocation. Given the distinct nature of the two interventions, it is unlikely that blinding of participants was feasible.	High Risk
Blinding of outcome measure (detection bias)	Comment: The authors did not specify whether outcome assessors were blinded to group allocation. However, participants' physical activity was recorded using an accelerometer, and data were analyzed by an "independent person blinded to group allocation". Thus, it is unlikely that a lack of blinding of assessors would have impacted outcome determination.	Low risk
Incomplete outcome data (attrition bias) – 3 Month Follow-up	Comment: The number of participants missing at the three-month follow-up was 14(51.90%) and 11(39.30%) for the intervention and control groups respectively. These high attrition rates warrant concern for attrition bias. Additionally, the reasons for the dropouts were also different between the two groups.	High Risk
Selective reporting (reporting bias)	Comment: The outcome measures reported in the original RCT matched with that of the trial registry. The outcome measures of the follow-	Low Risk

	up paper that assessed participants at the three-month post-intervention timepoint were also the same as the main trial. Hence, it is unlikely that the researchers reported only statistically significant outcome measures.	
Other Bias	Not applicable	Low Risk

Mudge et al. (2009)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"Participants were randomly assigned to the exercise or control group through the use of computer-generated random numbers by an individual not associated with the study."	Low risk
Allocation concealment (selection bias)	"Participants were randomly assigned to the exercise or control group ... by an individual not associated with the study." "Randomization was revealed to each participant by the principal investigator after the second baseline assessment." Comment: Given that the participants were assigned to their respective groups by a third party and that participants were informed of their group allocation only after the second baseline testing, it is likely that allocation was adequately concealed.	Low Risk
Blinding of participants and personnel (performance bias)	"[The intervention groups] were led by 1 of the investigators ... assisted by 2 physiotherapy students." "Participants were not blind because they were aware of their own group allocation, which was revealed after the second testing session"	High Risk
Blinding of outcome measure (detection bias)	"Outcome assessment was performed by an independent physiotherapist blind to treatment assignment." "Participants were instructed not to discuss group allocation with the assessor. The testing sessions were carried out in the same rehabilitation clinic as the intervention groups but were scheduled at different times to maintain blinding of the assessor."	Low Risk

	"Unmasking of the independent assessor occurred in the case of 3 participants who inadvertently stated or implied their group allocation." Comment: The authors took precautionary measures to blind the outcome assessor. Participants' physical activity was also measured using Step Watch Monitors, thus outcome determination would not have been affected by the three unblinding events.	
Incomplete outcome data (attrition bias) – 3 Month Follow-up	"Intention-to-treat analysis was used for all outcomes, and a carry-forward method was used to account for missing data." Comment: The number of participants missing at the three-month follow-up was 4(12.90%) and 4(14.81%) for the intervention and control group respectively. The reasons for loss to follow-up were similar in both groups. Additionally, the authors performed an intention-to-treat analysis to account for the missing data. Hence, we suspect that the attrition rate did not bias the results.	Low Risk
Selective reporting (reporting bias)	All outcome measures reported in the trial registry matched with the published report.	Low Risk
Other Bias	None to report.	Low Risk

Olney et al. (2006)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"The study statistician prepared a computer-generated randomization list stratified by walking speed (≥0.40 and <0.40 m/s) and study center."	Low Risk
Allocation concealment (selection bias)	"The treatment assignments were concealed by the method of sealed envelopes. After informed consent was obtained and after the baseline assessment was performed, a research assistant opened the next sequential envelope and assigned the subjects to the supervised or unsupervised group accordingly."	Low Risk

Blinding of participants and personnel (performance bias)	"It was not possible to blind participants to group membership." Comment: It is unclear whether personnel were blinded to group allocation since the authors did not specify who delivered the interventions.	High Risk
Blinding of outcome measure (detection bias)	"Because of fiscal constraints, testers were not blinded."	High Risk
Incomplete outcome data (attrition bias) – 3 Month Follow-up	"All subjects were analyzed as randomized according to the intent-to-treat principle, although no imputation was made for missing data." Comment: The number of participants missing at the three-month follow-up was 7(18.42%) and 7(19.44%) for the intervention and control groups respectively. These figures are within the acceptable attrition rates. The reasons for loss to follow-up were also similar for both groups.	Low Risk
Incomplete outcome data (attrition bias) – 6 Month Follow-up	Comment: The number of participants missing at the six-month follow-up was 9(23.70%) and 11(30.60%) from the intervention and control groups respectively. The reasons for loss to follow-up were also similar for both groups. However, the attrition rates are not within acceptable ranges.	High Risk
Selective reporting (reporting bias)	Comment: No protocol or registry was found for this trial. However, the study reported all outcomes measures that were highlighted in the methods section. All significant and non-significant results were also reported adequately.	Low Risk
Other Bias	Nothing to report	Low Risk

