

**ASSESSING THE IMPACT OF MINDFUL MEDITATION, COMBINED WITH
EXERCISE, ON MOBILITY AND COGNITIVE FUNCTION AMONG OLDER ADULTS
WITH CHRONIC STROKE: A PROOF-OF-CONCEPT STUDY**

by

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Abstract

Introduction

Deficits in balance, mobility and executive functions are common among chronic stroke survivors and contribute to increased falls risk. Targeted exercise training reduces falls risk among older adults with chronic stroke and is a promising strategy to promote cognitive function. Specifically, the Otago exercise program (OEP) reduces falls risk and improves executive functions in older adults with a history of falls. Mindful based meditation (MBM) may be a complementary approach to the OEP for promoting balance and mobility and cognitive outcomes among older adults with chronic stroke.

Purpose

The purpose of this proof-of-concept study was three-folds: 1) To examine whether MBM combined with OEP (OEP+MBM) is more efficacious than OEP alone (OEP-only) on improving balance, mobility and cognitive outcomes among older adults with chronic stroke. 2) To explore whether OEP-only or OEP+MBM has benefits for mindful attention, as measured by the Five Factor Mindfulness Questionnaire. 3) To assess components of feasibility to optimize larger repeat trials.

Methods

Subjects: Twenty-three community dwelling adults aged ≥ 55 years, who experienced a single ischemic or hemorrhagic stroke at least 12 months prior to study

Study Design: 12-week proof-of-concept, assessor single-blinded randomized controlled trial

Results:

There is preliminary evidence for meditation practice as a safe intervention for older adults with chronic stroke. Although no statistically significant effects were found, two cognitive variables

with marginally significant improvements for the OEP+MBM group provide support for MBM to improve attention and processing speed. Examination of the between-group differences on the outcome variables standardized to standard deviation values provide tentative support for the OEP+MBM intervention and rationale for further research. Self-reported levels of mindfulness did not increase for either group. The feasibility of conducting future repeat studies was verified with 27 subjects recruited to attend information sessions within six weeks, 24/27 (.89) consenting to study participation and strong adherence (>.80) to interventions for all participants.

Conclusions:

This proof-of-concept study provides an early indication that future studies are warranted to examine whether the addition of MBM to therapeutic exercise has the potential to positively impacts balance, mobility, and cognitive outcomes in older adults with chronic stroke.

Preface

This dissertation is original and unpublished work by the author, Tracy Dignum, graduate student, Department of Physical Therapy, Faculty of Medicine, University of British Columbia (UBC). The principal investigator identified for this study is Dr. Teresa Y.L. Liu-Ambrose, Associate Professor, Department of Physical Therapy, UBC. Co-investigators and committee members are Dr. Janice Eng, Professor, Department of Physical Therapy, UBC, and Dr. Ruchika Prakash, Assistant Professor and Director of the Clinical Neuroscience laboratory, Department of Psychology, Ohio State University. Additional co-investigators include: John R. Best, Post-Doctoral Fellow, Department of Physical Therapy, Faculty of Medicine, UBC, Jennifer C. Davis, Post-Doctoral Fellow, Faculty of Medicine, UBC, Glen Landry, Post-Doctoral Fellow, Department of Physical Therapy, Faculty of Medicine, UBC, Cindy Barha, Post-Doctoral Fellow, Department of Physical Therapy, Faculty of Medicine, UBC, Chun Liang Hsu, PhD student, Elizabeth Dao, PhD student, Lisanne ten Brinke, PhD student, Ryan Falck, PhD student, Larry Dian, MD, Clinical Associate Professor, Department of Geriatric Medicine, Faculty of Medicine, UBC, Michelle Munkacsy, Research Coordinator, Department of Physical Therapy, Faculty of Medicine, UBC, Winnie Cheung, Research Assistant, Wency Chan, Research assistant, and Christopher Lim, Research Assistant. A minimal risk human ethics application to UBC's Research Ethics Board was approved to conduct this research.

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List of Abbreviations

FFMQ	Five Facet Mindfulness Questionnaire
MBCT	Mindfulness Based Cognitive Therapy
MBM	Mindful Based Meditation
MBSR	Mindfulness Based Stress Reduction
MMSE	Mini Mental State Examination
MoCA	Montreal Cognitive Assessment
OEP	Otago Exercise Program
TUG	Timed Up and Go Test

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*The only time that any of us have to grow, change, feel, or learn anything
is in the present moment.
But we are continually missing our present moments, almost willfully,
by not paying attention.*

-Jon Kabat-Zinn

Chapter 1: Introduction

Strokes are an increasingly common health concern and a major cause of disability¹. As populations are aging, the incidence of stroke is increasing and the burden of the resultant functional impairments and need for enhanced health resources is an ongoing concern².

Deficits in balance, mobility and executive functions are common among chronic stroke survivors (i.e., ≥ 12 months since stroke event)³. Impaired balance reactions and physical abilities result in an increased risk of falls for stroke survivors⁴. Diminished executive functions also reduce functional independence and contribute to this increased falls risk⁵.

Exercise training reduces falls risk and falls in older adults with and without a history of falls^{6,7,8}. More targeted studies have found that exercise reduces falls for older adults with chronic stroke⁹. Research also supports that exercise is a promising strategy to promote cognitive function¹⁰.

The Otago exercise program (OEP) is an evidence-based falls prevention home program consisting of muscle strengthening and balance exercises plus a regular walking program¹¹. The OEP improves executive functions and reduce falls in older adults with a history of falls⁶.

Mindful based meditation (MBM) is gaining recognition for its positive impact on both physical and cognitive health and may improve both balance performance and recovery¹². There is emerging evidence that MBM may promote cognitive function, hippocampal volume, and functional brain connectivity¹³. Thus, MBM may be a complementary approach to exercise training for promoting physical and cognitive outcomes among stroke survivors.

The intention of this study was to establish whether the combination of exercise, in the form of the OEP, and meditation (MBM) would have a greater degree of benefit than exercise alone on physical and cognitive outcomes for individuals living with chronic stroke.

Chapter 2: Literature review and background

2.1 Stroke

Each year, over 40 000 Canadians experience a stroke and approximately 40 percent of stroke survivors are left with moderate to severe impairment¹. Strokes result from a restriction of blood flow to a portion of the brain causing cell death. The cause of stroke is generally either a blood clot or a rupture of a blood vessel and the effects of the stroke depend on the location and size of the brain-damaged area¹⁴. Deficits may be physical, sensory, emotional, or behavioural with additional complications including depression, emotional lability and fatigue¹⁵.

Although considered one of the most preventable of all life-threatening health problems, stroke is the leading cause of disability for Canadian adults and the third leading cause of death¹⁴.

Population growth and demographic changes are resulting in increasing numbers of Canadians living with impairments caused by stroke². In 2013 an estimated 405 000 Canadians were living with the effects of stroke¹⁵. Between 2000 and 2013, the number of Canadians experiencing the effects of stroke increased by 31% as a result of population growth and aging¹⁵. This number is projected to increase from 405000 in 2013 to between 654 000 and 726 000 in 2038 – an expected increase between 62-79%¹⁵.

An Australian community stroke study followed individuals with suspected stroke over an 18-month period for 5 years¹⁶. Of the 370 cases of first-ever stroke, 277 (76%) survived to 30 days. Of these early survivors, 152 (55%) were alive at five years. The cumulative risk of new major disability after a first-ever stroke was 36% at 5 years.

2.2 Consequences of Stroke

Deficits following stroke are common; approximately two thirds of stroke survivors live with neurological deficits¹⁷. A 2010 study by Goljar et al.¹⁸ aimed to describe function and disability in stroke survivors with the International Classification of Functioning Disability and Health (ICF). Considering 197 stroke survivors, the tool captured the most commonly reported impairments following stroke. The body functions reported most commonly as severely impaired were exercise tolerance, gait pattern, urination and defecation, and language. The body functions most commonly affected with mild to moderate impairment were control of voluntary movement, muscle power, vision, attention and memory.

These functional impairments elevate the falls risk of stroke survivors³. Changes to cognitive mechanisms further compromise balance and mobility in older adults with stroke⁵.

2.2.1 Falls in Older Adults with Chronic Stroke

Impaired balance is common among stroke survivors and is associated with diminished function in activities of daily living, limited mobility, and increased falls risk^{3,4}. Falls are common after stroke; 73% of stroke survivors fall in the first year post-stroke¹⁹. Even less serious falls may lead to stroke survivors developing a fear of falling and limiting activity^{19,20}.

A 2002 study followed 111 home-dwelling stroke survivors and compared them to control subjects of a similar age who had not experienced a stroke²¹. The stroke survivors were more than twice as likely to fall as compared to the control group. Most of the stroke survivors fell

while walking, half of them outdoors. Those with depressive symptoms were at greater risk of experiencing falls.

A 2008 British study recruited 115 stroke patients upon discharge from hospital²². All were assessed in their homes within two weeks of discharge for balance, function, mood and attention. The participants were assessed again at twelve months. The participants kept falls diaries to track falls. At twelve months, 55% had experienced one or more falls, 42% had experienced repeated falls, and 54% had experienced near-falls. The two best fall predictors identified in this study were near-falls in hospital and poor upper limb function at time of discharge from hospital.

It is evident that stroke survivors are at elevated risk of falls and potential resultant injuries. A 2002 review of community dwelling older adults found that for individuals who have had at least one fall, over 90% experience a fear of falling⁷. This fear may reduce mobility and limit daily function and social activities resulting in reduced quality of life⁸.

2.2.2 Executive Functions in Older Adults with Chronic Stroke

Executive functions are also commonly negatively affected by stroke⁵. Executive functions refer to high-level cognitive processes including initiation, planning, sequencing, monitoring, solving novel problems, modifying behaviour in light of new information, performing two tasks concurrently, generating strategies, inhibition and working memory²³.

Between 19-75% of stroke survivors live with impaired executive function skills^{15,16}. Persistent deficits in executive functions of stroke survivors negatively impact recovery with an elevated

risk of functional dependence, failure to return to work, and poor social participation¹⁶. A 2015 study examined the correlation between executive functions and the quality of functional independence in stroke survivors²³. The results identified a significantly lower level of functional independence including self-care and locomotion in stroke survivors with reduced executive functions. Those without impairment to executive functions achieved significantly higher scores in the areas of communication and socialization.

Deficits impacting planning and problem solving may result in unsafe physical maneuvers and increase the risk of falls¹⁶. Of particular relevance to falls, executive dysfunction has been found to be independently associated with performances of balance and mobility in community-dwelling older adults after mild stroke⁵. A 2007 randomized controlled trial of 63 men and women aged 50 and over with mild stroke evaluated the outcomes of a community based exercise program⁵. Participants in the trial had impaired executive functions and were considered to be at risk of falls. The study found that cognitive flexibility, as measured with set shifting, was independently associated with balance and mobility providing evidence that impaired executive functions in stroke survivors elevates falls risk.

A systematic review of the efficacy of interventions targeting executive function after stroke found “limited but encouraging” evidence that interventions may improve aspects such as problem solving, goal management and planning everyday activities when compared to no treatment²⁴. The interventions considered in this review included computer based and compensatory approaches. However, no studies were identified that used controls; comparing these interventions to conventional therapy or an alternative intervention. Interventions that

reduce mind-wandering, and allow for a more rapid re-engagement with executive functions from a mind wandering state may merit consideration for fall prevention as mind wandering is associated with falls risk²⁵.

2.3 The Benefits of Exercise for Older adults with Stroke

Exercise has been suggested as an appropriate intervention to enhance both physical and cognitive outcomes for older adults with chronic stroke¹⁹. Previous studies have observed improvements to postural reflexes, balance and mobility following exercise programs for community dwelling older adults with chronic stroke¹⁹. The positive effect of physical exercise on global cognitive functioning following stroke has also been established²⁶.

2.3.1. Exercise Training to Reduce Falls Risk in Older Adults with Stroke

Exercise training has been shown to reduce falls risk among older adults, including those with chronic stroke⁹. A 2005 randomized controlled trial by Marigold et al.⁹ of community dwelling older adults with chronic stroke examined the results of both agility exercises and stretching/weight-shifting exercises on mobility, balance and falls. The study concluded that both types of exercise programs improve postural reflexes, functional balance and mobility and are recommended to reduce falls in this population.

A 2005 community based fitness and mobility exercise program for older adults with chronic stroke randomized 63 participants into an exercise and a control group²⁰. The exercise group completed a fitness and mobility exercise program including cardiorespiratory fitness, leg strengthening and balance exercises. After completing three sessions per week for 19 weeks,

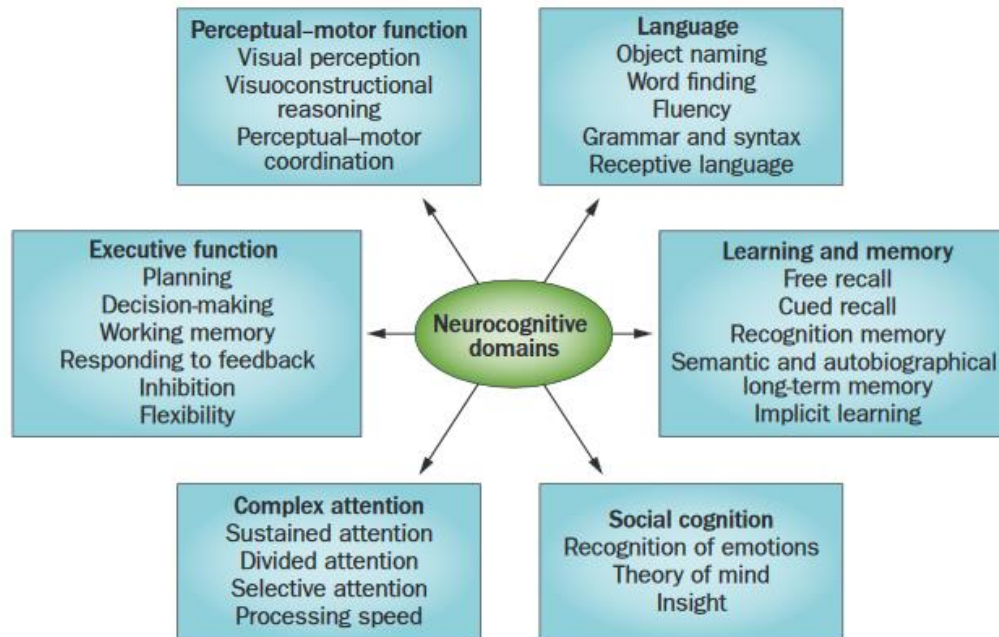
participants demonstrated improvements in cardiorespiratory status, leg strength and mobility compared to the control group who completed a sitting upper extremity exercise program. This study did not find a significant difference with respect to balance outcomes but the gains in leg strength and mobility contributed to improved ambulation which is linked with reduced falls in this population¹⁹.

However, a 2013 Cochrane review of interventions for preventing falls in people after stroke did not find sufficient evidence supporting exercise or other interventions to reduce falls in stroke survivors¹⁹. This finding was attributed to the limited number of studies focusing on people after stroke and a need for more research in this area.

2.3.2 Exercise Training to Promote Cognitive Function in Older Adults

Exercise is a promising strategy to promote cognitive function in older adults²⁶. Cognitive function refers to the higher order processes in the brain; key cognitive domains as defined by DSM-5 are illustrated in Figure 1 consisting of perceptual motor function, language, learning and memory, social cognition, complex attention and executive function²⁷. Each of these domains is further described with sub-domain functions. Depending on the site of the brain lesion, stroke may negatively impact any of these cognitive domains.

