BMJ Open

An occupational therapy-led mindfulness-based stress reduction for older adults living with subjective cognitive decline or mild cognitive impairment in primary care: a feasibility randomized control trial protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035299
Article Type:	Protocol
Date Submitted by the Author:	26-Oct-2019
Complete List of Authors:	Tran, Todd; Women's College Hospital, Family Practice; Queen's University, Aging and Health Donnelly, Catherine; Queen's University Faculty of Health Sciences, Rehabilitation Therapy Nalder, Emily; University of Toronto, Occupational Science and Occupational Therapy; March of Dimes Canada, Trothen, Tracy; Queen's University Faculty of Health Sciences Finlayson, Marcia ; Queen's University, School of Rehabilitation Therapy
Keywords:	PRIMARY CARE, MENTAL HEALTH, Anxiety disorders < PSYCHIATRY, Delirium & cognitive disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Old age psychiatry < PSYCHIATRY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

An occupational therapy-led Mindfulness-Based Stress Reduction for older adults living with subjective cognitive decline or mild cognitive impairment in primary care: A feasibility randomized control trial (RCT) protocol

Key words: mindfulness, occupational therapy, subjective cognitive decline, mild cognitive impairment, primary care

Date: October 1, 2019 version 2

There is no conflict of interest to declare.

Authorship (my committee members – are the only people to have access to research data)

(1) Todd Tran; Principal Investigator: Todd.Tran@wchospital.ca
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada

Clinical Site: Women's College Hospital
76 Grenville St.
Toronto, Ontario, M5S 1B2, Canada
1-416-301-5881

(2) Catherine Donnelly; Supervisor: Catherine.Donnelly@Queensu.ca
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-533-6385

(3) Emily Nalder; Emily.Nalder@utoronto.ca
University of Toronto
Department of Occupational Science & Occupational Therapy
500 University Ave., Toronto, ON, M5G 1V7, Canada
1-416-978-5937

(4) Tracy Trothen; Tracy.Trothen@Queensu.ca
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building

31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-273-8438

(5) Marcia Finlayson; Marcia.Finlayson@Queensu.ca
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-533-2576

Word count: (under 4000 words -excludes the title page, abstract, tables, acknowledgements, contributions and references.)

Funding:

Centre for Aging & Brain Health Innovation
3560 Bathurst Street
Toronto, ON
M6A 2E1 Canada

This funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Data Management procedure of this study is at the clinical site.

Abstract

Introduction: Community-dwelling older adults living with subjective cognitive decline (SCD) or mild cognitive impairment (MCI) may experience a decreased efficiency in their functional performance, and this may result in anxiety, low mood, perceived stress, a decrease in emotional well-being and quality-of-life. These psychosocial issues may further exacerbate cognitive decline.

Primary care may be the first point of contact, and pharmacological interventions to address concomitant psychosocial issues have limited benefits such as side-effects, drug-drug interaction and polypharmacy. Consequently, exploring alternative non-pharmacological intervention is vital in enabling individuals to manage these psychosocial issues. Mindfulness-Based Stress Reduction is an 8-week program that is beneficial in alleviating psychosocial issues; however, its impact on perceived satisfaction on functional performance has not been evaluated. The overarching aim of this study is to explore the feasibility of conducting an RCT of an occupational therapist-led MBSR program.

Methods: We will use a convergent mixed-methods, feasibility RCT with 40 participants from an interprofessional primary care team in Toronto, Ontario. Participants randomized into an 8-Week MBSR group or a wait-list control are compared at baseline, post-intervention and four-weeks follow-up. The primary outcome will be functional performance and satisfaction measured by the Canadian Occupational Performance Measure. Secondary outcomes will include anxiety, mood, QoL, acceptance and mindfulness traits.

Analysis: Investigators will analyze both the quantitative and qualitative data strands separately. Descriptive statistics, focus group and interviews will then be merged and further analyzed to best understand both the feasibility and preliminary clinical outcomes from the study.

Ethics and dissemination: The study is approved by Women's College Hospital (2017-0056-E), and Queen's University, Kingston, Ontario (6026418). This study is registered at Clinicaltrials.gov (NCT03867474). The study will be reported following the SPIRIT protocol. The results will be published in peer-reviewed academic journals and disseminated to patient organizations and media.

Trial registration: ClinicalTrials.gov NCT03867474; Pre-results

Strength and Limitations of this Study

- The first study to evaluate the impact of MBSR in improving perceived satisfaction on functional performance and psychosocial outcomes with community-dwelling older individuals living with SCD or MCI in primary care
- The only study to explore the qualitative perspective of both participants and health care providers in terms of barriers, enablers and facilitators of implementing and delivering the MBSR program within a primary care setting

- The study is innovative in exploring the acceptability of technology (i.e. iPADs) as a method of delivery of the intervention and data collection with this population

- The study will provide valuable data on feasibility outcomes such as rates of recruitment, adherence, retention and satisfaction to determine whether occupational therapy-led MBSR is appropriate for a larger clinical trial in the future

- The lack of having an active control group is a study limitation

Introduction

By 2036, approximately one-in-four Canadians will be 65 years and over [1], and an estimated one-third of community-dwelling older adults will experience memory complaints [2]. The earliest sign of memory impairment is subjective cognitive decline (SCD), a self-reported decline in cognition without "objective evidence," characterized by increasing compensatory cognitive efforts and subtle cognitive decline [3]. If SCD is to decline further, the next stage is mild cognitive impairment (MCI), 10 - 20% of older adults will develop MCI by age 65 [4]. Features of MCI is clinically characterized as: (i) concern raised by the individual or an informant, or clinician, (ii) cognitive impairment in one or more cognitive domains relative normative data for that individual, and (iii) preservation of functional independence [5, 6].

There is a large body of evidence that demonstrates that those living with memory complaints face a decline in performance of everyday tasks, most notably in complex instrumental activities-of-daily living (iADLs) [7]. These functional changes result in a general sense of decreased satisfaction and discontentment with their overall functional performance [8].

Living with SCD or receiving a diagnosis of MCI is usually life-altering, and has been found to have a negative impact on an individual's emotional health, and well-being [9], with increased risk of depression and anxiety disorders [10]. There is limited evidence that supports the use of pharmacologic interventions to improve concomitant anxiety disorders [11] and depression among those living with cognitive impairment [12]. Medications may increase the risk of adverse side-effects, especially for those with multiple comorbidities, including drug-drug interactions, polypharmacy [13] and falls[14]. Exploring non-pharmacologic interventions to mitigate psychosocial factors and to support functional performance is critical [10, 15]. Successful adaptive coping strategies to improve depression and anxiety symptoms in this population is essential to prevent or delay further cognitive decline [10].

Evidence from the past 20 years suggests that mindfulness meditation, such as Mindfulness-Based Stress Reduction (MBSR), could benefit those living with SCD and MCI [16, 17]. MBSR may be neuroprotective against cognitive decline [17] and has demonstrated mental health benefits for those living with chronic illnesses [18]. Also, MBSR has been found to reduce emotional distress [19] and enhance physical functioning in different populations [20]. For those living with MCI, there is evidence that MBSR significantly reduces worry severity in individuals [21].