Vanroy et al. (2017)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"Patients were stratified after baseline according to the type of stroke, motor impairment severity, and aerobic capacity … A permuted block design of 4 was used, created by a computer random-number generator, with	Low Risk

	an allocation ratio of 2:2. After the 3-month program, in the ACG, a second group allocation was performed based on the initial stratified randomization procedure."	
Allocation concealment (selection bias)	"Concealed allocations were achieved by contacting the holder of the allocation schedule who was offsite."	Low Risk
Blinding of participants and personnel (performance bias)	"Patients were aware of different programs" Comment: It is unclear whether personnel were blinded to group allocation since the authors did not specify who delivered the interventions.	High Risk
Blinding of outcome measure (detection bias)	"The assessor was blinded to the group assignment. Patients were aware of different programs but instructed not to inform the assessor."	Low Risk
Incomplete outcome data (attrition bias) – 3 Month Follow-up	Comment: The number of participants missing at the three-month follow-up was 1(6.25%) and 2(8.00%) for the intervention and control group respectively. However, the reasons for loss to follow-up were similar in both groups.	Low Risk
Incomplete outcome data (attrition bias) – 6 Month Follow-up	Comment: The number of participants missing at the six-month follow-up was 1(6.25%) and 3(12.00%) for the intervention and control group respectively. The reasons for loss to follow-up were similar in both groups.	Low Risk
Selective reporting (reporting bias)	Comment: Two manuscripts were published (in 2017 and 2019) from the same registered trial (NCT01070459). Measures from the manuscript published in 2017 corresponded with the ones included in the registry. However, the PA outcome measures (Steps walked per day, PASIPD, energy expenditure) included in the 2019 version of the manuscript did not correspond with the registry.	High Risk
Other Bias	None to report	Low Risk

Wan et al. (2016)

Category	Reasoning	Assessment
Random Sequence generation (selection bias)	"The random allocation sequence was computer-generated by a researcher not involved in recruitment and who had no contact with the patients."	Low Risk

Allocation concealment (selection bias)	"Group allocation was determined using a sealed opaque envelope with a serial number on the outside and a folded sheet of paper inside with the group name. The study coordinators enrolled patients and assigned them to different groups according to the serial numbers."	Low Risk
Blinding of participants and personnel (performance bias)	"Patients in the control group were also blinded to the intervention, whereas patients in the intervention group were asked not to divulge information regarding the intervention to other patients and assessors." Comment: Knowledge of group allocation could have affected the physical activity behavior of participants in the intervention group. The authors also did not specify whether the nurses delivering the interventions were blinded to group allocation.	High Risk
Blinding of outcome measure (detection bias)	"Outcomes were assessed by graduate-level nursing students blinded to the intervention." "Data entry was conducted by an individual blinded to the group allocation."	Low Risk
Incomplete outcome data (attrition bias) – 3 Month Follow-up	Comment: The number of participants missing from the intervention and control group was 6 (13.04%) and control 4 (11.11%) respectively. The reasons for loss to follow-up were also similar between the intervention and control groups.	Low Risk
Selective reporting (reporting bias)	Comment: The trial registry was not well maintained, which prevented verification of the outcome measures included in the published manuscript. However, the measures included in the methods section corresponded with the results. Additionally, the authors adequately described both significant and non-significant results.	Low Risk
Other Bias	Nothing to report	Low Risk

Appendix E Behavior Change Wheel

The Behavior Change Wheel (BCW) is composed of eight steps that provide a framework for designing behavior change interventions (126). **Steps 1-3** focus on explicitly specifying the target behavior to change, which for our study was: *achieving 500 MET-min of energy expenditure from MVPA/week and maintaining this activity level for a minimum of 6-months after the intervention period* (*Table A.1*). We will describe in detail the application of **Steps 4-8** of the Behavior Change Wheel that focuses on participants and the intervention design.