Figure 1: Cognitive Domains²⁷



Research findings concerning the impact of exercise training on these cognitive domains in older adults may be divided into observational studies, randomized controlled trials, and systematic reviews. Overall, findings suggest that exercise training primarily impacts the domains of executive functions and complex attention²⁸.

Observational Studies

Longitudinal observational studies provide evidence for an association between higher levels of physical exercise and a reduced risk of cognitive impairment²⁸. Exercise is related to brain changes and higher-level executive functions benefit more with exercise than lower-level functions²⁸. Desjardins et al²⁹ observed that higher levels of physical activity were significantly associated with greater processing speed and improved executive functions but not with memory

performance. Exercise programs that combine aerobic, resistance and coordination training are optimal to induce changes across multiple cognitive domains²⁶.

Randomized Controlled Trials

A 2010 study examined the feasibility of an exercise program to improve executive functions in older adults with chronic stroke³⁰. The participants demonstrated significant deficits in executive functions at the start of the study. Significant improvements were seen at both three and six months in the domains of complex attention (dual tasking) and executive functions (inhibition and working memory).

A 2012 study of stroke survivors who completed a six-month exercise program of aerobic and resistance training found significant improvements in Montreal Cognitive assessment (MoCA) scores as well as in concentration abilities (complex attention) and executive functions³¹.

Systematic Reviews

A 2016 systematic review of studies conducted between 1999 – 2014 examined the cognitive benefits of physical exercise in stroke and traumatic brain injury patients and verified the positive effect of physical exercise on global cognitive function, especially in the chronic stages of brain injury³². A combination of aerobic training and resistance training showed promising results on cognitive outcomes although the research was limited and a need exists for further clinical trials in this area.

A 2014 systematic review and meta-analysis on the impact of exercise on the cognitive function of older adults found significant improvements on measures of reasoning for resistance training compared to a stretching and toning program³³. The same review found that exercise in the form of Tai Chi resulted in significant improvements in complex attention (sustained attention and processing speed) compared to no exercise controls.

2.4 Otago Exercise Program

The Otago exercise program (OEP) is an evidence-based falls prevention home-program. The four original OEP randomized controlled trials reduced falls among community dwelling adults aged 65 to 96 years by 30 percent^{7,8,11,34}. The OEP consists of muscle strengthening and balance exercises (three times per week) and a walking plan (twice per week)¹¹. The OEP has been found to improve both falls and executive functions in older adults at risk of falls due to impaired strength, mobility or balance reactions³⁵.

A 2016 study of the effects of the OEP on falls efficacy, activities of daily living and quality of life in elderly stroke patients examined the impact of the OEP on a small sample of community dwelling stroke survivors³⁶. The OEP was found to significantly improve falls efficacy but did not improve activities of daily living or quality of life.

Stroke survivors often have physical impairments and fatigue that significantly limit their ability to exercise³⁷. Individualized home exercise programs prescribed by physiotherapists allow stroke survivors to exercise with reduced overall energy demands by removing challenges of transportation and accessibility. However, as compliance with home exercises has been found to

be negatively influenced by a lack of motivation, participation in a concurrent organized group program is recommended to improve adherence to exercise³⁷.

2.5 Mindful Based Meditation

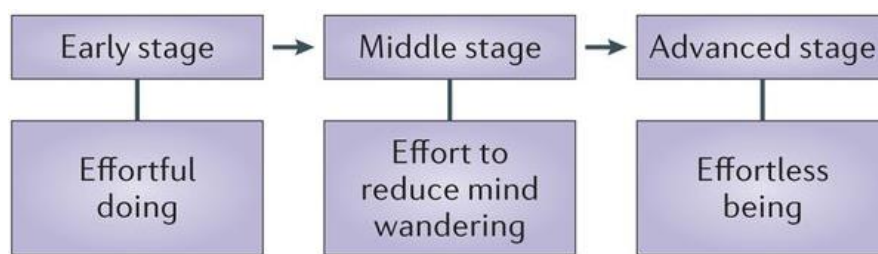
Mindful based meditation (MBM) is gaining recognition for its positive impact on both physical and cognitive health. MBM is a process of “training the mind to function in a nonjudgmental minute to minute mode”³⁸. MBM aims to reorient the individual to the present and broaden self awareness¹⁰. MBM has many forms including Mindfulness-based stress reduction (MBSR), Mindfulness-based cognitive therapy (MBCT), Mantra-based meditation and Buddhist-based mindfulness practices³⁹.

MBM has been found to improve both balance performance and recovery¹². Moreover, there is emerging evidence that MBM may promote cognitive function, hippocampal volume, and functional brain connectivity¹³. Notably, these neuroimaging changes were observed after only eight weeks of MBM⁴⁰.

A systematic review of the benefits of mindfulness-based interventions following transient ischemic attack and stroke included four studies with results demonstrating a positive trend in favor of the benefits across a range of outcomes including anxiety, depression, mental fatigue, blood pressure, perceived health and quality of life⁴¹. Unexpected findings in a PhD thesis investigating Mindfulness Based Cognitive Therapy (MBCT) were improvements in mobility and upper extremity outcome measures⁴². Thus, MBM has potential as an adjunct treatment to exercise training for reducing falls risk and promoting executive function in stroke survivors.

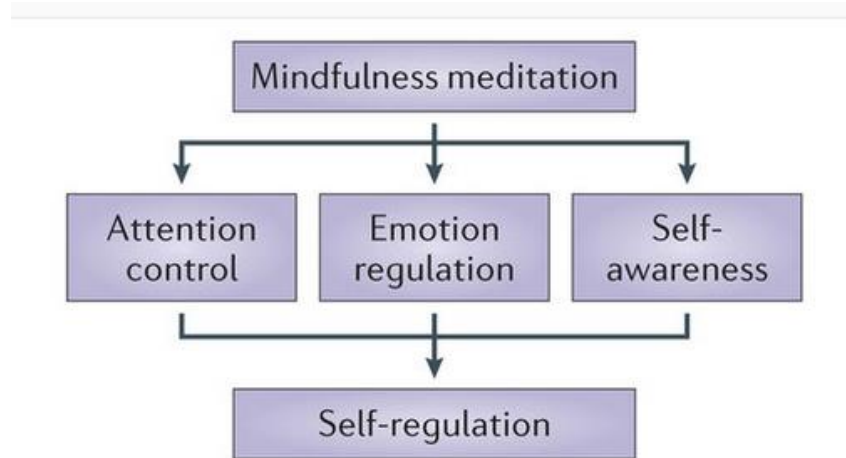
Within MBM practice, there are a variety of meditation exercises for beginner to advanced meditators³⁹. The cognitive mechanisms and potential impacts may differ depending on the meditations completed. These practice-specific responses may be illustrated with the similar phenomenon of the impact of physical exercise which is dependent on the type, frequency, resistance and intensity of the exercise as well as the fitness level of the individual. Early meditation practice generally consists of breathing and body scan meditations and requires significant effort⁴³. Figure 2 depicts a typical progression of meditation practice with early, middle and advanced stages of meditation practice⁴⁴. As one progresses from a beginner to an advanced meditator the effort to maintain attention tends to diminish.

Figure 2: Progression of Meditation Practice⁴⁴



Three objectives of MBM are outlined in Figure 3 – attention control, emotion regulation and self-awareness⁴⁴. Early-stage breathing and body scan meditations target attention control. As meditators become more experienced with longer and more complex meditations they strive for emotion-regulation. These meditations provide strategies to influence which emotions arise and to alter the experience and expression of emotions. With further practice, advanced meditators may strive to achieve self-awareness, reducing attachment to a static sense of self⁴⁴.

Figure 3: Mindfulness Meditation Process⁴⁴



Breathing meditation involves focusing on one's breath and returning focus to the breath each time one's mind begins to wander. This is an example of an early-stage meditation aiming to improve attention control. This attention control or "executive attention" relates to the ability of the brain to maintain attentional focus, reduce distractions and increase the ease of returning to focus when drawn away by a distraction⁴⁴. This beginning practice may be considered a "building block" or pre-requisite for meditation practitioners as the attention regulation development is required to a sufficient degree to effectively meditate towards other outcomes and without distraction⁴³.

During these early-stage meditations, the executive network of the brain is activated to maintain attention to a single focus and avoid mind-wandering. The meditating brain switches away from the default-mode network which is associated with mind-wandering⁴⁵. Mind-wandering has been shown in MRI studies to recruit the medial PFC, posterior cingulate/precuneus, and posterior temporoparietal cortex - regions that form the default network⁴⁵. The anterior cingulate cortex

(ACC) of the brain is activated as it detects and regulates distractions. The ACC and the frontal insular cortex relay control signals throughout the brain to improve attention to a task. Functional MRI of meditators has demonstrated this ACC recruitment during meditation as well as increased cortical thickness of the ACC in meditators⁴³. The right insula is implicated in mediating one's ability to switch between the executive and default-mode networks and the left inferior frontal gyrus with the function of refocusing after mind-wandering^{46,47}.

MBM is a highly appropriate intervention for older adults with chronic stroke. As opposed to physical interventions requiring adequate levels of mobility, individuals are able to participate regardless of the severity of physical impairment.

An additional positive consideration is the suggestion that MBM may reduce the risk of future stroke. A study of hypertensive adults provided transcendental meditation training to half of the participants and an education intervention to the other half⁴⁸. After nine months a significant observation was made favouring the meditation group. A reduction in carotid intima-media thickness was seen in the meditation group "similar to that achieved by lipid lowering drugs and extensive lifestyle changes"⁴⁸. A meta-analysis of nine randomized controlled trials established that regular practice of transcendental meditation may have the potential to create clinically meaningful reductions in both systolic and diastolic blood pressure. These studies suggest meditation's potential to reduce risk of future stroke^{49,50}.

Chapter 3: Rationale, Objectives and Hypotheses

3.1 Rationale

Although a significant number of studies have been published, there is a need for well-structured randomized clinical trials investigating the potential benefits of meditation practice. This study is novel in terms of the combined potential of an exercise program with meditation for stroke survivors. The results of this study may encourage further research and exploration into applications of MBM for stroke survivors within physical therapy as it represents a low cost and low risk intervention option.

3.2 Objectives

The following research objectives were identified for this study:

1. To examine whether MBM combined with OEP is more efficacious than OEP alone on improving mobility and cognitive outcomes among older adults with chronic stroke. Specifically, to assess whether the subjects who participate in 12 weeks of both OEP and MBM show more significant improvements in the following measures:
 - a. Timed Up and Go (TUG) and Timed Up and Go Dual Task⁵¹
 - b. Short Physical Performance Battery (SPPB)⁵² testing for balance
 - c. SPPB 4-metre walk test for mobility⁵²
 - d. Stroop Colour Word Test⁵³ for response inhibition
 - e. Trail Making Tests (A&B)⁵⁴ for set shifting
 - f. Digit Symbol Substitution Test⁵⁵ for psychomotor speed

2. To explore whether mindful attention is impacted by either or both interventions as measured by the Five Facet Mindfulness Questionnaire (FFMQ) ⁵⁶.
3. To assess components of feasibility to optimize larger repeat trials through analysis of recruitment and attendance documentation and participant logs for rates of recruitment and withdrawal and adherence to the interventions.

3.3 Hypotheses

The following hypotheses were identified for this research:

1. OEP combined with MBM (i.e., OEP+MBM) would be more efficacious than OEP-only in improving balance, mobility and executive functions among stroke survivors.
2. OEP combined with MBM (i.e., OEP+MBM) would be more efficacious than OEP-only in improving mindful attention among stroke survivors.

Chapter 4: Research Methods

4.1 Introduction

This study involved a 12-week proof-of-concept randomized controlled trial (RCT) with 23 older adults with chronic stroke.

4.2 Methods

4.2.1 Sample Size

No formal sample size was calculated as this was a proof-of-concept study. A sample size of approximately 20 participants was selected based on feasibility and existing resources

4.2.2 Recruitment

Recruitment of individuals with chronic stroke was achieved between January 11 and March 31, 2016 through advertisements placed in local community centers and presentations to stroke support groups in Greater Vancouver area. Recruitment also included past study participants who had consented to being contacted for future studies and who had not participated in an interventional research project in the six months previous. Interested individuals were initially screened by telephone by the research coordinators using the inclusion criteria. Those who appeared eligible were invited to an information session. During the information sessions on February 16, March 9 and March 31, 2016, potential participants were provided with details of the study and had the opportunity to ask questions. A consent and screening session was arranged for those who were interested in participating at the end of the information sessions. Those who remained eligible after the screening session proceeded to baseline assessments.

4.2.3 Eligibility Criteria

The study *included* community-dwelling adults who had an ischemic or hemorrhagic stroke (confirmed by previous MRI or computed tomography scan and verified by physician). In addition, individuals were required to meet the following inclusion criteria: 1) age 55 years and over; 2) had a history of a single stroke of at least one year prior to study enrollment; 3) had a Mini-Mental State Examination (MMSE)⁵⁷ score of 22/30 or greater at screening, including a perfect score on the 3-step command to ensure intact comprehension and ability to follow instructions; 4) were community-dwelling; 5) were living in the Greater Vancouver area; 6) were able to comply with scheduled visits, treatment plan, and other trial procedures; 7) were able to read, write, and speak English with acceptable visual and auditory acuity; 8) were not expected to start or were stable on a fixed dose of cognitive medications (e.g., donepezil, galantamine, etc.) during the study period; 9) were able to walk for a minimum of six metres with rest intervals with or without assistive devices; 10) based on interview, had an activity tolerance of 30 minutes with rest intervals; 11) were not currently participating in any regular therapy or progressive exercise; 12) had not participated in an interventional study for at least six months; and 13) provided a personally signed and dated informed consent document indicating that the individual (or a legally acceptable representative) had been informed of all pertinent aspects of the trial.

The study *excluded* individuals who were: 1) diagnosed with dementia of any type; 2) diagnosed with another type of neurodegenerative or neurological condition (e.g., Parkinson's disease) that affects cognitive function and mobility; 2) at high risk for cardiac complications during exercise and/or unable to self-regulate activity or to understand recommended activity level (i.e., Class C

of the American Heart Risk Stratification Criteria⁵⁸); 3) experiencing clinically significant peripheral neuropathy or severe musculoskeletal or joint disease that impair mobility, as determined by his/her family physician; 4) taking medications that may negatively affect cognitive function, such as anticholinergics, including agents with pronounced anticholinergic properties (e.g., amitriptyline), major tranquilizers (i.e., typical and atypical antipsychotics), and anticonvulsants (e.g., gabapentin, valproic acid, etc.); 5) aphasic as judged by an inability to communicate by phone; or 6) currently practicing meditation.

4.2.4 Randomization

Participants were randomized in one to one ratio (1:1) to either: 1) OEP-only (OEP) (n=12); or 2) OEP+MBM (n=11) after completion of baseline assessments. To ensure concealment of the treatment allocation, the randomization sequence was generated at www.randomization.com and held remotely.