Other studies have demonstrated that mindfulness helps older adults with loneliness, depression, anxiety, and sleep problems [22-26] in general community settings and secondary care, e.g., neurology clinics. However, primary care providers are often the first point of contact

when older adults and their families are concerned about cognitive problems [27]. There is an increasing emphasis on interprofessional primary care teams or patient medical homes to address the challenges of an ageing population. Currently, no studies to date have examined the feasibility of MBSR for those living with SCD or MCI receiving care from interprofessional primary care teams. A growing number of occupational therapists working in primary care teams are ideally positioned to support individuals with SCD and MCI through their expertise in understanding the impact of cognitive impairment on daily function. Examining effective interventions such as an occupational therapist-led, MBSR for individuals at the early stages of cognitive changes is critical to support ageing-in-place [28].

The overarching purpose is to determine whether occupational therapy-led MBSR is appropriate for a larger clinical trial in the future. The study has two aims:

Primary Aim:
To explore the feasibility of conducting an RCT of an occupational therapist-led, 8-week MBSR program. The following objectives will assess feasibility outcomes:

1a. Assess participant recruitment, intervention adherence, and study retention (Quantitative)
1b. Explore the acceptability of delivering technology-based tablets (iPads) for intervention, and data collection in the MBSR program (Qualitative)
1c. Explore the perspectives of participants and healthcare providers concerning satisfaction (e.g., the intervention and it's delivery), perceived value, and barriers and facilitators of implementation of the MBSR program in a primary care setting (Qualitative)

Secondary Aim:
To evaluate MBSR's impact on satisfaction with functional performance and psychosocial outcomes in individuals with SCD or MCI in an interprofessional primary care setting, with the following objective:

2a. Describe the effect sizes of satisfaction on functional performance and psychosocial outcomes (Quantitative)

Methods

This study will use a convergent mixed-methods, single-blind RCT with two parallel groups and will follow SPIRIT guidelines for randomized feasibility trials. See Trial Design **(See Figure 1 and 3)**

Study Setting

The study will take place at an interprofessional primary care clinic in the province of Ontario, Canada. Interprofessional team members include occupational therapy, physiotherapy, nursing, pharmacy, social work, and dietetics. There are approximately 18,000 rostered patients with the clinic, 78% of whom are female.

Eligibility Criteria

To qualify for the study, participants will be screened using the Montreal Cognitive Assessment (MoCA), with the score in the MCI range (22 [+/4]) or higher along and the Geriatric Depression Scale (GDS) with a score of < 6. Scores of > 6 on the GDS and < 22 on the MCI will warrant further assessment with their family physician. The inclusion and exclusion criteria are:

Inclusion Criteria:

(1) age ≥ 60 years;
(2) English fluency;
(3) living independently (non-assisted living, e.g. retirement or any long-term care facility; self-report);
(4) have a self- reported SCD or an MCI diagnosis in their chart
(5) must be a patient with the interprofessional primary care clinic

Exclusion Criteria:

(1) History of prior participation in any MBSR or other mindfulness-based interventions in the past or having 2-3 times per week or more of either mindfulness or yoga practice;
(2) History of significant medical (e.g. cancer), neurological (e.g. brain injury) or psychiatric condition (e.g. depression with 6 or greater on the GDS), active psychosis, bereavement that significantly impacts on mood, i.e. depression;
(3) Alcoholism or other substance abuse;
(4) MoCA of 21 (+/- 4) [29, 30] or under and
(5) if participating in other cognitive or memory training programs in the community or is involved in another research study

Intervention/Treatment (MBSR) Group

Participants randomized to the intervention arm will participate in an 8-week MBSR program established in 1979 by Kabat-Zinn [31]. Four occupational therapists trained in MBSR will be involved in the delivery of the intervention group. The group will be 3-hours in duration (with a 15-minute break) for 8-weeks, along with an orientation and an all-day retreat. Sessions will consist of: lying down (body scan), sitting (focusing on the breath), and mindful movement (yoga and walking). Homework practice will be given daily for approximately 30 to 45 minutes outside of class for the six out of the seven days for the duration of the program.

We will distribute mini-iPads to each participant to access the App, Insight Timer, for the duration of the study. Insight Timer contains guided homework practices. Homework is logged directly by Insight Timer, and this data is downloaded at the end of the program. If participants have difficulty with using tablets, additional support is given during or after class. If any participant does not have access to Wi-Fi, we will provide them with CDs for ease of adherence for their guided homework practices, and homework will be tracked weekly by using pencil and paper sheets as logged hours. Similarly, if participants have difficulty with using iPads, switching to CDs will be offered as an alternative low technology option.

Monitoring of adherence would include (i) attendance records (ii) home practice log (iii) iPad (log-in, frequency, duration) and (iii) field notes from clinicians in regards to the level of participation and engagement and group process.

Any participants who experience emotional issues (e.g. increased anxiety, low mood) during the group is referred to other health-care professionals on the FHT (e.g. Social Worker) for psychosocial support.

The control group or usual care is the comparison group and will receive MBSR three months after the intervention group is completed.

MBSR Fidelity

The *training fidelity* is significant as the teacher's embodiment of mindfulness is central to the participant's learning within the 8-week curriculum. To examine program efficacy, the Qualified MBSR teacher will have adhered to the intervention integrity [32]. Additionally, the implementation of the MBSR curriculum will follow the teacher training protocol and also the Mindfulness-Based Interventions Teaching Assessment Criteria (MBI: TAC), a tool that assesses mindfulness-based teaching fidelity.

Outcome Measures

Demographic data is collected at baseline (age, education, income, physical activity, etc.) along with primary and secondary outcome measures.

Quantitative Data

The *primary outcome* will be changed scores on perceived satisfaction with functional performance as measured by the *Canadian Occupational Performance Measure (COPM);* [33].

Secondary outcomes will measure change with mood, anxiety, perceived stress, mindfulness, Quality-of-Life and acceptance, which include:

1. Patient Health Questionnaire-9 (PHQ-9); [34, 35]
2. Geriatric Anxiety Inventory (GAI); [36]
3. Perceived Stress Scale (PSS); [37]
4. Cognitive and Affective Mindfulness Scale-Revised (CAMS-R); [38]
5. Quality of Life-Alzheimer's Disease (QoL-AD); [39]
6. Acceptance and Action Questionnaire (AAQ-II); [40]

Time of Outcome Measures

Outcome measures will be assessed at baseline (Time 1: Week 1) on completion of the intervention at (Time 2: Week-8) and one-month post-intervention follow-up (Time 3: Week-12). **See Figure 2**

Primary Outcome

Canadian Occupational Performance Measure (COPM)

The COPM is a standardized assessment for eliciting performance issues from the client's perspective and capturing perceived changes in performance and satisfaction over time [41]. Each participant self-rate on a 10-point scale for self-perceived satisfaction on their functional performance. Strong test-retest reliability for both the performance and satisfaction scores with a range of 0.85 ($p<0.001$) for performance and similarly 0.82 ($p<0.01$) for satisfaction [42], supporting criterion and construct validity [42-44]. A change of 2 points or more on the COPM is considered clinically significant [41].