Table A.1 Components of the Target Behavior

Questions	Content
1. Target behavior	Participating in 500 MET-minutes or 150 minutes of MVPA over 7 days
2. Who needs to perform the behavior?	Adult (>18yrs) stroke survivors (Refer to "eligibility criteria" for additional sample details)
3. What do they need to do differently to achieve the desired change?	Increase and/or maintain their MVPA participation
4. When do they need to do it?	Anytime during the waking hours of the day
5. How often do they need to do it?	As often as necessary to meet recommended physical activity guidelines.
6. With whom do they need to do it?	Alone, with the assistance of a caregiver, or in a group

Step 4: Identify what needs to be changed

Components of the ***capability, opportunity, motivation, and behavior (COM-B) model*** were investigated to determine how each construct affects the physical activity maintenance behavior of stroke survivors(125). *Table A.2* summarizes our findings and decisions.

I. Capability

Capability entails both the *physical capacity* (physical strength, skill, and stamina) and *psychological capacity* (knowledge or psychological skill) to engage in a behavior(125).

To gauge whether the response measure (500 MET-minutes or 150 minutes of MVPA/week) was realistic for our study population, we explored the physical activity levels reported in studies where participant characteristics were similar to the inclusion criteria of FIT for FUNCTION(137). Hui et al. (2018) reported participants of FIT for FUNCTION performing 117 minutes (SD=72minutes) of moderate-intensity and 0.9 minutes (SD=1.7minutes) of vigorous-intensity activity per day but included a small sample (n=12)(58). Stroke survivors (n=45) of the ReTrain pilot trial also demonstrated high activity levels, performing >30 minutes of MVPA/day at the intervention-end, 3-, and 6-month follow-up timepoints(108). However, these participants had a high baseline physical activity level (>50 minutes of MVPA/day) that remained similar at the later timepoints(108). In a cross-sectional trial, Moore et al. (2013) reported stroke survivors (n=31) performing 27 minutes per day of MVPA after one-week post-stroke(158). Similarly, a trial by Kanai et al. (2018), which included self-monitoring as an intervention, reported participants (n=13) undertaking an average of 22 minutes (SD=14.4 minutes) of MVPA per day at 3-month follow-up(109). In general, the evidence suggests that stroke survivors meeting the eligibility criteria for FIT for FUNCTION would possess the stamina to meet the physical activity targets of this trial. Other components of *physical capacity* (i.e. having adequate skill and strength to improve free-living physical activity) can be addressed by the group exercise sessions of FIT for FUNCTION(137).

With regards to *psychological capacity*, a systematic review by Nicholson et al. (2012) listed perceived physical impairments from stroke as one of the key barriers to physical activity participation(155). Jurkiewicz et al. (2015) and Morris et al. (2017) also reported that such

impairments, along with a decreased skill-level post-stroke, discouraged individuals from adhering to the recommended exercise programs(138,154). However, when individuals adjusted their expectations of skill level and capability, high levels of activity were achieved(138). Knowledge about where and how to exercise, provided by qualified personnel, have also been identified by stroke survivors as an important facilitator of physical activity(156,157). Hence, SMART interventions can target psychological capacity through information provision and helping survivors adjust the expectations of their skill level.

II. Opportunity

Opportunity is classified as the factors outside an individual that allow or prompt a behavior to take place and is subdivided into *physical opportunities* (time, triggers, resources, locations, and physical barriers) and *social opportunities* (interpersonal influences, social cues, cultural norms) opportunities(125)

Adequate transportation, access to economically feasible exercise programs, and availability of time were identified as *physical opportunities* that promote physical activity(138,154–157). FIT for FUNCTION is a well-established program within the community, and while it does not cover nor subsidize transportations costs, financial aid is available for program membership that can facilitate access. Time management education may be provided to target the perceived barrier of lack of time to participate in physical activity.