4.2.5 Interventions

For the OEP-only protocol, participants received a revised version of the OEP - an evidence-based falls prevention strategy of home strength and balance exercises tailored for older adults. Throughout the 12-week intervention, five home visits were made by the study's physical therapists (PT); four experienced clinicians registered and in good standing with the College of Physical Therapists of British Columbia. Participants were asked to perform the individually PT-prescribed OEP exercises three times per week. Compliance was tracked through calendars provided by the research team and were reviewed by the study physical therapists during each home visit. In order to provide an active control situation, the OEP participants also attended six small group sessions, one-hour in length, on topics relating to fall prevention.

For those participants in the OEP-only group, time requirement was an additional 29 hours (to the four hours dedicated for assessments) over the 12-week study period; five one-hour home visits with a physiotherapist, three 30-minute home exercise sessions per week for 12 weeks, and six one-hour small group falls prevention education sessions at the Robert Ho building on the Vancouver General Hospital campus instructed by qualified guest speakers not involved with the study.

For the OEP+MBM protocol, participants received the OEP as described above. In addition, they were provided with mindfulness based meditation (MBM) training, delivered by graduate student Tracy Dignum, who has a background in post-secondary education and training and experience in Mindfulness Based Stress Reduction techniques through the University of Massachusetts. Participants in the OEP+MBM group received MBM coaching via six small group sessions at the Robert Ho building on the Vancouver General hospital campus, 60 minutes each session. These participants were each provided with a CD player and were expected to practice at home following a CD of audio recordings from the UCLA Mindful Awareness Research Center a minimum of five times per week for 20-30 minutes⁵⁹. Participants completed meditation logs to record their practice.

For those participants in the OEP+MBM group, time requirement was an additional 59 hours (to the four hours dedicated for assessments) over the 12-week study period; five one-hour home visits with a physiotherapist and three 30-minute sessions for 12 weeks of the OEP exercises at home, in addition to six one-hour formal MBM sessions and five 20-30 minute MBM home training sessions per week for 12 weeks.

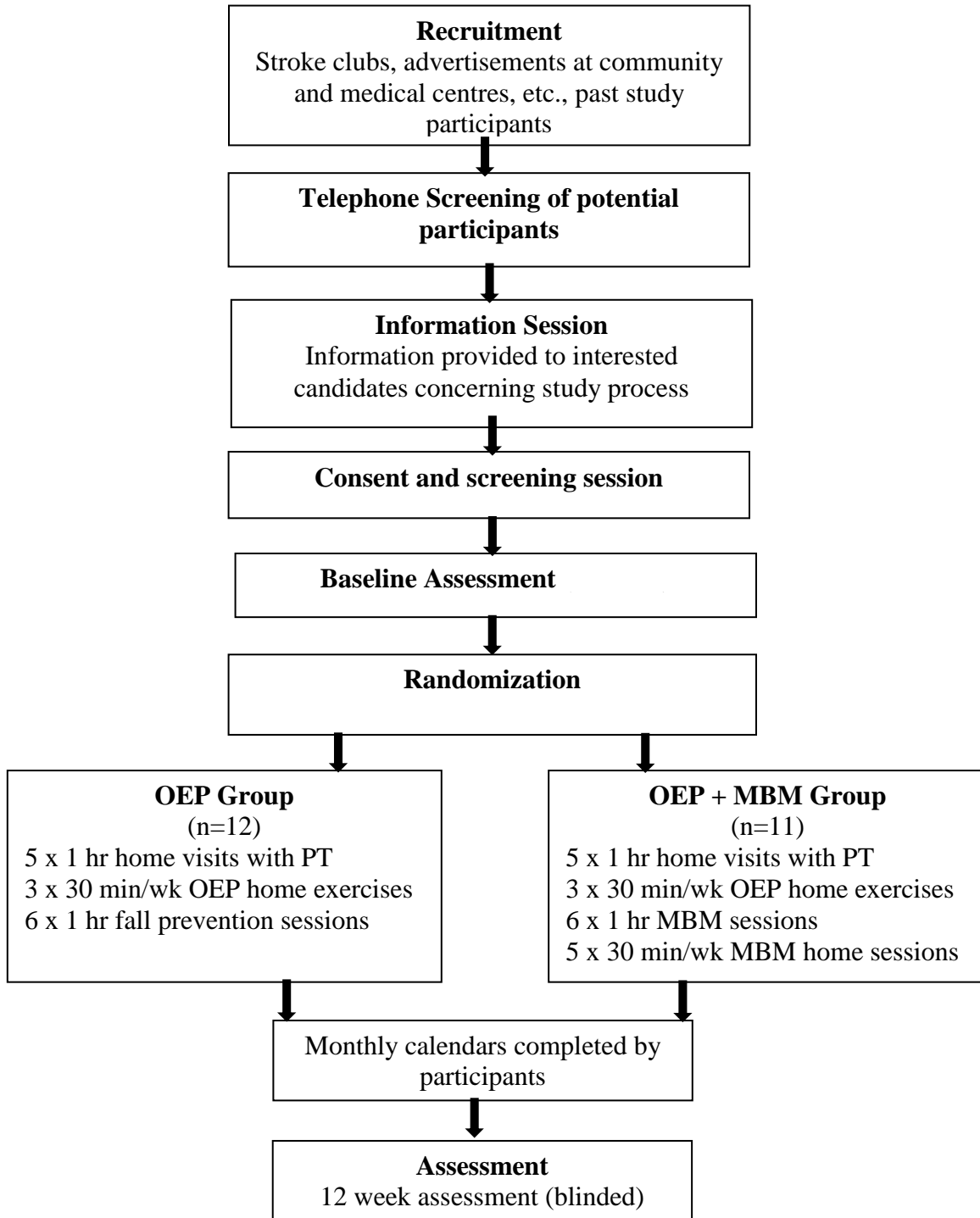
4.2.6 Strategies to Promote Adherence

All efforts to optimize retention were made including follow-up phone calls for missed sessions, encouragement at education sessions and support with transportation methods including parking reimbursement.

4.2.7 Adverse Events Monitoring

Participants were monitored for adverse events including any safety issues or concerns. The physical therapists were instructed to document and report any adverse events with respect to the exercise program. Participants were provided with telephone contacts to report any issues or events related to any of the study interventions.

Figure 4. CONSORT Study Flow



4.2.8 Measurements

As illustrated in Figure 1 - CONSORT flow chart, the study had two measurement sessions - baseline and study completion. Each measurement session was approximately two hours in duration.

As this is a proof-of-concept study, one single primary outcome measure was not selected. Rather, a battery of outcome measures was identified, based on their relevance to the study's objectives. All measurements were acquired by trained and blinded assessors.

Mobility and Balance

Mobility and balance were measured by: 1) Timed Up and Go Test (TUG)⁵¹; and 2) Short Physical Performance Battery (SPPB)⁵². For the TUG test, participants were instructed to rise from a standard chair, walk a distance of three meters, turn, walk back to the chair and sit down. The TUG has been found to be a reliable measure of mobility; a score of 20 seconds or less is associated with independence in activities of daily living⁵¹. The TUG test is sensitive to detect falls in the older adult community dwelling population⁶⁰.

For the SPPB, participants were assessed on performances of standing balance, walking, and sit-to-stand. For the balance test, the participants were required to hold three standing positions for ten seconds each – feet side by side, feet in semi-tandem stance and tandem stance. For the gait speed test participants were timed while walking a four-metre marked course at normal walking speed with or without walking aids. The chair-stand test required the participant to stand from a sitting position in an armless chair with their arms folded across their chest. If they were able to

do so, they were then timed while performing five consecutive sit-to-stands as quickly as possible. Each component was rated out of four points, for a maximum of 12 points. Poor performance with a score of nine or below on this scale predicts subsequent disability⁵². A 2012 study of the validity and reliability of the SPPB in older adult populations in Quebec found that the reliability for the total score (.89) and the gait components (.90) were high, and for the chair stand (.78) and balance scores (.75) was substantial⁶¹. With respect to validity, the same study found the SPPB to have a high predictive value for impairments of mobility and activities of daily living⁶¹.

Cognitive Outcomes

For the cognitive outcomes, measures focused on executive processes as they are most related to mobility and are commonly impaired among those with stroke. Three specific executive processes were included based on the work of Miyake and colleagues⁶² and frequency of inclusion in clinical batteries: 1) response inhibition; 2) set shifting; and 3) working memory. Response inhibition involves deliberately inhibiting dominant, automatic, or prepotent responses. Set shifting requires one to go back and forth between multiple tasks or mental sets. Working memory involves monitoring incoming information for relevance to the task at hand and then appropriately updating the informational content by replacing old, no longer relevant information with new incoming information.

Assessment of response inhibition was completed with the Stroop Colour Word Test which required the subject to name the colour of a word while ignoring the actual printed word⁵³. The total number of correct responses in a time period resulted in a score; higher scores are indicative

of superior response inhibition abilities. This test has been found to be highly reliable and with respect to construct validity correlates well with measures of attention and prepotent response inhibition⁶¹. Within the Stroop test there are three conditions; neutral, congruent or incongruent. In the neutral condition the word is either a colour-neutral word or a meaningless string of characters. In the congruent (CON) condition the ink colour matches the colour name of the word. In the incongruent (INC) the word shown is the name of a different colour than the colour in which it is written. Typically, reaction times are longer for the incongruent than the congruent which is known as the Stroop effect⁶⁴. Stroop INC-CON relates to the difference in time taken between the time to recognize incongruent words versus congruent words. Stroop neutral accuracy relates to the speed and accuracy of response of the neutral condition items. The standard deviation of the Stroop neutral trials illustrates the consistency of speed of response across all of the neutral trials in the test.

Set shifting was assessed with the Trail Making Tests (Parts A & B)⁵⁴. In part A subjects connected a series of 25 numbers in order. In part B subjects connected 25 numbers and letters in numerical and alphabetical order by alternating between numbers and letters. Part A tests for visual searching, processing speed and motor speed skills and part B tests for higher cognitive skills including mental flexibility. Calculation of the difference in time between tests (B-A) provides an index of the level of interference and an indication of set shifting abilities⁵⁴. The trail making tests have been found to have excellent interrater reliability but can be susceptible to practice effects if competed repeatedly within short periods of time (i.e., less than 6 weeks)⁵⁴.

The Digit Symbol Substitution Test (DSST) requires subjects to match symbols with corresponding digits using a key to identify correct pairs. The DSST assesses complex attention, information-processing speed, and psychomotor functioning⁶³. Reliability for DSST has been supported but practice effects may be an issue. A sufficient time delay between pre-test and follow-up testing is needed to mitigate these practice effects⁶⁵.

Working memory was assessed with the verbal digits tests (forward and backward tests)⁶⁶. Subjects were asked to repeat back a verbal series of digits in the same or reverse order. The sequences increased in length until the participant made an error or the maximal span was reached. Combining the numbers of forward and backwards span produced a total score. The tests have been found to have high internal validity (.70-.90) and fair test-retest reliability (.50-70)^{66,67}.

In addition, participants were assessed for dual-tasking using the Timed Up and Go Dual Task Test⁶⁸. This task assessed the ability of a participant to simultaneously perform the Timed Up and Go Test while performing the cognitive task of serial sevens (i.e., counting backwards from 100 by sevens). The Timed Up and Go Test Dual Task has been found to have good predictive validity with high sensitivity to the positive prediction of falls. It has excellent inter- and intra-rater reliability and excellent test-retest reliability⁵¹.

Mindfulness Outcomes

Initial assessment for mindfulness was measured with the Five Facet Mindfulness Questionnaire (FFMQ)⁵⁶. This is a thirty-nine item measure with five subscales (observing, describing, acting

with awareness, non-judging of inner experience, and non-reactivity to inner experience). The FFMQ takes approximately fifteen minutes to complete. The FFMQ has been used in many studies since 2006 and has been found to have satisfactory internal consistency, good test-retest reliability and excellent construct validity⁵⁶.

Proof of Concept Outcome Measures

Attendance was documented for all meditation and education classes and for the physiotherapy home visits. Analysis was completed for rates of recruitment and withdrawal using recruitment documentation and class attendance sheets and adherence to the exercise and mindfulness interventions with review of the participant exercise and meditation logs. Compliance was calculated as a percentage of the scheduled sessions attended and percentage of assigned sessions per week of home OEP and MBM completed.

4.2.9 Statistical Analyses

Descriptive statistics were computed to describe the two groups on baseline measures. Between-group differences in changes from baseline to twelve weeks were compared using multiple linear regression analysis. In these analyses, the change score (computed as post-test minus pre-test) for a particular variable was regressed on the baseline score for that variable, as well as experimental group (OEP-only versus OEP+MBM) and baseline Montreal Cognitive Assessment (MoCA) scores⁶⁹. Two individuals (one from each group) had missing baseline MoCA scores; we imputed the average score for their assigned group (22.7 for the OEP-only group and 21.9 for the OEP+MBM group) to replace their missing values. Analyses were conducted using the statistical package R (r-project.org) version 3.2.2. No adjustment for multiple endpoints will be made since

in a proof-of-concept study a Type II error is of more concern than a Type I error⁷⁰. Statistical significance was set at $p < .05$.

4.3 Results

4.3.1 Characteristics of Participants

Table 1 provides the baseline sample characteristics for both groups. The two groups are comparable with respect to demographic variables. Fifty percent of participants in the OEP-only group were female compared to 36% in the OEP+MBM group. In the OEP-only group four participants ambulated with a cane and two participants arrived at the classes in a power mobility chair or scooter. For the OEP+MBM group, three used a cane and three utilized power mobility.

The physical and cognitive baseline capabilities as evaluated by the MoCA and the Fugl Meyer lower extremity assessment illustrate the similar capabilities of the two groups and variability within the groups^{69,71}. Baseline group mean MoCA scores were very similar; 22.7 for OEP-only group and 21.9 for the OEP+MBM group. Fugl Meyer lower extremity mean group scores out of a maximum of 34 were 21 for the OEP-only and 29.4 for the OEP+MBM group. The standard deviations of these scores are relatively high indicating similar variability of scores within the groups.

The baseline values for all the outcome measures are also provided in Table 1. Overall, the groups were similar in all measures.