Secondary Outcome

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a self-administered tool that scores each of the 9 DSM-IV criteria as "0" (not at all) to "3" (nearly every day), giving a total score of 27 [34]. PHQ-9 represents a reasonable alternative to the GDS with older adults in primary care settings [34, 35]. The internal reliability of the PHQ-9 was excellent, with a Cronbach's of 0.89 in the PHQ-9 Primary Care Study, and the test-retest reliability is noted to be excellent [34]. PHQ-9 has a sensitivity of 88% and a specificity of 88% for major depression.

Geriatric Anxiety Inventory (GAI)

The GAI consists of 20 "Agree/Disagree" items designed to assess typical common anxiety symptoms in the last week [36]. GAI were developed specifically for community-dwelling older adults. The GAI has high internal consistency ($\alpha = .76$), as well as high inter-rater ($r = .89$) and test-retest ($r = .86$) reliability [36].

Perceived Stress Scale (PSS)

PSS is an assessment of the global appraisal of stress instead of focusing on a particular event [37]. The focus of the question is reporting on the lives of respondents using a 4-point scale (0-Never and 4-Very Often) with ten questions. The PSS is a short and easy questionnaire to use with acceptable psychometric properties. Test-retest reliability was assessed to be >0.70 and studies demonstrate that it's satisfactory [45].

The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)

CAMS-R is a brief measure designed to capture mindfulness comprehensively based on Jon Kabat-Zinn's definition of mindfulness [38]. The questionnaire has a 4-point scale (1 –Rarely to 4 -Almost Always) with 10 questions. It has a high Cronbach's alpha that ranges from 0.61 to 0.81 and has a moderate correlation with other measures of mindfulness (r's = 0.51 to 0.67) [38].

Quality-of-Life in Alzheimer's Disease (QoL-AD)

The survey has 13-items covering domains (e.g. health, mood, living situation, memory, money etc.) [46]. It demonstrates good test-retest reliability. Has excellent inter-rater reliability with Cohen's kappa values >0.70 and internal consistency is also high with Cronbach's alpha coefficient of 0.82 [39].

Acceptance and Action Questionnaire-II (AAQ-II)

AAQ-II measures psychological flexibility and inflexibility [47]. It has shown that psychological flexibility—broadly defined—is a prominent factor in understanding psychological health [48]. AAQ-II demonstrates good test-retest reliability with alpha co-efficient at 3-months at 0.81 and 12-months at 0.79 [47].

***Feasibility Outcome Measures*:**

As a feasibility study, the overarching purpose is to determine whether MBSR is worthwhile for a definitive larger clinical trial for community-dwelling older adults living with SCD or MCI. As such, the following feasibility measures will be taken to evaluate its *acceptability*. The Principal Investigator (PI) and clinicians will collect all data during the period of the intervention.

Acceptability will be evaluated by:

i. Recruitment rate: defined as feasible for a future study if 30-40 participants are recruited within three to four months (May to August 2019), similar to other feasibility studies [49].

ii. Retention rate: will be deemed feasible if at least 66% of participants complete six or more of the nine sessions as well as a follow-up assessment at T3.

iii. Adherence rate: deemed adequate adherence for a future study if participants complete 3 log-ins per week and practice homework for at least 1.5 hr per week (duration), which would be deemed moderate adherence rate at 51-79 [50, 51]. The treatment adherence rate is determined by the number of sessions completed in full (180 minutes).

iv. Acceptability of using iPad as a tool for practice delivery is determined by (i) using field notes by clinicians, (ii) research team will document any participants that may need to switch to traditional low technology such as CDs or e-mail link for the homework practices during duration of the 8-Weeks, and (iii) focus groups at follow-up at the end of 8-Weeks (T2) of their perceived value and benefits of using technology.

v. Satisfaction with the MBSR program will be assessed by the overall experience of the 8-Week intervention by surveys, e.g., field notes, research meeting notes, interviews with clinicians (T3-Week-12) and participant focus groups (T2-Week-8). The satisfaction of the program will include length (number of weeks), difficulty (e.g. pacing, workload or other challenges), and session duration (e.g. too short, too long).

Figure 2
Time Frame of Measurements (Participant Timelines)

Timeframe of Measurements for participants in MBSR Intervention

Measures Taken		**(Time 1)**							**(Time 2)**	**(Time 3)**
Item	Week-0	Week-1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week-8 (Post-MBSR)	Week-12 (Follow-Up)
Screening										
(MoCA and GDS)	X									
Feasibility Measures		X		X	X	X	X	X	X	X
Qualitative Measures										
Focus Group (Participants)									X	
Interview with Clinicians										X
Evaluations (Participants)					X				X	
Weekly Research Meeting Notes		X		X	X	X	X	X	X	
Weekly Field Notes		X		X	X	X	X	X	X	
Quantitative Measures										
COPM (Satisfaction / Performance)		X							X	X
PHQ-9 (Mood)		X							X	X
GAI (Anxiety)		X							X	X
CAMS-R (Mindfulness)		X							X	X
PSS (Stress)		X							X	X
QoL-ADAS (Quality-of-Life)		X							X	X
AAQ-II (Acceptance)		X							X	X

Sample Size

The goal is to recruit approximately 40 participants (e.g. 20 MBSR and 20 wait-list controls) to account for an expected 20% attrition rate based on other feasibility studies [49, 52]. This number is thought to be feasible and will enable examination of study objectives to inform the completion of a larger RCT in the future.

Recruitment

Participants are recruited within the interprofessional primary care clinic with posters placed in the waiting area, clinic and physician consult rooms. Clinicians may also inform potential patients about the study. Interested participants will be instructed to call the PI, who will explain the purpose of the research and study activities. If interested, participants will be scheduled for an intake assessment to screen for study eligibility. If eligible, the informed consent process is reviewed with the individual, written consent obtained, and then randomization into one of the two groups will be completed.

Treatment allocation and randomization

A randomization block size of four design will be used to balance the two in the Control and two in the MBSR group, which is the ideal size for a sample size of 40. A research staff member, not involved in the trial, will prepare the sealed opaque envelopes to ensure allocation concealment for distribution. All research staff, except the PI, will be blinded to the randomization list. At screening, if participants are eligible, the PI will obtain informed consent, assign participants a study number and collect baseline data. Last, a randomization envelope with the same study number of the participant is opened, and allocation will be to one of the two treatment groups [53], MBSR (Group 1) or a wait-list control (Group 2). Randomization will be evaluated to ensure both groups are identical in terms of demographics (e.g. age, income, education, physical activity) along with baseline screens and outcome measures. The wait-list control group will receive the MBSR intervention three months later when the experimental group is completed.