FIT for FUNCTION offers various *social opportunities* for participants to have contact with individuals with lived experiences with stroke through group-based sessions, which have been identified as an important facilitator of physical activity participation(138,155). Family support(138,154) and professional support(138,155–157) with guiding and facilitating physical

activity have also been identified as important *social opportunities* for motivating physical activity, which can be targeted by SMART interventions.

III. Motivation

Motivation is distinguished between *reflective motivations*, which involves evaluations and plans, and *automatic motivation*, involving emotional reactions, impulses, and desires, required to change a behavior(125). Stroke survivors who had positive beliefs about physical activity influencing recovery, preventing recurrent strokes, and increasing participation in life roles were motivated to undertake planned exercises (*reflective motivation*)(138). Contrarily, fear of recurrent strokes, fear of falling, and embarrassment were identified as demotivating factors for free-living physical activity participation (*automatic motivation*)(138,155). Thus, SMART interventions can be designed to provide evidence-based knowledge regarding the consequences of physical activity participation and incorporate behavioral change techniques to reduce the fear and embarrassment experienced by stroke survivors.

Table A.2 Evidence summary and potential targetability of the COM-B components in SMART interventions for influencing free-living physical activity after stroke

Component	Summary of Findings	Decision
Capability		
Physical	Participants have the stamina to meet recommended physical activity guidelines	No change needed
Psychological	Lack of information, perceived impairments, and reduced skills are barriers	**Potential target**
Opportunity		
Physical	Accessibility to and costs of transportation, accessibility, and costs of community exercise programs, and lack of time can act as barriers	**Potential target**: time management

Social	Contact with individuals with stroke, family support, professional staff can positively influence participation	**Potential target**
Motivation		
Reflective	Beliefs about the benefits of physical activity for stroke recovery impacts physical activity participation	**Potential target**
Automatic	Fear of recurrent stroke, fear of falling, and embarrassment can act as demotivating factors	**Potential target**

Step 5: Identifying Intervention Functions

In this step, the research team judged the nine intervention functions, included within the BCW guide, according to its affordability, practicability, effectiveness, acceptability, side effects/safety, and equity (APEASE)(126). In the end, education, persuasion, environmental restructuring, and enablement were chosen as target intervention functions because they met the APEASE criteria and were not included (in the desired format) within the existing FIT for FUNCTION program(137). See Table A.3.

Table A.3: Intervention Components Judged According to the APEASE Criteria and Availability in the F4F Program

Intervention Function	**APEASE met?**	**Availability in FIT for FUNCTION**
Education	Yes	No. Education could focus on current physical activity guidelines (response measure), including instructions on how, how much, and at what intensity physical activity can be performed, and evidence of benefits of physical activity
Persuasion	Yes	No. Persuasion could be focused on creating a positive perception of free-living physical activity, adjusting individual capability and skill post-stroke, and reducing fears and embarrassment
Incentivization	No. Not affordable nor practicable	No
Coercion	No, Not practicable nor acceptable	No
Training	Yes	Yes. Addressed in a group-based exercise
Restriction	No. Not practicable or acceptable	No

Environmental Restructuring	Yes	No
Modelling	Yes	No. Modelling was not used for performing free-living moderate-vigorous physical activity
Enablement	Yes	No. Enablement was not incorporated in the context of performing free-living physical activity

Step 6: Identifying Policy Categories

The research team determined that "service provision" met the APPEASE criteria for delivering the intervention(126). The components of both the existing FIT for FUNCTION program and the *FIT for FUNCTION+* behavioral interventions would constitute the service that is provided to the participants.

Step 7: Linking Behavioral Change Techniques to the Intervention Functions

Behavioral change techniques (from the behavioral change technique taxonomy version 1 (92) that were associated with the selected intervention functions, met the APEASE criteria, and not included in the existing FIT for FUNCTION program(137) were considered for the design of the SMART interventions. Additionally, "social reward", "graded tasks", and "verbal persuasion of capability" were also selected because they could easily be included within the program(92). Table A.4 lists the intervention functions, the associated COM-B components, and selected BCTs.