Table 1. Baseline Sample Characteristics, mean (standard deviation)

Variable	OEP only N = 12	OEP + MBM N = 11
<i>Demographic variables</i>		
Gender, female	6 (50 [*])	4 (36 [*])
MoCA ^{**} score	22.7 (2.7)	21.9 (3.4)
Fugl Meyer, lower extremity score	21.0 (7.6)	29.4 (9.2)
Assistive devices: Cane Power mobility	4 (33 [*]) 2 (17 [*])	3 (27 [*]) 3 (27 [*])
<i>Mobility and Physical Performance</i>		
Regular TUG ^{**}	18.45 (15.58)	16.08 (9.43)
NIA ^{**} Standing Balance (max. 4 pts)	3.42 (1.16)	3.64 (0.67)
NIA Walking (max. 4 pts)	2.92 (1.31)	3.00 (1.10)
NIA Walking Time (sec)	7.58 (7.43)	6.10 (3.65)
NIA Sit to Stand (max. 4 pts)	1.67 (1.37)	1.91 (1.38)
NIA Sit to Stand Time (sec)	10.39 (7.97)	17.45 (5.43)
NIA Total Score (max. 12 pts)	8.00 (3.28)	8.55 (2.66)
<i>Dual-Task</i>		
Dual-task TUG ^{**} (sec)	24.72 (20.21)	18.81 (10.55)
Dual-task TUG minus reg TUG (sec)	6.28 (5.96)	2.73 (3.15)
TUG Serial Correct	3.29 (1.54)	3.27 (2.47)
TUG Serial Attempted	4.92 (1.22)	4.23 (2.37)

Variable	OEP only N = 12	OEP + MBM N = 11
TUG Serial Proportion Correct (%)	0.71 (0.30)	0.74 (0.31)
<i>Cognition – Speed</i>		
TMT ^{**} A (secs)	45.54 (21.68)	54.61 (19.07)
TMT B (secs)	114.54 (70.06)	150.63 (60.06)
TMT B-A (secs)	69.00 (53.29)	96.02 (43.84)
DSST ^{**} (# correct)	23.17 (7.88)	19.00 (5.48)
Stroop Neutral (ms)	1065 (161)	1040 (162)
Stroop INC-CON ^{**} (ms)	147 (112)	165 (137)
Stroop Neutral Std Dev (ms)	177 (56)	202 (74)
<i>Cognition – Accuracy</i>		
Digits Forward	6.75 (1.91)	6.73 (2.37)
Digits Backward	6.08 (2.11)	5.45 (2.16)
Digits Forward Minus Backward	0.67 (1.23)	1.27 (1.62)
Stroop Neutral ACC ^{**} (%)	97.8 (4.9)	97.9 (3.4)
Stroop INC-CON ACC (%)	-6.1 (8.4)	-5.6 (8.4)
MMSE ^{**}	28.25 (2.05)	28.00 (2.24)
<i>Mindfulness and Mood</i>		
Observing	29.09 (4.3)	28.55 (4.27)
Describing	30.18 (5.88)	26.09 (2.91)
Acting	29.45 (4.68)	28.36 (5.97)

Variable	OEP only N = 12	OEP + MBM N = 11
Non-judging	26.73 (6.69)	27.55 (7.72)
Non-reactivity	24.27 (3.20)	23.64 (4.08)
Total FFMQ ^{**} Score (/195)	139.73 (16.16)	134.18 (14.65)
State Mind	3.55 (5.35)	5.91 (7.09)
Depression (CES-D ^{**})	7.17 (5.97)	12.30 (12.28)
CES-D score 16+ ^{***}	.17*	.18*

* Denotes percentage versus standard deviation

** MoCA: Montreal Cognitive assessment; TUG: Timed Up and Go; NIA: Short Physical Performance Battery; TMT: Trail Making Test; DSST: Digit Symbol Substitution Test; INC: incongruent; CON: congruent; ACC: accuracy; MMSE: Mini Mental Status exam; FFMQ: Five Factor Mindfulness Questionnaire; CES-D: Center for Epidemiologic studies depression scale

*** CES-D score 16+ indicative of prevalence of depression

4.3.2 Feasibility Considerations

As this is a proof-of-concept study, components of feasibility were assessed to optimize future, larger repeat trials. Criteria considered included recruitment, enrollment and retention rates, adherence to interventions, equipment and adverse events.

Table 2 provides data concerning feasibility components. Recruitment was not challenging with a strong level of interest in the study. Participants appeared to be initially motivated primarily by the incentive of receiving five home physical therapy sessions free-of-charge and several participants expressed curiosity about meditation.

Twenty-seven subjects attended three information sessions over six weeks and 24/27 (.89) consented to participate in the study. At the initial assessment one participant disclosed previous

meditation experience so was withdrawn from the study due to not meeting this exclusion criterion. None of the participants withdrew from the study although one participant in the OEP-only group did not complete the OEP intervention, attend classes or receive physiotherapy due to an extended absence for a family emergency. This participant did complete initial and final assessments and this data was included in the results and in the compliance data and calculations.

Both groups had a high level of compliance with the interventions. For the education sessions, the OEP-only group participants attended 60/72 (.83) sessions and the OEP+MBM group attended 57/66 (.86) sessions.

The physical therapy sessions were well attended. For the OEP-only group, 48/60 (.80) sessions were completed noting that this includes the previously mentioned participant who did not participate in interventions. For the OEP+MBM group the attendance for physical therapy sessions was 53/55 (.96).

Compliance with the home exercise program was similar for both groups. For the OEP-only group, 316/384 (.82) sessions were completed, according to participant journals. For the OEP+MBM group 339/396 (.86) sessions were completed.

The OEP+MBM group were instructed to meditate 60 times over the length of the study but were not discouraged from meditating more frequently. Four participants meditated more than 60 times (61, 70, 78, 84 times). When included in the totals, the group completed 532 meditation sessions out of a prescribed 660 sessions which is a compliance rate of .81. However, if these

extra meditation sessions are not included in the calculations, the group completed 479/660 sessions at a compliance rate of .73.

With respect to technology and equipment, two incidents with two different individuals in the meditation group delayed meditation practice by one week as they were not able to utilize the audio recordings. One CD was not functioning initially and one CD player failed to work after several weeks. Both were replaced and the participants resumed meditation practice. There were no reported adverse events or safety incidents.

Table 2. Feasibility Components

Component	Feasibility	
Recruitment rate	27 subjects recruited to attend information sessions within 12 weeks	
Enrollment	24/27(.89) subjects attending information session consented to study participation	
Attrition	1 participant was removed from the study after initial assessment due to not meeting an exclusion criterion No subjects withdrew from the study	
	OEP only N = 12	OEP + MBM N = 11
Attendance at education sessions	60/72 sessions attended .83 compliance	57/66 sessions attended .86 compliance
Compliance with PT sessions	48/60 sessions completed .80 compliance	53/55 sessions attended .96 compliance
Compliance with OEP	316/384 sessions completed .82 compliance	339/396 sessions completed .86 compliance
Compliance with meditation	n/a	479/660 sessions completed* .73 compliance Or 532/660 sessions completed* .81 compliance

Component	Feasibility	
	OEP only N = 12	OEP + MBM N = 11
Technology issues	n/a	1 CD required replacement and delayed meditation practice x 1 week 1 CD player required replacement and delayed meditation practice x 1 week
Safety incidents	No reported incidents	No reported incidents

*The first compliance numbers (479/660) assume the maximum number of meditations to be 60 as prescribed. As four participants exceeded prescribed number of meditation sessions (61, 84, 78, 70 meditations completed) the second compliance numbers (532/660) include these.

4.3.3. Between and Within Group differences over time

Table 3 provides an analysis of the results detailing the within and between-group comparisons for the outcome variables separated by the assessment domain. The scores have been adjusted for baseline MoCA score⁶⁹.

While no statistically significant differences between groups were found for the physical performance or cognition variables based on $p < .05$, marginally significant results with $p < .10$ were observed in two areas. For the Trail Making Test A we observed a marginally significant difference between the groups (difference = -9.65 seconds, SE = 4.98, $p = .07$). Specifically, the OEP-only group became slower over time (change = 5.13 seconds, SE = 3.39) and OEP+MBM group became faster at this task (change = -4.52, SE = 3.55). For the Stroop neutral accuracy test, a marginally significant difference was observed (difference = 3.5, SE = 1.8, $p = .06$). The OEP-only group became less accurate over time (change = -2.2, SE = 1.2) while the OEP+MBM group became more accurate over time (change = 1.5, SE = 1.3).

A significant observation was made regarding mindfulness as measured by the Five Factor Mindfulness Questionnaire (FFMQ)⁵⁶. For the total FFMQ score, an improvement to self-reported mindfulness was observed for the OEP-only group while this declined for the OEP+MBM group. A significant difference was observed (difference = 8.93, SE = 3.74, $p = .05$) with the OEP-only group showing an improvement in score (change = -2.18, SE = 3.70) and the OEP +MBM group a reduction in score (change = -11.11, SE = 5.34).

The significance of within-group changes was determined by dividing the within-group estimate by its standard error. Values greater than the absolute value of 1.96 are significant at a two-tailed p value of 0.05 and are highlighted in blue in Table 3. Statistically significant changes were found for the MBM+OEP group for standing balance, sit to stand, total score of the SPPB, TUG serial correct, and Stroop neutral standard deviation. For the OEP-only group, significant changes were observed for the total FFMQ score and the non-reactivity factor score within the FFMQ. Significant changes indicating a decline in performance for both groups was found for the Digits Backwards test. Significant changes were also seen for both groups in the Digits Forward Minus Backwards scores which appear to be attributed to the significant decline in the Digits Backwards test results.

Table 3. Within and Between-group differences in outcome variables over time with adjustment for baseline MoCA score and variable of interest

Variable	Within-Group Changes [†]		Between-group Differences ^{††}	
	Exercise	Exercise + Mindfulness	Estimate (SE)	P value
<i>Mobility and Physical Performance</i>				
Regular TUG* (secs)	2.09 (1.21)	0.51 (1.26)	-1.57 (1.77)	.38
NIA* Standing Balance	0.12 (0.13)	0.32 (0.14) ***	0.20 (0.19)	.31
NIA Walking	0.07 (0.27)	0.20 (0.28)	0.14 (0.39)	.73
NIA Walking Time (secs)	0.21 (0.53)	-0.37 (0.53)	-0.59 (0.75)	.45
NIA Sit to Stand	0.37 (0.20)	0.60 (0.21) ***	0.23 (0.29)	.44
NIA Sit to Stand Time (secs)	0.14 (1.25)	-2.67 (1.32)	-2.81 (1.95)	.16
NIA Total Score	0.56 (0.43)	1.11 (0.45) ***	0.55 (0.63)	.39
<i>Dual-Task</i>				
Dual-task TUG	1.10 (1.80)	2.43 (1.88)	1.32 (2.65)	.62
Dual-task TUG minus reg TUG	-0.25 (1.22)	1.11 (1.28)	1.35 (1.85)	.47
TUG Serial Correct	0.62 (0.67)	1.37 (0.70) ***	0.75 (0.98)	.45
TUG Serial Attempted	0.24 (0.46)	0.83 (0.48)	0.58 (0.67)	.40
TUG Serial Proportion Correct	0.01 (0.07)	0.09 (0.08)	0.07 (0.11)	.49
<i>Cognition – Speed</i>				
TMT* A (secs)	5.13 (3.39)	-4.52 (3.55)	-9.65 (4.98)	.07**
TMT B (secs)	8.02 (12.79)	8.56 (13.38)	0.54 (18.90)	.98
TMT B-A (secs)	3.24 (11.29)	12.69 (11.82)	9.44 (16.69)	.58
DSST* (# correct)	-1.37 (1.41)	1.40 (1.48)	2.77 (2.10)	.20

Variable	Within-Group Changes [†]		Between-group Differences ^{††}	
	Exercise	Exercise + Mindfulness	Estimate (SE)	P value
Stroop Neutral (ms)	11.65 (36.64)	-34.08 (38.29)	-45.73 (53.32)	.40
Stroop INC-CON* (ms)	15.87 (26.99)	-24.72 (28.20)	-40.59 (39.28)	.31
Stroop Neutral Std Dev (ms)	-15.39 (12.28)	-31.80*** (12.85)	-16.41 (18.08)	.38
<i>Cognition - Accuracy</i>				
Digits Forward	0.38 (0.31)	0.04 (0.33)	-0.34 (0.46)	.47
Digits Backward	-0.60*** (0.28)	-1.07*** (0.29)	-0.47 (0.40)	.26
Digits Forward Minus Backward	0.96*** (0.40)	1.13*** (0.42)	0.17 (0.59)	.78
Stroop Neutral Accuracy (%)	-2.2 (1.2)	1.5 (1.3)	3.6 (1.8)	.06**
Stroop INC-CON ACC* (%)	-1.9 (2.2)	1.1 (2.3)	3.0 (3.2)	.37
MMSE*	-0.44 (0.49)	0.12 (0.51)	0.56 (0.71)	.44
<i>Mindfulness and Mood</i>				
Observing	2.82 (2.10)	-0.91 (2.07)	-3.73 (2.99)	.23
Describing	0.35 (0.90)	-1.04 (0.89)	-1.39 (1.33)	.31
Acting	1.48 (1.35)	0.76 (1.33)	-0.72 (1.93)	.71
Non-Judging	1.85 (1.55)	-1.07 (1.52)	-2.92 (2.21)	.20
Non-Reactivity	2.21*** (0.82)	0.38 (0.81)	-1.83 (1.17)	.14
Total FFMQ*	8.93*** (3.74)	-2.18 (3.70)	-11.11 (5.34)	.05**
State Mind	1.61 (1.84)	3.17 (1.81)	1.56 (2.63)	.56
Depression	0.003 (1.23)	-0.07 (1.35)	-0.08 (1.87)	.98

† For within group changes, positive values indicate improvements

†† For between group differences: (OEP+MBM) – (OEP only)

* TUG: Timed Up and Go; NIA: Short Physical Performance Battery; TMT: Trail Making Test; DSST: Digit Symbol substitution test; INC: incongruent; CON: congruent; ACC: accuracy; MMSE: Mini Mental Status exam; FFMQ: Five Factor Mindfulness Questionnaire

**Between group marginally significant results at $p < .10$

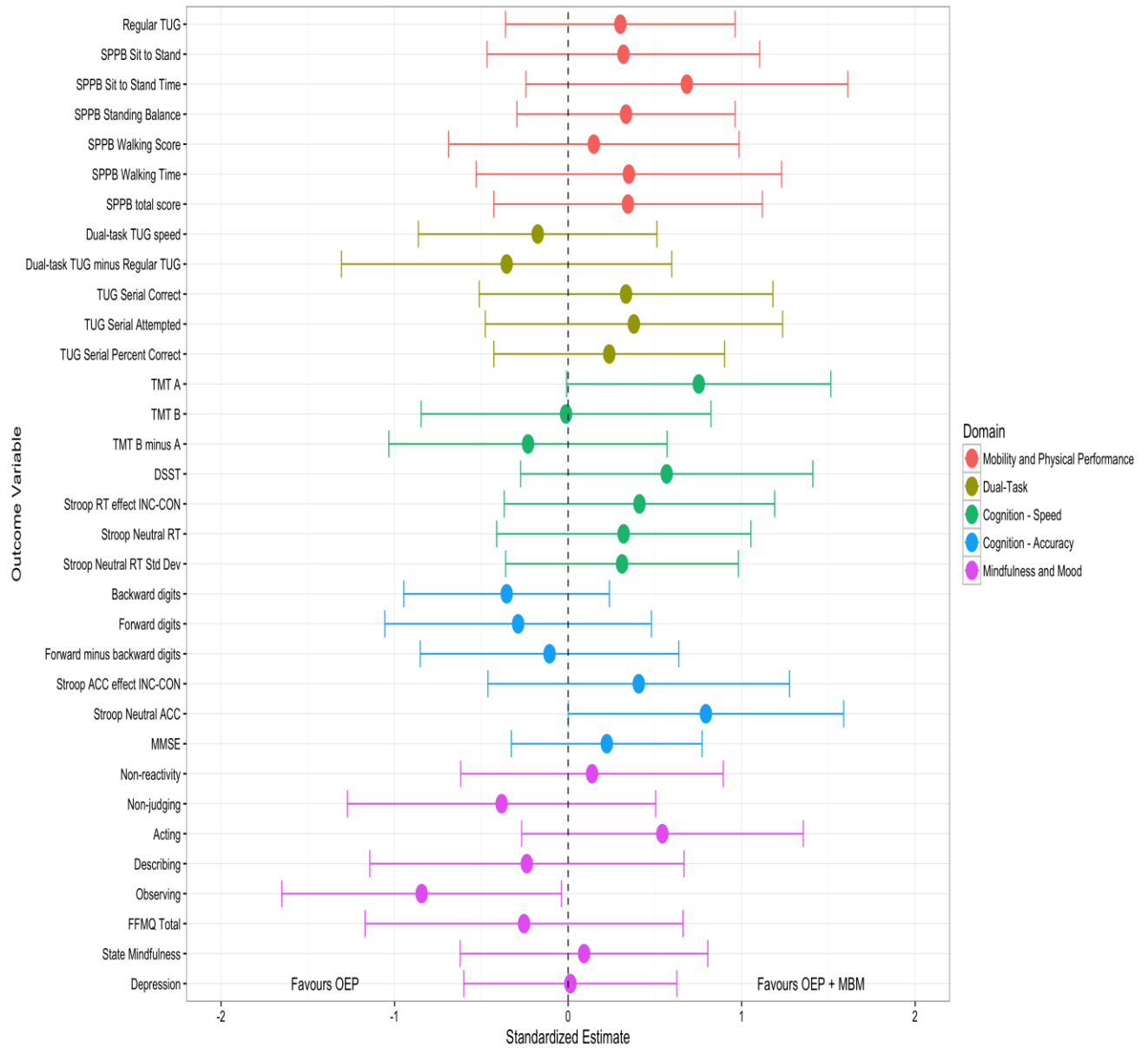
*** Within group differences of statistical significance at $p < .05$

Figure 5 shows the between-group differences across all outcome variables, separated by domain. The outcome variables have been standardized (mean = 0, standard deviation = 1), allowing us to compare the group-differences across variables. The variables are colour-coded by domain. The error bars represent the 95% confidence interval.