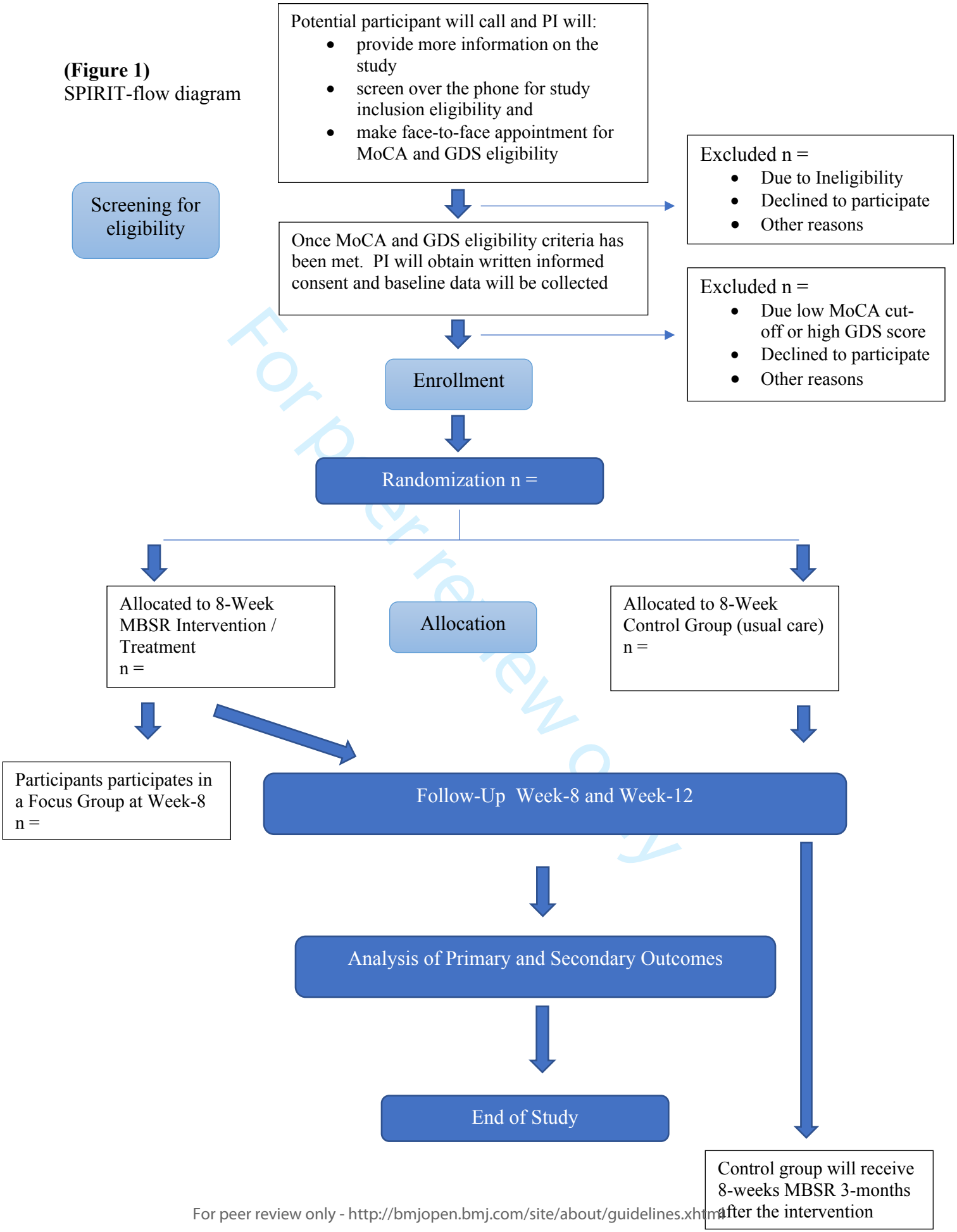
Blinding

The PI will assess baseline outcome measures for eligible participants at T1-Week-1. A blinded independent assessor will evaluate post-MBSR at T2-Week-8 and at T3-Week-12, to minimize bias. The wait-list control (Group 2) is assessed at T2-Week-8 and T3-Week-12, along with the intervention (Group 1). The study occupational therapists delivering the intervention will not be blinded to the group allocation as they are providing the intervention being tested.

Data Management

The PI and research assistant will perform data checking, diagnosing errors, and editing suspected errors or abnormalities. Participants' data will be de-identified and will be identified only by a study ID number. A master log (saved on hospital site internal server) with personal identifiers will be kept and stored separately from the study data. All iPads are encrypted and have no participants' information other than their ID number.

(Figure 1)
SPIRIT-flow diagram



Qualitative Outcomes

Qualitative data is collected from both clinicians and participants. Clinician data will include field notes, weekly meeting notes and semi-structured interviews conducted on completion of the intervention. Participant data will consist of feedback surveys at week-4 (mid-point) and T2-week-8 (program completion) and a focus group. The focus group will seek to understand satisfaction (e.g. intervention and delivery), acceptability, perceived value, barriers and facilitators of an 8-Week occupational therapy-led MBSR program in primary care.

Qualitative Analysis

Participant focus group and clinician interviews will be audio-recorded and transcribed verbatim. All transcripts will be de-identified and pseudonyms given to each of the participants. Transcripts will be read and re-read by both the PI and the research team consist of description will be used to analyze the interview data [54]. An inductive process of sorting, initial coding and grouping the data into broad topic-oriented categories, which is refined into fewer analytical themes, will be used. Critical discussion with the research staff of emerging themes will occur throughout the analysis process. The qualitative software package NVivo 11 (QSR International) will be used to support the analysis.

To enhance trustworthiness [55], *member checking* is used. Trustworthiness will involve validation of the data by participants from where the data is collected. P*eer debriefing* will also be used to clarify interpretations of the data, which may identify possible sources of bias. Each of these strategies will enhance trustworthiness to ensure dependability, credibility and transferability in the qualitative analysis [56].

Quantitative Analysis

Descriptive statistics will be used for demographics and to determine baseline differences between the intervention and control group, a paired t-test or ANOVA in which pre, post and follow-up scores of each participant for each of the outcome measures are used. Due to the small sample size of the study, and recognizing the limited power, standard deviation (SD) will be reported with 95% confidence intervals of the mean difference, and significance levels at alpha equal 0.05.

Statistical Methods

The primary and secondary outcome measures will be analyzed using IBM Statistical Package for Social Sciences software (SPSS) based on intent-to-treat (ITT), an approach that includes every randomized participant. This ITT analysis preserves the same sample size and reduces type I error. Every attempt to minimize missing data is implemented; however, missing data is dealt with by using the last observation carried forward (LOCF) method, where the last available measurement for each participant at the point before withdrawal from the study, is retained and used in the analysis. Data will be cleaned, checked for accuracy and checked for normal distribution using the Shapiro-Wilk test.

T1-week-1 to T2-week-8 and T1-week-1 to T3-week-12 mean change scores and SD will be conducted using paired *t*-test or ANOVA, calculated for normally distributed data, and Cohen's *d* effect sizes and confidence intervals are used as it provides an estimate of the strength of the treatment or relationship [57]. Effect sizes will be calculated to determine baseline and post-intervention outcome variable values.

Similarly, feasibility outcomes will be analyzed using descriptive statistics of intervention (e.g. acceptability), at baseline and post-intervention outcome.