Table A.4 Assigning behavioral change techniques to intervention functions and associated COM-B components

Relevant COM-B Components	**Common Behavioral Change Techniques**	**Behavioral Change Techniques meeting APEASE criteria and not included in FIT for FUNCTION**
Intervention Function: **Education**		
Psychological capability Reflective motivation	Information about social and environmental consequences	Information about health consequences Feedback on Behavior

	Information about health consequences Feedback on behavior Feedback on outcome(s) of the behavior Prompts/cues Self-monitoring of behavior	Prompts/cues Self-monitoring of behavior
Intervention Function: **Persuasion**		
Automatic motivation Reflective motivation	Credible source Information about social and environmental consequences Information about health consequences Feedback on behavior Feedback on outcome(s) of behavior	Credible source Information about health consequences Feedback on behavior
Intervention Function: **Environmental Restructuring**		
Social opportunity Automatic motivation	Adding objects to environment Prompts/cues Restructuring physical environment	Prompts/cues
Intervention Function: **Modelling**		
Psychological capability Reflective and automatic motivation Social opportunity	Demonstration of behavior	Demonstration of behavior
Intervention Function: **Enablement**		
Psychological capability Social opportunity Automatic motivation	Social support (unspecified) Social support (practical) Goal setting (behavior) Goal setting (outcome) Adding objects to environment Problem solving Action planning Self-monitoring behavior Restructuring physical environment Review behavior goal(s) Review outcome goal(s)	Social support (unspecified) Goal setting (behavior/outcome) Problem Solving Action planning Self-monitoring of behavior Review behavior goal(s)

The BCTs that fit the APEASE criteria were further narrowed to fit two behavioral change theories: Control Theory and Social(135) Cognitive Theory(136). Michie et al. (2008) originally outlined the BCTs that fit with these two theories(159), which we translated to the current BCTTv1(92). Table A.5 outlines the selected BCTs and their fit with the theoretical constructs.

Table A.5 Behavioral change techniques by theoretical constructs

Theoretical Framework	**Behavioral Change Technique**	**Equivalent BCTTv1 Taxonomy**
Control Theory Constructs		
Goal setting	Prompt specific goal setting	1.3 Goal Setting (outcome) 1.4 Action Planning
Behavioral monitoring	Prompt review of behavior goals	2.4 Self-monitoring outcomes of behavior
Receiving feedback	Prompt self-monitoring of behavior	2.2 Feedback on behavior
Prompt self-monitoring of behavior	Provide feedback on performance	1.5 Review behavior goals
Social Cognitive Theory Self-Efficacy Constructs		
Mastery of experiences	Prompt intention formation	1.9 Commitment 1.1 Goal Setting (outcome)
	Set graded tasks	8.7 Graded tasks
Verbal persuasion	Provide general encouragement	3.1 Social support
Social modelling	Provide instructions	4.1 Instruction how to perform behavior
	Model or demonstrate behavior	9.1 Credible source 6.1 Demonstration of behavior
	Opportunities for social comparisons	6.1 Demonstration of behavior
Improving physical and emotional states	Information on consequences	5.1 Information about health consequences
	Prompt barrier identification	1.2 Problem solving

Step 8: Mode of Delivery

Based on the current structuring of the F4F program and the BCTs identified, face-to-face (individual and group) interactions and telephone consultations met the APPEASE criteria.

Appendix F Treatment fidelity checklist

Rater ID:		Date dd/mm/yyyy:	
Participant ID:	Physiotherapist ID:	Time Start:	Time End:

Intervention Select one:
☐***FIT for FUNCTION*+ Level 1** during *Stage 1* (Complete Box 1)
☐***FIT for FUNCTION*+ Level 1** during *Stage 2* (Complete Box 2)
☐***FIT for FUNCTION*+ Level 2** (Complete Box 3)
☐***FIT for FUNCTION*+ Level 3** (Complete Box 4)

BOX 1 *FIT for FUNCTION*+ Level 1 during *Stage 1*	
Behavioral Change Techniques	Decision
1.1 Goal Setting Description: Did the physiotherapist and participant agree on a goal to achieve 150 minutes of moderate-vigorous physical activity/week (or 500 MET-min of energy expenditure/week) within *four weeks*?	☐Yes ☐No
1.2 Action Planning Description: Did the physiotherapist and participant discuss how to achieve the physical activity goal by planning for: • intensity (moderate-vigorous) • duration (how long per day and per week), and • frequency (how many times per day and per week) of the behavior?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
1.3 Self-monitoring Description: Did the participant use the Fitbit™ provided to self-monitor physical activity levels?	☐Yes ☐No