Of the 32 variables examined, the estimated effect sizes of 21 variables are greater than zero, favouring the OEP+MBM group. Nevertheless, for all variables, the 95% confidence interval spans include the value 0 – indicating no significant differences between the two groups favouring OEP+MBM.

The effect size is positive for the OEP+MBM group for all seven variables in the mobility and physical performance domain but the 95% confidence intervals span the value zero. The speed-related cognitive outcome measures which are indicators of complex attention including the TMT A, DSST and three of the Stroop variables have positive effect sizes favouring the OEP+MBM group although the 95% confidence interval spans include the value zero. Four of the mindfulness and mood variables have estimated effect sizes of less than zero favouring the OEP-only group but the only significant result is for the Observing facet of the FFMQ as for the other variables have 95% confidence intervals that cross the 0-line. For the remaining two variables, State Mindfulness and Depression, their estimated effect sizes are essentially zero with the 95% confidence interval spanning zero.

Figure 5. Between group differences separated by domain with error bars representing 95% confidence interval



4.4 Discussion

This study was developed as a proof-of-concept study and the small sample size allowed for assessment of feasibility considerations but limited the likelihood of revealing statistically significant differences between the two groups.

The two groups were comparable with respect to demographic variables. The groups were well balanced for initial values of mobility, physical performance, dual task, cognition and mindfulness allowing for effective comparison between groups following intervention.

With respect to feasibility, this study demonstrated that future similar trials may be warranted. Recruitment and retention were not challenging; of attendees at information sessions, .89 consented to participate and there was no attrition from the study. There were high levels of compliance to the physical therapy sessions with .80 attended for OEP-only group and .96 for OEP+MBM group. Education classes for the OEP-only group were well attended with .83 compliance. Meditation class attendance for the OEP+MBM group was .86. Meditation practice compliance was .73 of prescribed sessions. If additional sessions completed by four of the members of the OEP+MBM group are considered that exceeded the prescribed amount, this mean level of compliance with meditation increases to .81. The two groups were similar with respect to attendance and compliance allowing for comparison.

The interesting finding that four of the participants in the OEP+MBM group exceeded the prescribed number of weekly meditation minutes provides support for the notion that the

meditation practice was a positive experience for these participants and motivation was not a limitation for most participants in this group.

There were two technology challenges which could be addressed in future studies. CD players were utilized to minimize dependence on internet access and to simplify access for those with upper extremity impairment. To avoid delays in replacing faulty equipment, participants should be reminded to contact the researchers immediately to replace items rather than waiting to report them at the next scheduled meditation class.

There were no reported safety issues or concerns. It may be assumed that the evidence-based OEP is a safe home exercise program when prescribed by a physical therapist. The meditation practice did not appear to impact any of the participants in a negative way; it appears that this is a low-risk intervention for stroke survivors.

Significant within-group changes were observed in both physical and cognitive measures for the OEP+MBM group. These significant changes were observed for the physical outcomes of standing balance, sit to stand, and the total Short Physical Performance Battery score indicating significant improvements in mobility and balance which likely reduced falls risk for this group. These improvements may be attributed to the effects of the Otago exercise program but were not observed in the OEP-only group. In the cognitive testing, significant within-group changes were observed for the TUG serial correct and Stroop Neutral standard deviation scores for the OEP+MBM group. The TUG serial correct indicates improvements to dual-tasking and the Stroop neutral standard deviation reduction in score over time indicates that this group became

more consistent in their response times; likely due to improved attention. These findings were not observed in the exercise-only group.

While no significant between-group findings were observed favouring the OEP+MBM group, marginally significant differences favouring the meditation intervention were found for two of the cognitive variables – Trail Making Test A and the Stroop neutral accuracy test^{53,54}. TMT Part A tests for visual searching, processing speed and motor speed skills within the complex attention and perceptual motor domains of cognition and are categorized as Cognitive-Speed in Figure 5. Whereas the mean time taken for the OEP-only group became slower over the course of the study, the meditation group became faster on average.

The Stroop neutral accuracy test is a measure of attention and processing speed within the complex attention cognitive domain and are categorized as Cognitive – Accuracy in Figure 5⁵³. The OEP-only group demonstrated lower levels of accuracy at the end of the study while the meditation group's mean scores showed higher levels of accuracy at the end of the study.

Considering these findings with respect to the key cognitive domains as defined by DSM-5 and illustrated in Figure 1 the significant within-group changes to the TUG serial correct and Stroop Neutral standard deviation measures suggest that the OEP+MBM group may have improvements within the complex attention (processing speed, divided attention and sustained attention) domain. The marginally significant between-group findings for Trail Making Test A and Stroop Neutral Accuracy favouring the OEP+MBM group add further support to the suggestion that this group may have had improvements within the complex attention domain and perhaps also within

the perceptual motor and executive function cognitive domains. Improvements in complex attention is an expected finding as the participants were in early stage meditation practice completing meditations targeting attention control⁴¹. Meditation may have created changes in the anterior cingulate cortex (ACC) and insula allowing for more effective detection and regulation of distraction and improved attention to task⁴³. The right insular cortex and left inferior frontal gyrus may have been impacted thus improving the ability to switch away from the mind-wandering default-mode to the executive default mode resulting in improved focus on the task at hand^{45,46}. As falls are associated with an increased propensity to mind-wander, this improved ability may have reduced their fall risk^{25,72}.

A surprising finding relates to perceptions of mindfulness. One of the objectives of this study was to explore whether mindful attention is impacted by either or both interventions as measured by the Five Facet Mindfulness Questionnaire (FFMQ)⁵⁶. At the end of the study, the FFMQ mean scores for the OEP+MBM group had declined. A significant difference was observed with the non-meditators showing an improvement in mean score and meditators a reduction. Two possible explanations for this phenomenon may be considered. Firstly, the meditation intervention primarily focused on the formal practice of meditation and although it was based on the Mindfulness-based stress reduction (MBSR) program, only a small portion of class time was devoted to mindful exercises and discussions⁷³. The homework activities from the MBSR program were not included in the intervention. A second explanation is that the meditation group may have altered their understanding of mindfulness over the course of the study. With a new definition and expanded insight, they may have re-evaluated their initial responses to the FFMQ and these final scores may have been more representative of their trait mindfulness.

Examining the between-group differences on the outcome variables separated by domain and standardized to standard deviation values provided an interesting perspective (Figure 5).

Although these findings must be taken lightly as the 95% CI included the value 0 – indicating there were no significant differences in how the two groups changed over the 12-week study, examining these values on Figure 5 provides a general sense that the majority of the variables favour the MBM+OEP group. All the physical function variables favoured the OEP+MBM group including sit-to-stand ability and time, timed walking, standing balance, TUG test and Total SPPB score. The two physical outcomes most strongly favoured by OEP+MBM group were the time taken for five sit-to-stand repetitions and the timed walking test. These findings are clinically relevant; predictive validity for individuals with chronic stroke has been established for both tests. The sit-to-stand test has an excellent degree of correlation with muscle strength of affected and unaffected knee flexors and the timed walking test has an excellent degree of correlation with dependence in instrumental activities of daily living^{74,75,76}.

In addition, five of the seven cognitive speed tasks favoured the OEP+MBM group. The Digit Symbol Substitution test (DSST) favoured the OEP+MBM group suggests improved complex attention, information-processing speed, and psychomotor functioning⁶⁵. All the Stroop test results favoured the OEP+MBM including the INC-CON, Neutral and the standard deviation of the Neutral Stroop results. These findings are suggestive of response inhibition favouring the OEP+MBM group. The fact that both the neutral condition items and the standard deviation of the neutral items favour the OEP+MBM group suggests that this group became faster and more accurate as well as more consistent across the neutral trials which may indicate more effective sustained attention for this group.

It is acknowledged that these between-group differences on the outcome variables standardized to standard deviation values should not be over-interpreted. However, should these results be extrapolated to a larger sample one may expect to see significant results across physical and cognitive measures.

4.5 Limitations

The primary limitation of this research is the small sample size which did not allow for adequate statistical power to detect a significant intervention effect. However, as this is a proof-of-concept study which demonstrated feasibility, there is potential for repetition with a well-sampled randomized controlled trial.

A secondary limitation is the fact that participants volunteered to take part in the study. They may not be representative of the stroke survivor population as they demonstrated a desire to be involved in further rehabilitation and education. It is not realistic to recruit participants in a non-voluntary manner so this limitation must simply be acknowledged.

Limited demographic information was collected; more data may have provided additional insight with respect to any difference in impact relating to size, height or age. Researchers did not establish the type or location of the strokes which limits the implications of the findings. MRI results with detailed stroke history might have allowed for evaluation of the impact of the interventions with specific stroke presentations. Obtaining participant medical history including history of depression would have added relevant information.

The meditation classes were based on the Mindfulness-based stress reduction program (MBSR) but were abbreviated in length and content. Homework activities relating to mindfulness in daily life were not included in the study. As mindfulness was evaluated with the FFMQ it may be advisable to consider providing a full MBSR program although this may provide an additional challenge of creating a balanced control group experience – the educational classes would need to be enhanced and supplemented with homework as well.

Chapter 5: Conclusions and Future directions

5.1 Summary of Findings

This proof-of-concept study was limited primarily by its small sample size but provides insight into the potential effectiveness of meditation in combination with exercise for older adults with chronic stroke. The two groups were balanced allowing for effective comparisons. The feasibility of conducting future repeat studies was verified with no recruitment or retention challenges and strong adherence to interventions for all participants. Compliance to the meditation practice was strong with four participants spending more time meditating than prescribed which suggests the meditation to be a positive experience. Two minor technology challenges could be avoided in future with improved communication and no adverse events were reported. This study provides early support for meditation practice as a safe intervention for older adults with chronic stroke and supports the claim that MBM is an appropriate intervention for this population. All the participants were able to participate in meditation regardless of the severity of their physical impairment.

The two objectives of the study were to establish whether OEP combined with MBM (OEP+MBM) would be more efficacious than OEP-only in improving balance, mobility and executive functions among stroke survivors and whether OEP+MBM would be more efficacious than OEP-only in improving mindful attention among stroke survivors.

The first objective was not achieved due to an absence of significant findings at $p < .05$. However, two observations at a marginally significant level suggest that meditation in combination with exercise justifies further research. The within-group significant changes in

cognitive results for the OEP+MBM group and the two cognitive variables with marginally significant improvements favouring the meditation group support previous research suggesting that meditation practice improves one's attention and ability to focus on a task⁴¹. These findings are as expected as this study involved early-stage meditation practice and the meditations completed were intended to develop improved attention control⁴³. Subjects in the OEP+MBM group may have become better able to switch away from the default-mode network to the executive network to maintain single focus and avoid mind-wandering⁴⁵. As mind-wandering contributes to falls risk, these marginally significant findings suggest that meditation has potential to reduce falls risk in stroke survivors due to improved attention control^{25,72}.

The second objective was not met and may reveal a limitation of the study. The mindful meditation intervention may require more attention to mindfulness to allow for effective assessment of mindfulness with the FFMQ⁵⁶.

Examination of the between-group differences on the outcome variables standardized to standard deviation values provided tentative support for the meditation intervention and rationale for further similar research. Although this should not be overinterpreted as no findings were significant, the effect sizes for all of the mobility and physical performance variables in Figure 5 were positive thus appearing to favour the OEP+MBM group suggesting that these participants may have derived more benefit from the OEP. The speed-related cognitive outcome measures including the TMT A, DSST and three of the Stroop variables are on the right side appearing to favour the OEP+MBM group. These measures are indicators of cognition primarily within the complex attention domain as well as the perceptual motor and executive function domains. These

changes provide further support to the possibility that the meditators improved attentional control and therefore may have reduced falls risk^{25,72}.

5.2 Contributions of Research

Research in mindfulness is limited and there are few studies involving mindfulness that relate to physiotherapy or exercise interventions. With respect to stroke survivors, research on the impact of MBM and other mindful approaches has primarily focused on fatigue-related outcomes. The majority of studies in the field of mindfulness do not have active control groups so the results of this study represent an effective research approach to further explore the effectiveness of MBM.

This proof-of-concept trial provides an early indication that future studies are warranted to examine whether the addition of MBM to therapeutic exercise has the potential to impact outcomes of mobility, balance, and executive function. This study contributes to fall prevention research as it provides tentative early support for meditation to improve attentional control and reduce mind wandering in older adults with chronic stroke. A larger repeat trial is warranted to obtain significant findings to fully support this finding.

5.3 Potential Applications for Research Findings

With the increasing number of Canadians living with deficits caused by stroke, cost-effective therapeutic measures to enhance rehabilitation outcomes are a priority. Although this study will require replication on a larger scale, it provides early support for an accessible and low cost intervention for stroke survivors to potentially enhance outcomes of fall prevention home exercise programs. Meditation practice is a safe intervention for older adults with chronic stroke

and is appropriate intervention for this population regardless of the severity of physical impairment.

Experts in the area of mindfulness may be interested in the impact of the interventions on focus and attention in this population, providing further support for the positive impact of meditation on these cognitive functions.

Assuming that upon completion of a meditation session the brain is less prone to returning to default-mode activity and mind wandering, meditating immediately prior to a therapeutic exercise intervention or rehabilitation therapy session may enhance outcomes⁴⁶. Meditation completed prior to leaving the home for a walk may have a protective effect against falls due to improved attention. Walking meditation practice as instructed in the Mindfulness Based Stress Reduction (MBSR) program may be beneficial for fall prevention¹².

Clinicians may wish to consider mindful approaches and incorporating MBM into intervention delivery. These early findings suggest potential linkages between the MBM and improved exercise outcomes which may encourage clinicians, coaches, and others to seek out meditative practices to optimize training.