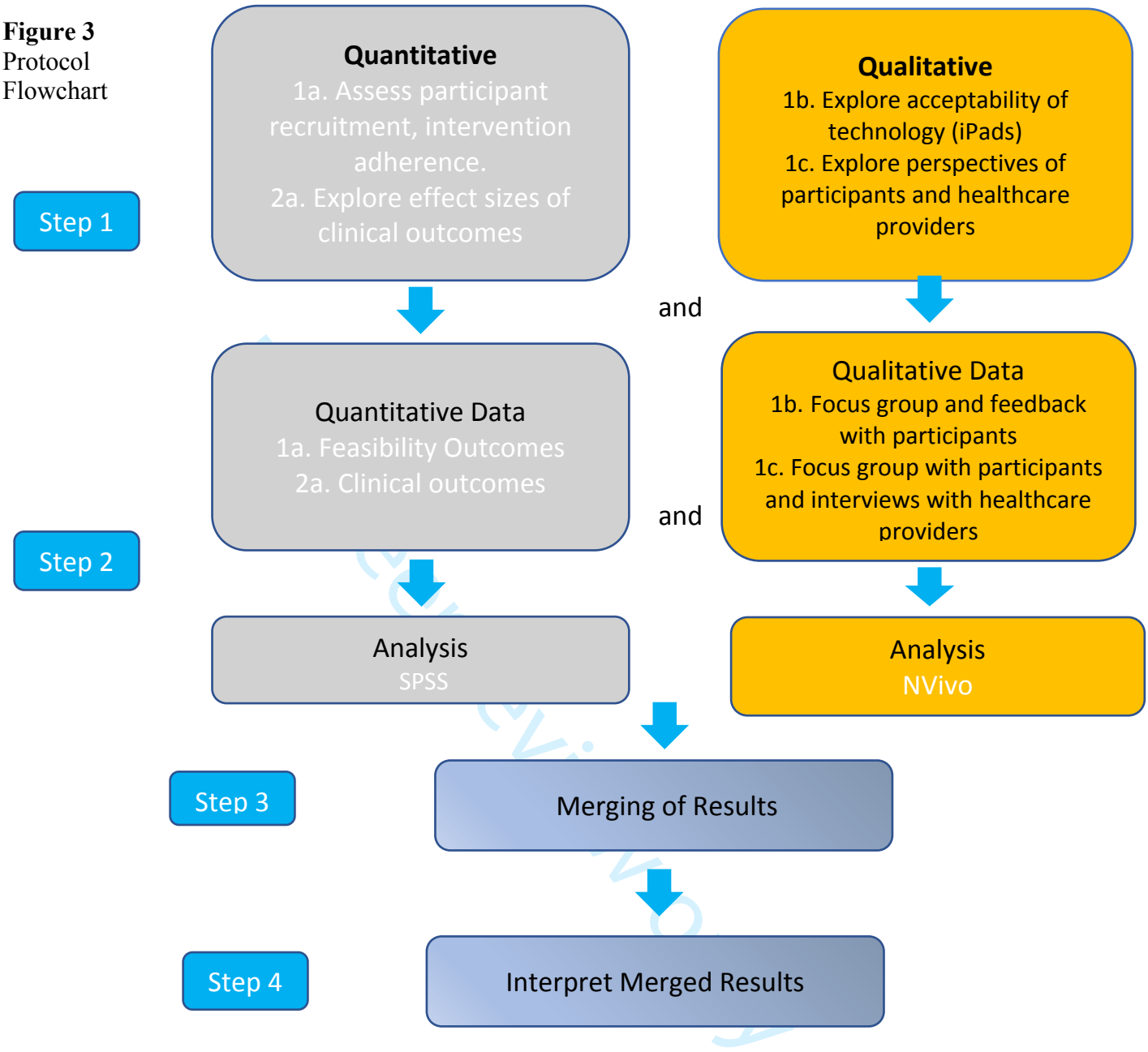
(*Insight Timer - App metrics*):

Both logged in time (frequency), length of homework practice (duration) is extracted by the following (days, weeks, months and total hours overall for the duration of the MBSR program). Descriptive statistics including paired-sample *t*-tests or Wilcoxon signed rank tests, is conducted to compare pre-post change scores on outcomes.

Conclusion

This protocol has been designed to explore the feasibility of conducting RCT to determine pre-clinical outcomes and whether an 8-Week MBSR program is feasible for a future larger clinical trial. As there are limited evidence-based approaches in primary care to support those living with SCD or MCI, preliminary results from this study may provide insight into the management of this unique population. There is growing recognition for team-based care, and this study is the first to explore an occupational therapy-led MBSR program within interprofessional primary care teams or patient medical homes. This study will provide acceptability and satisfaction of using technology such as iPads to deliver the MBSR program within a primary care setting. Last, findings from this trial will offer feasibility challenges that can be potentially avoided in a future clinical trial.

Figure 3
Protocol Flowchart



References

1. Canada Year Book. Seniors. 2011 [cited 2018; Available from: https://www150.statcan.gc.ca/n1/pub/11-402-x/2011000/chap/seniors-aines/seniors-aines-eng.htm.
2. Zuniga, K.E., et al., Subjective memory impairment and well-being in community-dwelling older adults. Psychogeriatrics, 2016. 16(1): p. 20-26.
3. Jessen, F., et al., A conceptual framework for research on subjective cognitive decline in preclinical Alzheimer's disease. Alzheimer's & Dementia: The Journal of the Alzheimer's Association, 2014. 10(6): p. 844-852.
4. Langa, K.M. and D.A. Levine, The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review. JAMA, 2014. 312(23): p. 2551-2561.
5. Petersen, R.C., et al., Mild cognitive impairment: a concept in evolution. Journal of Internal Medicine, 2014. 275(3): p. 214-228.
6. American Psychiatric, A. and D.S.M.T.F. American Psychiatric Association, Diagnostic and statistical manual of mental disorders: DSM-5. 5th ed. 2013, Washington, D.C: American Psychiatric Association.
7. Belchior, P., et al., Identification and assessment of functional performance in mild cognitive impairment: A survey of occupational therapy practices. Australian Occupational Therapy Journal, 2015. 62(3): p. 187-196.
8. De Vriendt, P., et al., The process of decline in advanced activities of daily living: a qualitative explorative study in mild cognitive impairment. International Psychogeriatrics, 2012. 24(6): p. 1-13.
9. Joosten-Weyn Banningh, E.W.A., et al., Mild cognitive impairment: coping with an uncertain label. International Journal of Geriatric Psychiatry, 2008. 23(2): p. 148-154.
10. Regan, B. and L. Varanelli, Adjustment, depression, and anxiety in mild cognitive impairment and early dementia: a systematic review of psychological intervention studies. International psychogeriatrics / IPA, 2013. 25(12): p. 1963.
11. Andreescu, C. and D. Varon, New Research on Anxiety Disorders in the Elderly and an Update on Evidence-Based Treatments. Current Psychiatry Reports, 2015. 17(7): p. 1-7.
12. Sepehry, A.A., et al., Effect of selective serotonin reuptake inhibitors in Alzheimer's disease with comorbid depression: a meta-analysis of depression and cognitive outcomes. Drugs & aging, 2012. 29(10): p. 793.
13. Kok, R.M. and C.F. Reynolds, Management of Depression in Older Adults: A Review. JAMA, 2017. 317(20): p. 2114-2122.
14. Dhalwani, N.N., et al., Association between polypharmacy and falls in older adults: a longitudinal study from England. BMJ Open, 2017. 7(10): p. e016358-e016358.
15. Moniz-Cook, E., Psychosocial interventions through memory clinics. Nursing & Residential Care, 2011. 13(4): p. 189-192.
16. Wells, R.E., et al., Meditation for Adults with Mild Cognitive Impairment: A Pilot Randomized Trial. Journal of the American Geriatrics Society, 2013. 61(4): p. 642-645.
17. Smart, C.M., et al., Mindfulness Training for Older Adults with Subjective Cognitive Decline: Results from a Pilot Randomized Controlled Trial. Journal of Alzheimer's disease, 2016. 52(2): p. 757.