BOX 2 *FIT for FUNCTION+* Level 1 during *Stage 2*	
Behavioral Change Techniques	Decision
2.1 Goal Setting Description: Did the physiotherapist and participant agree on a goal to continue achieving 150 minutes of moderate-vigorous physical activity/week (or 500 MET-min of energy expenditure/week) for an additional *eight weeks*?	☐Yes ☐No
2.2 Action Planning Description: Did the physiotherapist and the participant discuss how to achieve the physical activity goal by planning for: • intensity (moderate-vigorous) • duration (how long per day and per week), and • frequency (how many times per day and per week) of the behavior?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
2.3 Self-monitoring Description: Did the participant use the Fitbit™ provided to self-monitor their physical activity levels?	☐Yes ☐No

BOX 3 *FIT for FUNCTION+* Level 2	
Behavioral Change Techniques	Decision
3.1 Feedback on Behavior Description: At the beginning of Stage 2, did the physiotherapist provide feedback outlining the average minutes of MVPA/day and trajectory of minutes MVPA/week during Stage 1?	☐Yes ☐No
3.2 Review of Behavior Goals Description: At the beginning of Stage 2, did the participant and the physiotherapist review and keep/change the physical activity goals in light of the aforementioned feedback?	☐Yes ☐No

3.3 Goal Setting Description: Did the physiotherapist and the participant agree on a goal to achieve, or be close to achieving, 150 minutes of moderate-vigorous physical activity/week (or 500 MET-min of energy expenditure/week) within *four weeks*? Was this process repeated in the middle of Stage 2 to set goals for the next *four weeks*?	☐Yes ☐No ☐Yes ☐No
3.4 Action Planning Description: Did the physiotherapist and the participant discuss how to achieve the aforementioned physical activity goal by planning for: • intensity (moderate-vigorous), • duration (how long per day/per week), and • frequency (how many times per day/per week) of the behavior? Were action plans set in the middle of Stage 2 for the goals intended for the next *four weeks*?	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
3.5 Self-monitoring Description: Did the participant use the Fitbit™ provided to self-monitor their physical activity levels • At the middle (*8 weeks from baseline*)? • At the end (*12 weeks from baseline*) of Stage 2?	☐Yes ☐No ☐Yes ☐No

BOX 4 *FIT for FUNCTION+* Level 3	
Behavioral Change Techniques	Decision
4.1 Graded Tasks Description: Did the physiotherapist and participant negotiate and set incrementally larger physical activity goals every *two weeks* to eventually achieve 150 minutes of moderate-vigorous physical activity/week (or 500 MET-min of energy expenditure/week) by the end of Stage 2?	☐Yes ☐No

4.2 Action planning Description: Did the physiotherapist and participant discuss how to achieve the physical activity goal by planning for: • intensity (moderate-vigorous), • duration (how long per day/per week), and • frequency (how many times per day/per week) of the behavior? Were these action plans made for each of the *two-week* goals (4 action plans made in total)	☐Yes ☐No ☐Yes ☐No ☐Yes ☐No ☐Yes ☐No
4.3 Information about Health Consequences Description: At the beginning of Stage 2, did the physiotherapist and participant discuss evidence-based benefits of physical activity on stroke recovery?	☐Yes ☐No
4.4 Problem Solving Description: At the beginning of Stage 2, did the physiotherapist and participant discuss potential barriers that could impede performance of physical activity, and did they negotiate ways to reduce these barriers? Was this process repeated in the middle of Stage 2?	☐Yes ☐No ☐Yes ☐No
4.5 Instructions on how to perform the behavior Description: At the beginning of Stage 2, did the physiotherapist inform the participant to how to increase the intensity of everyday activities to moderate-vigorous levels?	☐Yes ☐No
4.6 Social Support Description: At the beginning of Stage 2, did the physiotherapist and participant explore sources of social support (e.g. caregivers) that the participant could access to help them be physically active? Did the physiotherapist provide encouragement (that was not dependent on the participant achieving previously set activity goals) every time they set new goals (*every two weeks*)?	☐Yes ☐No ☐Yes ☐No