5.4 Strengths and Limitations of Research

A primary strength of this study is that all participants received the benefits of the exercise intervention. For the OEP+MBM group, there was minimal cost in providing the meditation interventions as the audio recordings were available free of charge and permission was obtained

from UCLA Mindfulness Awareness Research Centre to utilize these recordings for this study⁵⁹. To allow for impartial access to both interventions, these audio recordings were made available to participants in the control group at the end of the study and meditation classes were also provided for this group.

Providing an active control for the OEP-only group with fall prevention education classes allowed all participants to have similar experiences with respect to socializing with other participants and facilitators. Ensuring that all participants experienced this socialization was particularly important as it likely impacted home exercise compliance⁷⁷. The socialization may also have impacted executive function measures; previous studies have suggested that having satisfying social relationships in later life is associated with a reduced risk of cognitive decline⁷⁸.

5.5 Future Directions of Research

This proof-of-concept study provides adequate support for similar repeat studies with larger numbers of participants. These repeat studies should consider including long term follow up with participants to provide further information both in terms of whether participants choose to continue to practice meditation. Follow-up studies may wish to investigate whether, for those who continue to progress to middle and advanced stages of meditation practice, outcomes also include emotion regulation and self- awareness findings. Follow up studies could also investigate fall incidence implications for the two groups over time.

Further studies could examine specific aspects of the intervention delivery such as optimal timing and sequencing. Data analysis to examine differences in response based on age, type of

stroke and other demographic factors would provide valuable insights for optimal therapeutic applications.

This area of research could extend to other similar populations such as brain injury survivors. The impact of MBM on brain healing in acute stages represents another research direction that would be highly relevant to these populations.

Mindful interventions and approaches to physiotherapy in a range of clinical contexts warrant investigation. Establishing connections between mindful interventions and improved therapeutic and exercise outcomes may also support further research in the fields of sports medicine, recreation, and kinesiology.

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Appendices

Appendix A - Advertisement

THE UNIVERSITY OF BRITISH COLUMBIA



Did you experience a stroke more than one year ago?

Are you concerned about falling and want to reduce your risk?

Researchers from the University of British Columbia and the Vancouver Coastal Health Research Institute are currently seeking participants for a study that looks at the benefits of an exercise program on known falls risk factors.

To be eligible for this study, individuals must be:

- 1) Residing within the community in the Lower Mainland (i.e. not residing in nursing home)
- 2) Aged 55 and older
- 3) Be able to walk six meters with rest intervals with or without a cane or walker;
- 4) Have an activity tolerance of 30 minutes with rest intervals;
- 5) Not be currently participating in any regular therapy or progressive exercise and;
- 6) Have a working computer with internet access and audio

If you are interested in participating in this study, please contact _____, **MHK, Research Coordinator, Mobility, & Cognitive Neuroscience Laboratory, University of British Columbia**

P. ____ - ____ - ____ ext. _____

**More than 2 (TIA's not
included)**

5. What was the date of your stroke (month and year)? _____
 a. (To be eligible it must be greater than 12 months ago) Y N
6. Can you read typical print material well (with or without reading classes as needed)? Y N
7. Do you have significant hearing loss? Y N
8. Can you read English without difficulty? Y N
9. Are you able to walk by yourself with or without a cane or walker for short distances? Y N
10. To your knowledge, have you been diagnosed with a neurological disease such as Parkinson's disease, dementia, Alzheimer's disease, or multiple sclerosis? Y N
11. Do you have significant joint problems like arthritis that get easily aggravated by exercise?
Y N
12. Has your doctor told you recently that you should not join a new exercise program? Y
N
13. Are you currently participating in any regular therapy or progressive exercise? Y N
14. Are you able to exercise for 30 minutes with rest intervals? Y N
15. Do you have a working computer with internet access and audio? Y N
16. Do you meditate on a regular basis (i.e., 3 or more times per week)? Y N
17. As part of this study, there are 2 measurement sessions will take place at the beginning and at the end of the study (12 weeks) at Vancouver General Hospital. Do you expect that you will have the time to attend the 2 measurement sessions? Y N
18. Over the 12 weeks for half of the participants there will be 5 or 6 one-hour educational classes at the University of British Columbia or Vancouver General Hospital. Do you expect that you will have the time to attend these classes? Y N
19. In order to have enough people for each class, the program may not start until this upcoming October (or other estimated date as needed). Are you willing to wait until then? Y N
20. Can you tell me if you think you are medically stable? Y N
 - a. Do you have hypertension? Y N
 - i. If yes, is it stable and controlled with medication? Y N
 - b. Do you have diabetes? Y N
 - i. If yes, is it well managed? Y N
 - c. Do you have atrial fibrillation or other heart conditions? Y N
 - i. If yes, are these conditions under control with medication? Y N
 - d. Have you had any recent episodes of angina or had a heart attack within the past year?
Y N
 - e. Are you currently taking medication for cognitive function (such as donepezil, galantamine, etc.)? Y N
 - i. If YES:
 1. Is it a stable dose? Y N
 2. Do you expect it to change within the next year? Y N
 - ii. If NO:
 1. Do you expect to start this medication within the next year (or has your doctor mentioned you trying one)? Y N

21. *In speaking with the potential participant throughout the phone call – Is the potential participant able to comprehend your speech adequately to follow instructions and give appropriate answers?* Y
N
22. *Since your stroke, have you noticed a significant change in your cognitive abilities, such as memory?* Y
N

Thank you. You are not eligible to take part in our study but I thank you very much for your time and interest.

OR

Thank you. It appears that you might be eligible to take part in our study based on these questions. If you are interested, I can provide you with more information regarding the study.

PART B. I would like to take a few minutes to provide you a brief summary of what this research project is about and it entails.

Each year, over 40 000 Canadians experience a stroke and approximately 40% of stroke survivors are left with moderate to severe physical impairment. As a result, balance problems are common for stroke survivors and they increase the risk of falls. Impaired cognitive (i.e., thinking) abilities are also common after a stroke and such impairments can also increase the risk of falls.

Exercise has been shown to reduce falls risk among older adults, including those have suffered a stroke. Moreover, exercise is a promising strategy to promote cognitive function. However, stroke survivors often have physical impairments that significantly limit their ability to exercise. Mindful based meditation is gaining recognition for its positive impact on both physical and cognitive health and we would like to explore its potential benefits for those who have suffered a stroke.

We are conducting a 12 week intervention study to examine the potential benefits of two enrichment programs on thinking and physical abilities in this specific population. We are seeking men and women who have experienced a stroke and are from the Lower Mainland to take part in this study. Based on the information you have provided me, you may be eligible for this study.

KEY POINTS (MUST BE COMMUNICATED TO THE INDIVIDUAL)

Overall, if you decide to participate in this study, we would ask you to:

- Attend 2 measurement sessions—they will occur at the beginning of the study and one at the end of the 12 weeks. During these sessions, we will measure both your physical (e.g., how strong you are) and your cognitive (e.g., how well you can remember lists of words) abilities.

- Once you have completed the first or baseline measurement, you may be selected to participate in one of 2 groups: an exercise program, or an exercise program with mindful meditation. The exercise program is completed in your home under the guidance of a physiotherapist who will make several visits to your home to support and guide you and the mindful meditation involves meditation instruction and meditation practice following audio recordings.

If you are selected to the Exercise program, you will do exercises aimed at improving your balance as well as improving your overall posture and range of motion. If you are selected to the Exercise plus mindful meditation group you will be taught mindful meditation techniques and encouraged to practice these for 30 minutes daily.

- We need to highlight that, in order to maintain high research standards, you will not be able to choose which type of exercise program, but rather, we will randomly assign you.

***Randomly assigned means that you have an equal chance of being in any group - this is like a flip of a coin. Once you are assigned to a group, you cannot switch**

Are you still interested in participating? Yes No

If you are still interested in participating, we would like to invite you to come to an information session and screening session at VGH. You are welcome to bring a friend or family member if you wish.

We strongly recommend all interested participants to attend an information session as we can provide in-depth information regarding this study, you will have the opportunity to meet the researchers involved, and ask as many questions as you would like in person.

I will now need to obtain your contact information so that I can send you an information letter about the study as well as a consent form for your review. We highly recommend that you review this material prior to attending your information session, a map directing you to the Centre, and a confirmation letter re: the information session.

Full Name:
Telephone:
Address:

Do you have any questions that you would me to answer right now?

Thank you very much for your time. I will be calling you again prior to the information session to confirm your attendance. Thank you again and I look forward to meeting to you soon.

Internal Use Only

1. Meets eligibility criteria? Yes No

2. Not eligible because: _____

3. Eligible but not interested? Yes No

4. Information Session Package Mailed: _____

5. Information Session (Date and Time): _____

Appendix C - Participant letter

THE UNIVERSITY OF BRITISH COLUMBIA



Dear [Participant Name]

Thank you for considering participating in this Mindful Meditation study investigating how two interventions can help to maintain, or even improve, mobility and balance as well as cognitive function in people who have had a stroke.

I look forward to seeing you at your screening session booked for _____.

Please feel free to contact me if you have any questions at this time.

Yours sincerely,

Master of Science Student in Rehabilitation Sciences
Department of Physical Therapy
University of British Columbia
_____._____@alumni.ubc.ca

Appendix D – Consent form

THE UNIVERSITY OF BRITISH COLUMBIA



Djavad Mowafaghian
CENTRE FOR BRAIN HEALTH



PARTICIPANT INFORMATION AND CONSENT FORM

**The impact of mindful meditation, combined with exercise,
on mobility and cognitive function
among the older adults with chronic stroke**

Principal Investigator: Dr. _____ PT, PhD

Associate Professor

Department of Physical Therapy

Faculty of Medicine

University of British Columbia

_____ ext _____

Co-Investigators:

Department of Physical Therapy
University of British Columbia

Department of Physical Therapy
University of British Columbia

Department of Physical Therapy
University of British Columbia

Department of Physical Therapy
University of British Columbia

Clinical Associate Professor
Geriatric Medicine

University of British Columbia

Sponsor:

UBC Department of Physical Therapy,

_____ Neurorehabilitation Seed Fund

UBC Start-Up Funds

For Non-Emergency Contact Numbers:

_____, Principal Investigator: _____ Ext _____

_____, Research Coordinator: _____ Ext _____

INTRODUCTION

You are being invited to take part in this research study because you have expressed an interest and may be eligible to participate in study exploring the effect of combining exercise with mindful based meditation on falls risk and cognitive function. We are specifically looking for individuals who have suffered a stroke at least 12 month ago. **If you are interested in participating in the research, please be advised that further screening will take place to determine your eligibility.** This consent form will outline all procedures, including screening

procedures. Before any further screening and/or testing can take place, your consent must be obtained.

Your participation in this study is entirely voluntary, so it is up to you to decide whether or not to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risk and discomforts.

This consent form tells you about the research study and what will happen if you decide to take part in it. You may take home an unsigned copy of this consent form to think about taking part of the study and/or discuss it with friends, relatives and/or your family doctor. You need to understand the risks and benefits of the study. **Please take time to read the following information carefully** before deciding whether or not to participate. At any time before or during the study, please ask the principal investigator or study coordinator to explain any words or information that you do not understand.

If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reasons for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

Please take time to read the following information carefully before you decide.

1. Who is conducting this study?

This study is being conducted by Dr. _____, Dr. _____, Dr. _____, _____, _____, and _____. This study is funded by a UBC research start-up grant and _____ Neurorehabilitation Seed Fund. There will be no involvement of any pharmaceutical company. Dr. _____ does not receive any personal financial compensation for this study.

2. Background

Each year, over 40 000 Canadians experience a stroke and approximately 40% of stroke survivors are left with moderate to severe physical impairment. As a result, balance problems are common for stroke survivors and they increase the risk of

falls. Impaired cognitive (i.e., thinking) abilities are also common after a stroke and such impairments can also increase the risk of falls.

Exercise has been shown to reduce falls risk among older adults, including those who have suffered a stroke. Moreover, exercise is a promising strategy to promote cognitive function. However, stroke survivors often have physical impairments that significantly limit their ability to exercise. Mindfulness based meditation is gaining recognition for its positive impact on both physical and cognitive health.

a) What is the purpose of the study?

The intent of this study is to investigate whether, in stroke survivors, the combination of the Otago exercise program (OEP) and mindfulness based meditation (MBM) may be more efficacious than OEP alone with respect to improving balance, mobility and cognitive abilities. The OEP is a physical-therapy-delivered, home-based strength and balance retraining program tailored for older adults.

b) Who may participate in this study?

You may participate in this study if you are: 1) aged 55 years or older; 2) community dwelling (i.e., not residing in a nursing home, extended care unit, or

assisted-care facility); 3) have had a stroke one or more years ago; 4) have a Mini-Mental State Examination (MMSE) score of 22 or more at screening; 5) live in the Greater Vancouver area; 6) be able to comply with scheduled visits, treatment plan and procedures; 7) not be expected to start or are stable on a fixed dose of cognitive medications (e.g. donepezil, galantamine, etc) during the study period; 8) be able to walk six metres with rest intervals with or without assistive devices; 9) have an activity tolerance of 30 minutes without rest intervals; 10) not be currently participating in any regular therapy or progressive exercise; and 11) own an operating computer with internet access and audio.

You should not participate in the study if you are: 1) diagnosed with dementia of any type; 2) diagnosed with another type of neurodegenerative or neurological condition (e.g., Parkinson's disease) that affects cognitive function and mobility; 3) at high risk for heart complications during exercise, such as a brisk walk; 4) taking medications that may negatively affect cognitive function; 5) aphasia as judged by an inability to communicate by phone; or 6) are currently practicing meditation.

c) What does the study involve?

If you agree to be in this study, you will perform a small series of cognitive tests and questionnaires to see if you are able to participate. This will take

approximately 45 minutes. You may be excluded from the study after this screening session. If you are able to participate, there will be two individually scheduled visits before and after the study: one visit at the beginning of the study and one visit after you finish the study at 12 weeks. Each visit will take approximately 2 hours and you will be asked to come to the Research Pavilion (Centre for Hip Health and Mobility), 828 West 10th Avenue.

During your first visit, you will be performing a small number of questionnaires about for example your general health, educational level and socioeconomic status. If there are questions that make you feel uncomfortable, you do not have to answer them. We will also measure your age, weight, and height. Additionally, you will complete a series of performance tasks to determine how well you walk, balance, get up from a chair, remember lists of numbers, make decisions, and multi-task. As well, we will measure your reaction time, vision, and how strong you are. If there are questions or tasks that make you feel uncomfortable, you do not have to answer or complete them.

You will be randomly assigned to one of two training groups: 1) a home-based exercise program called the Otago Exercise Program (OEP); or 2) OEP combined

with MBM (OEP +MBM). **Randomly assigned means that you have an equal chance of being in any of the two groups – it is like flipping a coin.**

If you are placed into the **OEP only group**, you will receive a physical-therapy-delivered, home-based strength and balance retraining program. Throughout the 12-week study, 5 home visits (1 hour per visit) will be made by our study physical therapist (PT). You will be asked to perform 30 minutes of individually PT-prescribed OEP exercises 3x/week. Your compliance will be tracked through calendars provided by the research team and will be reviewed by the study PT during each home visit. You will also be required to attend 6 one-hour education sessions on fall prevention. By being in this group, you will be required to commit 29 hours over the 12-week study period.