18. Fjorback, L.O., et al., Mindfulness-Based Stress Reduction and Mindfulness-Based Cognitive Therapy – a systematic review of randomized controlled trials. Acta Psychiatrica Scandinavica, 2011. 124(2): p. 102-119.
19. Smoski, M.J., A. McClintock, and L. Keeling, Mindfulness Training for Emotional and Cognitive Health in Late Life. Current Behavioral Neuroscience Reports, 2016. 3(4): p. 301-307.
20. Gotink, R., et al., Standardised mindfulness-based interventions in healthcare: An overview of systematic reviews and meta-analyses of RCTs. PLoS ONE, 2015. 10(4): p. e0124344.
21. Lenze, E.J., et al., Mindfulness-based stress reduction for older adults with worry symptoms and co-occurring cognitive dysfunction: MBSR in older adults. International Journal of Geriatric Psychiatry, 2014. 29(10): p. 991-1000.
22. Geiger, P.J., et al., Mindfulness-Based Interventions for Older Adults: a Review of the Effects on Physical and Emotional Well-Being. Mindfulness, 2016. 7(2): p. 296-307.
23. Creswell, J.D., et al., Mindfulness-Based Stress Reduction training reduces loneliness and pro-inflammatory gene expression in older adults: A small randomized controlled trial. Brain, Behavior, and Immunity, 2012. 26(7): p. 1095-1101.
24. Splevins, K., A. Smith, and J. Simpson, Do improvements in emotional distress correlate with becoming more mindful? A study of older adults. Aging & Mental Health, 2009. 13(3): p. 328-335.
25. Black, D.S., et al., Mindfulness Meditation and Improvement in Sleep Quality and Daytime Impairment Among Older Adults With Sleep Disturbances: A Randomized Clinical Trial. JAMA Internal Medicine, 2015. 175(4): p. 494-501.
26. Foulk, M.A., et al., Mindfulness-Based Cognitive Therapy With Older Adults: An Exploratory Study. Journal of Gerontological Social Work, 2014. 57(5): p. 498-520.
27. Knopman, D.S. and R.C. Petersen, Mild cognitive impairment and mild dementia: a clinical perspective. Mayo Clinic proceedings, 2014. 89(10): p. 1452-1459.
28. Ciro, C.A., Maximizing ADL Performance to Facilitate Aging in Place for People with Dementia. Nursing Clinics of North America, 2014. 49(2): p. 157-169.
29. Clarnette, R., et al., Comparison of the Quick Mild Cognitive Impairment (Qmci) screen to the Montreal Cognitive Assessment (MoCA) in an Australian geriatrics clinic. International Journal of Geriatric Psychiatry, 2017. 32(6): p. 643-649.
30. O'Caoimh, R., S. Timmons, and D.W. Molloy, Screening for Mild Cognitive Impairment: Comparison of "MCI Specific" Screening Instruments. Journal of Alzheimer's disease, 2016. 51(2): p. 619.
31. Kabat-Zinn, J. and C. University of Massachusetts Medical Center/Worcester. Stress Reduction, Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness. Delta trade pbk. reissue, 15th anniversary ed. 2009, New York, N.Y: Delta Trade Paperbacks.
32. Crane, R.S., et al., Development and Validation of the Mindfulness-Based Interventions – Teaching Assessment Criteria (MBI:TAC). Assessment, 2013. 20(6): p. 681-688.
33. Law, M. and T. Canadian Association of Occupational, Canadian Occupational Performance Measure. 4th ed. 2005, Ottawa, Ont: Canadian Association of Occupational Therapists.

34. Kroenke, K., R.L. Spitzer, and J.B.W. Williams, The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine, 2001. 16(9): p. 606-613.
35. Phelan, E., et al., A study of the diagnostic accuracy of the PHQ-9 in primary care elderly. BMC family practice, 2010. 11(1): p. 63-63.
36. Pachana, N.A., et al., Development and validation of the Geriatric Anxiety Inventory. International Psychogeriatrics, 2007. 19(1): p. 103-114.
37. Cohen, S., T. Kamarck, and R. Mermelstein, A Global Measure of Perceived Stress. Journal of Health and Social Behavior, 1983. 24(4): p. 385-396.
38. Feldman, G., et al., Mindfulness and Emotion Regulation: The Development and Initial Validation of the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R). Journal of Psychopathology and Behavioral Assessment, 2007. 29(3): p. 177-190.
39. Logsdon, R.G., et al., QUALITY OF LIFE IN ALZHEIMER'S DISEASE: LONGITUDINAL PERSPECTIVES. The Gerontologist, 1999. 39: p. 164.
40. Hayes, S.C., et al., Measuring experiential avoidance: A preliminary test of a working model. The Psychological Record, 2004. 54(4): p. 553-578.
41. Law, M.C., et al., Canadian occupational performance measure. 5th ed. 2014, Ottawa, Ontario: CAOT Publications ACE.
42. Carswell, A., et al., The Canadian Occupational Performance Measure: A Research and Clinical Literature Review. Canadian Journal of Occupational Therapy, 2004. 71(4): p. 210-222.
43. McColl, M.A., et al., Validity and Community Utility of the Canadian Occupational Performance Measure. Canadian Journal of Occupational Therapy, 2000. 67(1): p. 22-30.
44. Ven-Stevens, L.A.W.v.d., et al., Construct validity of the canadian occupational performance measure in participants with tendon injury and dupuytren disease. Physical Therapy, 2015. 95(5): p. 750-757.
45. Lee, E.-H., Review of the Psychometric Evidence of the Perceived Stress Scale. Asian Nursing Research, 2012. 6(4): p. 121-127.
46. Logsdon, R.G., Gibbons, L.E. McCurry, S.,M., Teri, L., Quality of Life in Alzheimer's Disease: Patient and Caregiver Reports Journal of Mental Health and Aging, 1999. 5(1): p. 21-32.
47. Bond, F.W., et al., Preliminary Psychometric Properties of the Acceptance and Action Questionnaire–II: A Revised Measure of Psychological Inflexibility and Experiential Avoidance. Behavior Therapy, 2011. 42(4): p. 676-688.
48. Hayes, S.C., et al., Acceptance and Commitment Therapy: Model, processes and outcomes. Behaviour Research and Therapy, 2006. 44(1): p. 1-25.
49. Aguirre, E., et al., Mindfulness-Based Cognitive Therapy (MBCT) programme for depression in people with early stages of dementia: study protocol for a randomised controlled feasibility study. 2017. 3.
50. Gearing, R.E., et al., Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. Clinical Psychology Review, 2011. 31(1): p. 79-88.
51. Perepletchikova, F. and A.E. Kazdin, Treatment Integrity and Therapeutic Change: Issues and Research Recommendations. Clinical Psychology: Science and Practice, 2005. 12(4): p. 365-383.