If you are placed into the **OEP + MBM** group, you will receive the OEP program, as described above, and in addition, you will be provided with mindfulness based meditation (MBM) training, delivered by graduate student Tracy Dignum, who has experience in mindfulness training. Specifically, you will receive MBM coaching via 6 small group sessions, 60 minutes each session, at the Djavad Mowafaghian Centre for Brain Health, University of British Columbia (Point Grey Campus) or Research Pavilion (Centre for Hip Health and Mobility), depending on the

preference of participants. You will be asked to practice at home following online audio recordings (free of charge from University of California, Los Angeles; <http://marc.ucla.edu/body.cfm?id=22>) and written instructions a minimum of five times per week for 30 minutes. You will track your practice time using a diary provided by the research team. By being in this group, you will be required to commit 59 hours over the 12-week study period.

This study will take place at the Research Pavilion (Centre for Hip Health and Mobility) at Vancouver General Hospital, Djavad Mowafaghian Centre for Brain Health at University of British Columbia, and in your home. All information obtained will be de-identified and kept confidential.

d) How much of my time is required?

Should you agree to participate in the study, you can expect to spend 3-5 hours per week for 12 weeks. Specifically, if you are in the **OEP only** group, you will be required to commit 29 hours over the 12-week study period, plus 4 hours for testing (2 sessions of 2 hours each). If you are in the **OEP + MBM** group, you will be required to commit 59 hours over the 12-weeks study period, plus 4 hours for testing (2 sessions of 2 hours each).

3. What are the possible harms and side effects of participating?

Muscle soreness may occur as a result of participating in the OEP program.

4. What are the benefits of participating in this study?

It is not possible to predict whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part. Discovered benefits of participating in the OEP include a reduction of falls and fall risk factors and improvements to cognitive performance.

5. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, you have the right to request the withdrawal of your information collected during the study. This request will be respected to the extent possible. Please note however that there may be exceptions where the data will not be able to be withdrawn for example where the data is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let your study doctor know.

6. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical.

7. What happens after the study is finished?

Once your participation in the study is concluded we will provide you with the results from your two assessments.

8. What will the study cost me?

You will not incur any personal expenses as a result of participating. You will receive reimbursement for any parking and travel expenses up to \$80.

9. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his or her designate by representatives of UBC Clinical Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

10. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, you can contact **Dr. _____** at _____ ext _____.

11. Who do I contact if I have any questions or concerns about my rights as a subject during the study?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of

Research Ethics by e-mail at _____@_____.ca or by phone at _____ (Toll
Free: _____)

SUBJECT CONSENT TO PARTICIPATE

**The impact of mindful meditation, combined with exercise,
on mobility and cognitive function
among the older adults with chronic stroke.**

I have read and understood the subject information and consent form.

I have had sufficient time to consider the information provided and to ask for advice if necessary.

I have had the opportunity to ask questions and have had satisfactory responses to my questions.

I understand that all of the information collected will be kept confidential and that the result will only be used for the scientific objectives.

I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.

Appendix E - Meditation Log

THE UNIVERSITY OF BRITISH COLUMBIA



Djavad Mowafaghian
CENTRE FOR BRAIN HEALTH



Meditation Log

Record the details of your meditation practice on these pages.

Aim to complete 30 minutes of mindful meditation practice 5 days per week

Audio recordings: <http://marc.ucla.edu/body.cfm?id=22>

Date	Title(s) of meditation	Total time	Comments (optional)
e.g. Tues, Sept 1, 2015	Breathing Breath, Sound, Body	25 minutes	Challenging to keep mind from wandering initially.

Appendix F – Participant Calendar

THE UNIVERSITY OF BRITISH COLUMBIA



Djavad Mowafaghian
CENTRE FOR BRAIN HEALTH



Vancouver
Coastal Health
Promoting wellness. Ensuring care.



CENTRE
for Hip Health
and Mobility



Participant Calendar for Home Exercises

Please indicate with an “x” any day exercises completed – aim for 3x/week.

Make note of days you start but do not finish exercises and provide reason.

Month:

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday

Appendix G – Mindful meditation script examples



MINDFUL MEDITATION Study

Mindfulness Meditations created by Diana Winston

for the UCLA MARC Center © 2015.

The Regents of the University of California.

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MARC UCLA Guided meditation audio recordings transcripts transcribed from:

<http://marc.ucla.edu/body.cfm?id=22>

1. Breathing meditation: (5 minutes)

“So find a relaxed comfortable position seated on a chair or on the floor on a cushion. Keep your back upright but not too tight; hands resting wherever they are comfortable; tongue on the roof of your mouth or wherever it’s comfortable. And you can notice your body from the inside; noticing the shape of your body, the weight, touch, and let yourself relax and become curious about your body seated here; the sensations of your body – the touch; the connection with the floor, the chair. Relax any areas of tightness or tension; just breathe, soften.

Now begin to tune into your breath in your body – feeling the natural flow of breath. You don’t need to do anything to your breath – not long, not short, just natural. And notice where you feel your breath in your body – it might be in your abdomen; it may be in your chest or throat or in

your nostrils. See if you can feel the sensations of breath one breath at a time. When one breath ends the other begins.

Now as you do this you might notice that your mind might start to wander – you might start thinking about other things. If this happens, this is not a problem; it's very natural. Just notice that your mind has wandered – you can say thinking or wandering in your head softly. And then gently redirect your attention right back to the breathing. So we will stay with this for some time in silence – just a short time noticing our breath, from time to time getting lost in our thoughts, and returning to our breath. See if you can be really kind to yourself in the process.

And once again you can notice your body; your whole body seated here. Let yourself relax even more deeply and then offer yourself some appreciation for doing this practice today – whatever that means to you- finding a sense of ease and well-being for yourself and this day.”

Chime

2. Body scan meditation: (3 minutes)

“Begin by bringing your attention into your body. You can close your eyes if that's comfortable to you. You can notice your body seated wherever it's seated – feeling the weight of your body on the chair, on the floor.

You can take a few deep breaths. And as you take a deep breath bring in more oxygen enlivening the body. And as you exhale have a sense of relaxing more deeply.

You can notice your feet on the floor – notice the sensations of your feet touching the floor – the weight and pressure, vibration, heat. And notice your legs against the chair- pressure, pulsing, heaviness, lightness.

Notice your back against the chair. Bring your attention into your stomach area. If your stomach is tense or tight let it soften. Take a breath.

Notice your hands – are your hands tense or tight? See if you can allow them to soften. Notice your arms – feel any sensations in your arms. Let your shoulders be soft.

Notice your neck and throat – let them be soft. Relax. Soften your jaw. Let your face and facial muscles be soft.

Then notice your whole body present. Take one more breath. Be aware of your whole body as best you can. Take a breath. And then when you are ready, you can open your eyes.”

Appendix H – Mindfulness education sessions

THE UNIVERSITY OF BRITISH COLUMBIA



Djavad Mowafaghian
CENTRE FOR BRAIN HEALTH



Mindfulness Education Sessions

6 x 1 hour sessions

1. Introductions/ Intro to Mindfulness Week 1
 - a. Introduce self and class (10 min)
 - b. Intro to Mindfulness:
 - i. What is Mindfulness? Video - “60 Minutes – Mindfulness featuring Jon-Kabat Zinn” (13 min)
 - ii. Informal and formal practices of mindfulness (10 min)
 - iii. Mindful eating activity and discussion (5 min)
 - iv. Formal practice: Body scan meditation (15 min)
 - v. Homework and log instructions: body scan 5-7x/week, mindful eating exercise (5 min)

2. Reflecting on Mindful practices Week 2
 - a. Re-introductions (5 min)
 - b. Body scan meditation (15 min)
 - c. Partner discussion re: formal and informal experiences this week (10 min)
 - d. Discuss strategies to enhance practice and overcome challenges (15 min)
 - e. Seated meditation (10 min)
 - f. Homework: body scan and seated meditation; mindful ADL daily (5 min)

3. Deepening your practice Week 4
 - a. Seated meditation (20 min)
 - b. Video: “Mindfulness – 9 attitudes with Jon Kabat Zinn: Non-Judging” (5 min)

- c. Partner discussion of experiences and challenges (10 min)
 - d. Mindfulness while exercising (10 min)
 - e. Mindful breathing (10 min)
 - f. Homework: body scan or seated meditation, mindful breathing (5 min)
4. Mindfulness in everyday life Week 6
- a. Body scan (20 min)
 - b. Group discussion of experiences, challenges, observations (10 min)
 - c. Mindful listening practice and discussion (15 min)
 - d. Mindful movements (10 min)
 - e. Homework: body scan or seated meditation, mindful listening task
5. Watching our thoughts Week 8
- a. Seated meditation (20 min)
 - b. Partner discussion of experiences, challenges, observations (10 min)
 - c. Learning to observe your thoughts during meditation (10 min)
 - d. Sitting with all senses meditation (15 min)
 - e. Homework: sitting with all senses meditation, body scan meditation (5 min)
6. Continuing your practice Week 10
- a. Sitting with all senses meditation (15 min)
 - b. Working with pain during meditation (15 min)
 - c. Group discussion, feedback of experiences (15 min)
 - d. Mindful movements (10 min)
 - e. Homework: body scan, seated meditation (5 min)

Appendix I – Active control education sessions

THE UNIVERSITY OF BRITISH COLUMBIA



Djavad Mowafaghian
CENTRE FOR BRAIN HEALTH



Fall prevention education classes

6 x 1 hour sessions

1. Introductions/ Intro to fall prevention Week 1
 - a. Introduce self and class / ice breaker (15 min)
 - b. Outline for 6 sessions (5 min)
 - c. Intro to falls:
 - i. Incidence and frequency in older adults / stroke survivors (5 min)
 - ii. Relevance of fall prevention: explain that falls not normal part of aging and majority of falls are preventable (5 min)
 - iii. Discuss why preventing and reducing falls and fall related injuries is important / common injuries and outcomes (10 min)
 - iv. Discuss common mechanisms of falls and have roundtable discussion on previous falls and mechanisms (10 min)
 - v. Discuss fear of falling and consequences (10 min)

2. Medical causes of falls / vision and hearing Week 2
 - a. Common medical conditions increasing fall risk (20 min)
 - b. Vision considerations and suggestions (20 min)
 - c. Hearing considerations and suggestions (20 min)

3. Fall prevention products and footwear/ medications? Week 4
 - a. Footwear suggestions and tips (consider inviting vendor) (20 min)
 - b. AFOs / splints (15 min)

- c. Hip protectors (10 min)
 - d. Impact of common medications on fall risk (15 min)
4. Household and lifestyle considerations and modifications Week 6
- a. Reducing clutter (10 min)
 - b. Surfaces (10 min)
 - c. Lighting (10 min)
 - d. Timing (10 min)
 - e. Incontinence (10 min)
 - f. Railings, walking aids and supports (10 min)
5. Sleep and falls: Guest lecture by Dr. Glenn Landry (60 min) Week 8
6. What to do if you fall? Week 10
- a. Demonstration falling techniques (15 min)
 - b. Demonstration of getting up from floor (15 min)
 - c. Practice session of getting down/ up from floor (30 min)

Appendix J – Mini Mental State Examination (MMSE)

MINI MENTAL STATE EXAMINATION (MMSE)

- | | | | |
|---|---|---------------------------------|--------------------------|
| 1 | 0 | What is the year? | TOTAL: _____ / 30 |
| 1 | 0 | What is the season? | |
| 1 | 0 | What is the month? | |
| 1 | 0 | What is the date? | |
| 1 | 0 | What is the day of the week? | |
| 1 | 0 | What country are we in? | |
| 1 | 0 | What province are we in? | |
| 1 | 0 | What city are we in? | |
| 1 | 0 | What is the name of this place? | |
| 1 | 0 | What floor are we on? | |

I am going to name three objects. After I have said them, I want you to repeat all 3 words. Remember these words because in a few minutes, I am going to ask you to recall them. The words are APPLE, TABLE, and PENNY.

- | | | |
|---|---|-------|
| 1 | 0 | Apple |
| 1 | 0 | Table |
| 1 | 0 | Penny |

Now I am going to give you a word. I would like you to first spell it forwards and then spell it in reverse. The word is WORLD.

5	4	3	2	1	0	_____	_____	_____	_____	_____
---	---	---	---	---	---	-------	-------	-------	-------	-------

What were the three words I asked you to remember?

1 0 Apple

1 0 Table

1 0 Penny

1 0 What is this (show watch) called?

1 0 What is this (show pencil) called?

1 0 I would like you to repeat this phrase after me: “No ifs, ands, or buts.”

1 0 I would like you to read the words on this page and then do what it says.
(Show paper with “Close your eyes” on it)

I’m going to give you a piece of paper. When I do, I would like you to...

1 0 Take the paper with your right hand

1 0 Fold it in half with both hands

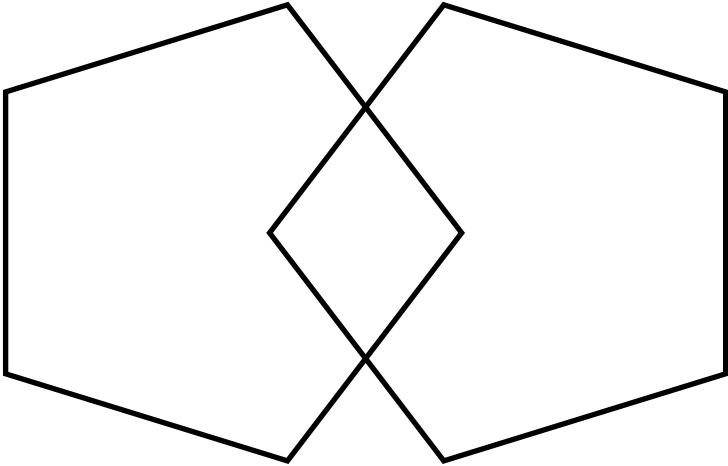
1 0 Drop it to the floor

1 0 Please write any complete sentence on the line provided.

1 0 Here is a drawing. Please copy the design in the space below.

Please write a sentence below:

Please copy the design below:



Appendix K - Trail making test

Part A Testing Instructions:

Place the **Part A** warm-up sheet in front of the participant.

“On this page (point), there are some numbers. Begin with the number one (point to “1”) and draw a line from one to two, (point to “2”), two to three (point to “3”), three to four (point to “4”), and so on, in order, until you reach the end (pointing to the circle marked “END”).

Draw the lines as fast as you can. Do not lift the pencil from the paper. Ready! Begin!”

After the warm-up, place the **Trail A** sheet in front of the participant.

“On this page, there are numbers from 1 to 25. Do the same thing. Begin at number one (point) and draw a line form one to two (point), two to three (point), and so on, in order, until you reach the end (point). Remember, work as fast you can and do not lift the pencil from the paper. Ready! Begin!

Part B Testing Instructions:

Place the **Part B** warm up sheet in front of the participant.

“On this page (point), there are some numbers and letters. Begin at number one (point) and draw a line from one to A (point), A to two (point), two to B (point), B to three (point), and so on; in order until you reach the end (point to circle marked “END”). Remember, first you have a number (point to “1”), then a letter (point to “A”), then a number (point to “2”), then a letter (point to “B”), and so on. Draw the lines as fast as you can. Do not lift the pencil from

the paper. Ready! Begin!”

After warm-up, place the **Trail B** sheet in front of participant.

“On this page, there are both number and letters. Do the same thing you did in the warm-up. Begin with number one (point) and draw a line from one to A (point), A to two (point), two to B (point), B to three (point), and so on, in order; until you reach the end (point to circle marked “END”). Remember, first you have a number (point), then a letter (point), and so on. Draw the lines as fast as you can. Do not lift the pencil from the paper. Ready! Begin!”

If the participant makes an error, DO NOT stop timing. Call it to his/her attention and have the participant proceed from the point at which the mistake occurred (i.e. from the most recent correct number).

At the end of both tests, record the time it took for the participant to complete the test and the number of errors made throughout the test. Also, on the **Trail** sheets, place a star beside the errors made.

Trail Making Results:

TRAIL	Time (seconds)	Number of Errors (#)
A		
B		

Appendix L – Digit Symbol Substitution test

Directions In the top row, there are 9 digit symbol pairs. Each number is associated with its very own symbol. For example, 1 is represented by a horizontal line, 2 is represented by an upside down T and so on.

For practice, complete the second row by copying down the corresponding symbol under each number. You will then be timed for one minute to do the same task and fill out as many boxes as you can.

	1	2	3	4	5	6	7	8	9					
	—	⊥	⌋	└	└	○	^	✕	=					
2	1	3	7	2	4	8	9	4	8	6				
2	1	3	2	1	4	2	3	5	2	3	1	4	5	
6	3	1	4	1	5	4	2	7	6	3	5	7	2	
8	5	3	4	6	3	7	9	2	8	1	9	5	8	
6	2	5	1	9	2	8	3	7	4	6	5	9	4	
8	3	7	2	5	4	6	3	9	2	8	1	7	9	
4	6	8	5	2	7	1	8	5	2	9	4	8	6	

Appendix M – Timed Up and Go test (TUG)



Mindful

The Timed “Up and Go” Test (TUG) Score Sheet

Walking Aid:

- 0 = None
- 1 = Cane (quadric cane; regular cane)
- 2 = Crutch (one side; both side)
- 3 = Walker (wheeled; regular)
- 4 = Brace (AFO or others: _____)

TUG	Time	Specific Comments
Trial 1		
Trial 2		
Mean		

Please read the following instructions:

“The purpose of this test is to measure how long you take to complete the following tasks:

Standing up from the chair, walking the 3 meters at your usual speed, turning around, walking back 3 meters and sitting down. **If possible, do not use arm rests to push off from the chair.**

When you are ready, I will say “Go”. As soon as you hear my “Go” you will start the test”.

PLEASE DEMONSTRATE once prior to having the person do this.

Start the watch as you say, "Go", and then stop the watch when the participant's bottom touches the seat. RECORD THE TIME AND **DO THIS TEST TWICE.**

Appendix N – Timed Up and Go dual task test

Dual Task Timed “Up and Go” Test (TUG) Score Sheet

Walking Aid:

0 = None

1 = Cane (quadric cane; regular cane)

2 = Crutch (one side; both side)

3 = Walker (wheeled; regular)

4 = Brace (AFO or others: _____)

Did the participant use armrests (should be the same as during normal TUG)? No Yes

Time	Serial 3s	Serial Score
TUG 1: _____	97 94 91 88 85 82 79 76 73 70	Total attempted_____ Total errors_____ Total correct_____
TUG 2: _____	72 69 66 63 60 57 54 51 48 45	Total attempted_____ Total errors_____ Total correct_____
Mean: _____		

Please read the following instructions:

“Just like you did in the last test, you will stand up from the chair, walk the 3 meters at your usual speed, turn around, walk back and sit down. This time, however, I would like you to count backwards by 3’s from 100 (or 75) (first trial 100, second trial 75). *Again, if possible do not use

*arm rests to push off from the chair.** When you are ready, I will say “Go”. As soon as you hear my “Go” you will start the test”.

Start the watch as you say, “Go”, and then stop the watch when the participant’s bottom touches the seat. RECORD THE TIME AND **DO THIS TEST TWICE.**

Appendix O – Five Facet Mindfulness Questionnaire (FFMQ)

Five Facet Mindfulness Questionnaire

Instructions:

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you.

1	2	3	4	5
never or very rarely true	rarely true	sometimes true	often true	very often or always true

- _____ 1. When I'm walking, I deliberately notice the sensations of my body moving.
- _____ 2. I'm good at finding words to describe my feelings.
- _____ 3. I criticize myself for having irrational or inappropriate emotions.
- _____ 4. I perceive my feelings and emotions without having to react to them.
- _____ 5. When I do things, my mind wanders off and I'm easily distracted.
- _____ 6. When I take a shower or bath, I stay alert to the sensations of water on my body.
- _____ 7. I can easily put my beliefs, opinions, and expectations into words.
- _____ 8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or otherwise distracted.
- _____ 9. I watch my feelings without getting lost in them.
- _____ 10. I tell myself I shouldn't be feeling the way I'm feeling.
- _____ 11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.
- _____ 12. It's hard for me to find the words to describe what I'm thinking.
- _____ 13. I am easily distracted.
- _____ 14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.

- _____ 15. I pay attention to sensations, such as the wind in my hair or sun on my face.
- _____ 16. I have trouble thinking of the right words to express how I feel about things
- _____ 17. I make judgments about whether my thoughts are good or bad.
- _____ 18. I find it difficult to stay focused on what's happening in the present.
- _____ 19. When I have distressing thoughts or images, I "step back" and am aware of the thought or image without getting taken over by it.
- _____ 20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.
- _____ 21. In difficult situations, I can pause without immediately reacting.
- _____ 22. When I have a sensation in my body, it's difficult for me to describe it because I can't find the right words.
- _____ 23. It seems I am "running on automatic" without much awareness of what I'm doing.
- _____ 24. When I have distressing thoughts or images, I feel calm soon after.
- _____ 25. I tell myself that I shouldn't be thinking the way I'm thinking.
- _____ 26. I notice the smells and aromas of things.
- _____ 27. Even when I'm feeling terribly upset, I can find a way to put it into words.
- _____ 28. I rush through activities without being really attentive to them.
- _____ 29. When I have distressing thoughts or images I am able just to notice them without reacting.
- _____ 30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.
- _____ 31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.
- _____ 32. My natural tendency is to put my experiences into words.
- _____ 33. When I have distressing thoughts or images, I just notice them and let them go.
- _____ 34. I do jobs or tasks automatically without being aware of what I'm doing.

_____ 35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.

_____ 36. I pay attention to how my emotions affect my thoughts and behavior.

_____ 37. I can usually describe how I feel at the moment in considerable detail.

_____ 38. I find myself doing things without paying attention.

_____ 39. I disapprove of myself when I have irrational ideas.

Reference:

Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment, 13*, 27-45.

Appendix P: TIDieR Guidelines Checklist

1. Brief name: Provide the name or a phrase that describes the intervention.

Mindfulness based meditation

Otago Exercise program

2. WHY: Describe any rationale, theory or goal of the elements essential to the intervention.

Page 1: The Otago exercise program (OEP) is an evidence-based falls prevention home program consisting of muscle strengthening and balance exercises plus a regular walking program¹¹. The OEP improves executive functions and reduce falls in older adults with a history of falls⁶.

Page 12: MBM has been found to improve both balance performance and recovery¹². Moreover, there is emerging evidence that MBM may promote cognitive function, hippocampal volume, and functional brain connectivity¹³. Notably, these neuroimaging changes were observed after only eight weeks of MBM³⁹.

A systematic review of the benefits of mindfulness-based interventions following transient ischemic attack and stroke included four studies with results demonstrating a positive trend in favor of the benefits across a range of outcomes including anxiety, depression, mental fatigue, blood pressure, perceived health and quality of life³⁹. Unexpected findings in a PhD thesis investigating Mindfulness Based Cognitive Therapy (MBCT) were improvements in mobility and upper extremity outcome measures⁴⁰. Thus, MBM has potential as an adjunct treatment to exercise training for reducing falls risk and promoting executive function in stroke survivors.

3. MATERIALS: Describe any physical or informational materials used in the intervention, including those provided to participants or used in the intervention delivery or in training of intervention providers. Provide information on where the information can be accessed. (e.g. URL)

Page 21: These participants were each provided with a CD player and were expected to practice at home following a CD of audio recordings from the UCLA Mindful Awareness Research Center a minimum of five times per week for 20-30 minutes⁵⁷

Page 51/52: For the OEP+MBM group, there was minimal cost in providing the meditation interventions as the audio recordings were available free of charge and permission was obtained from UCLA Mindfulness Awareness Research Centre to utilize these recordings for this study⁵⁷

Page 83: Audio recordings: <http://marc.ucla.edu/body.cfm?id=22>

4. PROCEDURES: Describe each of the procedures, activities and/or processes used in the intervention, including any enabling or support activities.

Page 20: For the OEP-only protocol, participants received a revised version of the OEP - an evidence-based falls prevention strategy of home strength and balance exercises tailored for older adults. Throughout the 12-week intervention, five home visits were made by the study's physical therapists (PT). Participants were asked to perform the individually PT-prescribed OEP exercises three times per week. Compliance was tracked through calendars provided by the research team and were reviewed by the study physical therapists during each home visit. In order to provide an active control situation, the OEP participants also attended six small group sessions, one-hour in length, on topics relating to fall prevention.

Page 21: For the OEP+MBM protocol, participants received the OEP as described above. In addition, they were provided with mindfulness based meditation (MBM) training, delivered by graduate student Tracy Dignum, who has a background in post-secondary education and training

and experience in Mindfulness Based Stress Reduction techniques through the University of Massachusetts. Participants in the OEP+MBM group received MBM coaching via six small group sessions, 60 minutes each session. These participants were each provided with a CD player and were expected to practice at home following a CD of audio recordings from the UCLA Mindful Awareness Research Center a minimum of five times per week for 20-30 minutes⁵⁷. Participants completed meditation logs to record their practice.

5. WHO PROVIDED: For each category of intervention provider describe their expertise, background and any specific training given.

Page 20: Throughout the 12-week intervention, five home visits were made by the study's physical therapists (PT); four experienced clinicians registered and in good standing with the College of Physical Therapists of British Columbia.

Page 20: six one-hour small group falls prevention education sessions instructed by qualified guest speakers not involved with the study.

Page 21: In addition, they were provided with mindfulness based meditation (MBM) training, delivered by graduate student Tracy Dignum who has a background in post-secondary education and training and experience in Mindfulness Based Stress Reduction techniques through the University of Massachusetts.

6. HOW: Describe the modes of delivery of the intervention and whether it was provided individually or in a group.

Page 20: three 30-minute home exercise sessions

Page 20: six one-hour small group falls prevention education sessions

Page 21: Participants in the OEP+MBM group received MBM coaching via six small group sessions, 60 minutes each session.

Page 21: These participants were each provided with a CD player and were expected to practice at home following a CD of audio recordings from the UCLA Mindful Awareness Research Center a minimum of five times per week for 20-30 minutes⁵⁷

Page 21: five one-hour home visits with a physiotherapist

7. WHERE: Describe the type of locations where the interventions occurred including any necessary infrastructure or relevant features.

Page 20/21: at the Robert Ho building on the Vancouver General Hospital campus

Page 20: home exercise sessions

Page 20/21: home visits with a physiotherapist

Page 21: MBM home training sessions

8. WHEN AND HOW MUCH: Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity and dose.

Page 20/21: Throughout the 12-week intervention, five home visits were made by the study's physical therapists (PT); four experienced clinicians registered and in good standing with the College of Physical Therapists of British Columbia. Participants were asked to perform the individually PT-prescribed OEP exercises three times per week. Compliance was tracked through calendars provided by the research team and were reviewed by the study physical therapists during each home visit. In order to provide an active control situation, the OEP participants also attended six small group sessions, one-hour in length, on topics relating to fall prevention.

For those participants in the OEP-only group, time requirement was an additional 29 hours (to the four hours dedicated for assessments) over the 12-week study period; five one-hour home visits with a physiotherapist, three 30-minute home exercise sessions per week for 12 weeks, and six one-hour small group falls prevention education sessions at the Robert Ho building on the Vancouver General Hospital campus instructed by qualified guest speakers not involved with the study.

For the OEP+MBM protocol, participants received the OEP as described above. In addition, they were provided with mindfulness based meditation (MBM) training, delivered by graduate student Tracy Dignum, who has a background in post-secondary education and training and experience in Mindfulness Based Stress Reduction techniques through the University of Massachusetts.

Participants in the OEP+MBM group received MBM coaching via six small group sessions at the Robert Ho building on the Vancouver General hospital campus, 60 minutes each session.

These participants were each provided with a CD player and were expected to practice at home following a CD of audio recordings from the UCLA Mindful Awareness Research Center a minimum of five times per week for 20-30 minutes⁵⁷. Participants completed meditation logs to record their practice.

For those participants in the OEP+MBM group, time requirement was an additional 59 hours (to the four hours dedicated for assessments) over the 12-week study period; five one-hour home visits with a physiotherapist and three 30-minute sessions for 12 weeks of the OEP exercises at home, in addition to six one-hour formal MBM sessions and five 20-30 minute MBM home training sessions per week for 12 weeks.

9. TAILORING: If the intervention was planned to be personalized, titrated or adapted then describe what, why, when and how.

Page 20: the individually PT-prescribed OEP exercises

Page 20: The programs were individualized as the OEP exercises are graded to meet strength and balance abilities of the participant.

10. MODIFICATIONS: If the intervention was modified during the course of the study describe the changes.

No changes were made to the interventions during the course of the study.

11. HOW WELL PLANNED: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.

Page 20: Compliance was tracked through calendars provided by the research team and were reviewed by the study physical therapists during each home visit.

Page 22: All efforts to optimize retention were made including follow-up phone calls for missed sessions, encouragement at education sessions and support with transportation methods including parking reimbursement. Attendance was documented for all meditation and education classes and for the physiotherapy home visits. Analysis was completed for rates of recruitment and withdrawal using recruitment documentation and class attendance sheets and adherence to the exercise and mindfulness interventions with review of the participant exercise and meditation logs.

12. HOW WELL ACTUAL: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.

Page 32/33: None of the participants withdrew from the study although one participant in the OEP-only group did not complete the OEP intervention, attend classes or receive physiotherapy due to an extended absence for a family emergency. This participant did complete initial and final assessments and this data was included in the results and in the compliance data and calculations.

Both groups had a high level of compliance with the interventions. For the education sessions, the OEP-only group participants attended 60/72 (.83) sessions and the OEP+MBM group attended 57/66 (.86) sessions.

The physical therapy sessions were well attended. For the OEP-only group, 48/60 (.80) sessions were completed noting that this includes the previously mentioned participant who did not participate in interventions. For the OEP+MBM group the attendance for physical therapy sessions was 53/55 (.96).

Compliance with the home exercise program was similar for both groups. For the OEP-only group, 316/384 (.82) sessions were completed, according to participant journals. For the OEP+MBM group 339/396 (.86) sessions were completed.

The OEP+MBM group were instructed to meditate 60 times over the length of the study but were not discouraged from meditating more frequently. Four participants meditated more than 60 times (61, 70, 78, 84 times). When included in the totals, the group completed 532 meditation sessions out of a prescribed 660 sessions which is a compliance rate of .81. However, if these extra meditation sessions are not included in the calculations, the group completed 479/660 sessions at a compliance rate of .73.

With respect to technology and equipment, two incidents with two different individuals in the meditation group delayed meditation practice by one week as they were not able to utilize the audio recordings. One CD was not functioning initially and one CD player failed to work after several weeks. Both were replaced and the participants resumed meditation practice. There were no reported adverse events or safety incidents.