52. Eldridge, S.M., et al., CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ, 2016. 355: p. i5239.
53. Altman, D.G., Avoiding bias in trials in which allocation ratio is varied. Journal of the Royal Society of Medicine, 2018. 111(4): p. 143-144.
54. Clarke, V. and V. Braun, Thematic analysis. The Journal of Positive Psychology, 2017. 12(3): p. 297-298.
55. Connelly, L.M., Trustworthiness in Qualitative Research. Medsurg nursing : official journal of the Academy of Medical-Surgical Nurses, 2016. 25(6): p. 435.
56. Hadi, M.A. and S. José Closs, Ensuring rigour and trustworthiness of qualitative research in clinical pharmacy. International Journal of Clinical Pharmacy, 2016. 38(3): p. 641-646.
57. Evans, A., Using basic statistics in the behavioral and social sciences. Fifth ed. 2014, Thousand Oaks, California: SAGE Publications, Inc.

Author Statement:

Todd Tran (PI and PhD Student)
Catherine Donnelly (my PhD supervisor)
Emily Nalder (committee member whom provided substantial feedback)
Tracy Trothen (committee member who provided written guidance)
Marcia Finlayson (committee member who provided substantial feedback)

Acknowledgements (non-authors):

Jaisa Sulit
Sarah Scheffe
Virginia Vander Hyden
Mubeenaa Rahman
Kareena Gurbaxani
Ken Callaghan

Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1-2
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	2
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	1-2
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	3,7
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5, 12
Methods:			
Participants,			

interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	7
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	7,9
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6,7

Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8-10
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	10
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	10
Methods:			
Assignment of			

interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	11
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	11
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	11

Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	6, 10 (8-9)
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	6, 13

Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	2,11,13
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-14
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in	1 (my committee members are involved as I'm a PhD student)

		the protocol. Alternatively, an explanation of why a DMC is not needed	
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	1 (PI, and only my committee members)
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7 (field notes)
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	n/a

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13 (de-identification)
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	1
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	1 (only my committee members)
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other	3

		relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	1 (it will be me the PhD Student)
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	3 (pre-results on clinicaltrials.gov)
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	20
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Notes:

- 18a: 6, 10 (8-9)
- 21a: 1 (my committee members are involved as I'm a PhD student)
- 21b: 1 (only my committee members)
- 22: 7 (field notes)

- 27: 13 (de-identification)
- 29: 1 (only my committee members)
- 31b: 1 (it will be me the PhD Student)
- 31c: 3 (pre-results on clinicaltrials.gov) The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY-ND 3.0. This checklist was completed on 21. October 2019 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

Consent for Focus Group (Clinicians)

Study Title: 8-Week Mindfulness-Based Stress Reduction (MBSR) Program

Principal Investigator: Todd Tran (PhD Student), Catherine Donnelly PhD (Supervisor)

Funder: Canadian Centre for Brain Aging and Health Innovation

---

Consent

This consent form will give you information in order for you to make an informed decision to participate in this study and in a focus group or not, which will occur at a later date of the study, at approximately week 12 (four weeks after the delivery of the 8-Week program). You do not have to decide today whether or not you will participate in the study. However, in terms of participation in the focus group, I will reconfirm with you again, to obtain consent once a date for the focus group has been set (based on everyone's availability to participate). Informed consent is an important process in order for you to decide to participate in this study. The process will involve explaining why the research is being done, what is the purpose of the study, and what is required of your participation, the risks and benefits from participating in the study, and that you have the right to leave at any time without any penalty, if you choose to withdraw from the study.

The informed decision is a voluntary agreement to participate in this study (and in the focus group). It is not merely a form that is signed but is a process, in which you will have an understanding of the research and its risks described below before agreeing (or not) to participate.

Please ask me to stop as we go through the information if you have any questions and I will take time to explain. It you have questions later, you can ask them of me as the Principal Investigator (PI), Todd Tran (TT). Please take as much time as you need in order to understand and to read through this document in order to make an informed decision to participate (or not) in this research study.

Introduction

I am the Principal Investigator (PI) and also a PhD student at Queen's University in the school of Rehabilitation Therapy; Aging and Health Stream and this study is part of my program. You are invited to participate as clinicians running this 8-Week Mindfulness-Based Stress Reduction (MBSR) for older adults 60+ years and older living with subjective cognitive decline (SCD) or mild cognitive impairments (MCIs) at Women's College Hospital (WCH), Family Health Team (FHT), in partnership with Queen's University. I am interested in having clinicians participating in a focus group 60 to 90 mins), after being involved with delivering the 8-Week MBSR program to provide information around your overall experience (e.g. satisfaction, value, barriers, facilitators, etc.) within a primary care context.

What is the purpose of this research study?
The aim of this study is to look at the feasibility of carrying out a mindfulness program that may benefit older adults 60+ years and older living with mild memory issues, on a FHT. First, the study will assess feasibility outcomes (e.g. participant's experiences, use of technology and acceptability with the overall experience in the MBSR program). Second, studies in the past 25 years have seen that MBSR can be used to reduce anxiety, low mood, perceived stress along with enhancing emotional well-being and quality-of-life. Thus, this study is to see if MBSR can be used to help with emotional well-being for those living with SCD or MCI to cope with memory problems. Third, the study will also look at how MBSR may influence participant's perceived satisfaction on functional performance on every-day tasks. Lastly, if you agree to participate, you will also be asked to be part of a focus group to explore your experience of delivering the 8-Week MBSR program.

What will happen in this study?
If you decide to participate, you will be involved with assisting in implementing the 8-Week MBSR program for older adults (Group 1) in the late Spring of 2019. Group 2 will be carried out by PI (TT) which is the control group at a later date in 2019. However, after running Group 1, at Time 3 (12-Week), if you agree to participate, you will also be asked to be part of a focus group which will be 1.5 hour in duration and will be audio-recorded, facilitated by an independent assessor that is not part of the study.

In implementing and delivering the group, the weekly sessions will be as follows:

- They will be held on Thursday afternoons from 1:30 pm to 4:30 with a 15-minute break.
- The program will run for 8-Weeks sessions (with an all-day Saturday retreat session – approximately from 9:30 to 3:30 but will be based on clinician's availability and either on the scheduled day of the program or to be held on a Saturday – which will be decided among all of the participants, please see schedule in appendix attached) and with one follow-up session four weeks after completion of the MBSR program
- A copy of the 8-Week MBSR Program agenda is also attached to this form for you to read
- We are hoping that the group will be made up of anywhere from 15-20 participants, of all genders

Activities, duties and responsibilities and other activities when participating in the study will include:

- Supporting and providing accommodation(s) to participants' needs for any of the activities in the MBSR program, e.g., supporting participants to lie down, sit and/or stand if they chose based on their health condition throughout the 8-Weeks
- Establishing group norms reinforcing this with the group e.g. confidentiality, privacy, etc. and WCH policy e.g. scent-free policy, etc. Therefore, creating a safe and comfortable environment for participants to feel free to speak and share their experiences fully

- Each clinician will be responsible for confidentiality as to anything pertaining to the study (e.g. field notes, meeting minutes, participants' data)

- Observing the group when PI is delivering the MBSR curriculum, and participating in guiding any of the mindfulness practices if you feel comfortable.

- Being present to assist in any technical support around the iPAD use if able

- Making written field notes (collected by the PI at the end of each session) on your clinical observation and what you may find "surprising" or communicating verbally to PI (one-on-one) or during the clinician's meetings for the duration of study

- Each clinician will also be expected to interact with the Research Assistant (RA) and to make sure the RA administrative duties are done (e.g. which participants to call if no show or is away, to make sure the surveys are collected, setting up the room, to answer any of the RA's questions if able, etc.)

- Assisting participants by answering any of their questions or concerns and by addressing any difficulties or challenging (e.g. physical or psychosocial) that may arise while participating in the study

- Please feel free to ask the PI anything that further needs clarification, that is not mentioned on this consent form, that may arise and need to be addressed

What are the possible harms of taking part in this study?
You may have short or long term concerns that may interfere with your ability to participate due time, work schedule and clinical caseload.

There may be unforeseeable harms that may arise (e.g. a participant may fall, may need more assistance with their iPad, need more verbal cueing). If you experience any difficulties, challenges or ability to follow and keep up with the pace of the study, you can speak to the PI to assist and support you in order to participate in this research study.

What are the possible benefits of participating in this study?
As a participant carrying out this study, you will be involved in mindfulness practices as well and may or may not experience any benefits of mindfulness as every participant is different. Most importantly, your feedback (throughout the study and also in the focus group), will help to further develop and enhance future MBSR groups for those living with SCD and MCI in primary care and other settings. Additionally, the study will assess the benefits of possibly using MBSR to ameliorate psychosocial issues and perceived satisfaction of functional performance for those living with SCD and MCI.

What happens if I decide not to take part in this research study?
Your participation in this study is completely voluntary as your decision to take part or not in this research study is completely optional. Participation or non-participation will have no effect on your employment at WCH. However, you are responsible to notify and to seek permissions from your manager(s) to be away from the typical work day for times when you are involved with running the study. If you wish for me to assist in any way to facilitate your involvement, please do not hesitate to contact me directly.

Do I have the right to withdraw?
You can withdraw from this study at any time by contacting the PI (TT). If you withdraw your participation, your data provided to date may still be used as part of the study. The iPAD will be given to you (even if you are unable to participate in the study) once the study is completed.

Length of Study

The length of the study will be 11 sessions in total, consisting of: i. Orientation (3 hours), ii. The 8-week MBSR program (3 hours per week), iii. An all-day Saturday retreat (this may be on a week day based on participant's and staff availability - 6 hours), and iv. A focus-group 1-month after the program (1.5 hours).

Confidentiality
We respect your privacy and will do our outmost to keep all information about yourself collected or obtained confidential. Only the research team members will have access to this information. The research study staff, the WCH Research Ethics Board, Queen's Committee Members and employees of the sponsor or funder of the study will have access to your data only for purposes related with this study. The research team and those mentioned are the only people authorized to view your research data only under the supervision of the PI and will be obligated to protect your privacy and not disclose your personal information. None of your personal information will be made public unless necessary by the law. If the research results are published, your identity will remain confidential. The risk of identifying you from the study data is negligible, however it can never be completely eliminated. The study data will be kept in a secure location for ten years, then destroyed.

It is important to note that as staff members, we are very serious about confidentiality, however, we cannot guarantee that other participants in the group will maintain confidentiality (if you were to discuss anything in a group or one-on-one to other participants). We will, however, convey the importance of maintaining confidentiality throughout the duration of program as this is something we would request from all participants in the study.

If I have questions or problems, whom should I contact?
If you have any questions, please feel free to contact the PI:

Todd Tran OT Reg (Ont),
Principal Investigator
416-323-6525
Todd.Tran@wchospital.ca

If you have questions or concerns about your experience as a research participant, you can contact the Chair of the Research Ethics Board at Women's College Hospital, Dr. Nancy Walton, at 416-351-3732, extension 2325. The Research Ethics Board are a group of people who are not involved in this study and who have ethical oversight of research activities.

Participant

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study

- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I have agreed to participate in this study

☐ I have consented to participating in this study

_____	_____	_____
Name of participant (print)	Signature	Date (MM/DD/YY)

Person obtaining consent
By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____	_____	_____
Name of participant Consent (print)	Signature	Date

I acknowledge my responsibility for the care and well-being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

Name: _____

Signature of PI: _____

Date: _____

Confirming Consent for Focus Group – (between Week-6 to Week-12)

☐ I consent to participate in an interview with a Research Assistant

☐ No, I do not consent to participate in a focus group

Name of participant	Signature	Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

Name of Person obtaining Consent (print)	Signature	Date

Our 8-Week Mindfulness-Based Stress Reduction MBSR Program will be as follows:

77 Grenville St.
Family Practice: Room 202
3.0 hours in duration (with a break)

Roles (if able):

- Taking field notes
- Observing participants
- Providing assistance (eg. Offering different positions in yoga, technology iPads) participants weekly
- Participate in regular research meetings
- Making sure we are following the Agenda
- Participating in a focus-group at approximately four weeks after the MBSR program, only if agreeable in participating

Agenda:

Week 1

Guidelines of the Program
Outline the principles and process of the Program with the participants and their companion
Completing intake surveys
Introductions (participants, companion and the team of six occupational therapists)
What is Mindfulness?
Discussion around Memory and dementia and the importance of Mindfulness practice
Q & A period
Introducing the concept of Formal and Informal Mindfulness practices
Handing out the iPad Mini and showing participants and their companion how to use it
In-class mindfulness practice – the Body Scan meditation 10 mins
Debrief
Home practice: Formal practice Body Scan meditation 10 minutes 2x/day

Week 2

Collecting surveys or completing surveys if not done
Introductions again if any new participants joining the group
Education around the importance of Mindfulness practice and tying it to Memory
In-class informal mindfulness practice with guided instructions ie. mindful eating
Debrief
Discussion around homework from last week (any barriers or challenges)
Discussion around difficulty with technology use etc…
In-class formal practice Body Scan 10 mins
Debrief
Home practice: Formal practice of the Body Scan meditation and 10 mins x/day and Informal practice in daily life ie. mindful eating

Week 3

In-class Breath meditation with guided instructions emphasizing present-moment, curiosity, open mind, wandering mind etc.. (10 mins)
Debrief

Discussion around technology use, other apps on the iPad Mini participants can learn and use ie. camera, setting up WiFi, FaceTime, etc..
Discussion around Memory strategies (visual, audio cues, reminders etc..)
In-class Breath meditation (5 mins)
Home practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: Eating

Week 4

In-class Breath meditation with guided instructions emphasizing present-moment, curiosity, open mind, wandering mind etc.. (10 mins)
Debrief
Discussion of last week's Home Practice
Sleep and it's affect on Brain health
Mental Exercises (cross word puzzles, Sudoku, spot the differences, etc..
Debrief
In class meditation (5 mins)
Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: eating
Emphasize that Mindfulness can be done anywhere, anytime

Week 5

In-class mindful listening meditation with guided instructions (10 mins)
Debrief
Discussion of last week's home practice
Application of mindfulness and Activities of Daily Living (ADL), communications (talking and listening)
In-class mindfulness exercises with guided instructions ie. Communicating with Awareness
Debrief
In-class Breath meditation with guided instructions emphasizing present-moment, curiosity, open mind, wandering mind etc.. (10 mins)
Home practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: Mindful communication

Week 6

In-class mindfulness meditation with guided instructions (10 mins)
Debrief
Discussion of last week's Home Practice
Application of mindfulness and Activities of Daily Living (ADL), medication management/adherence and (strategies)
Introduction of Mindful Walking (10 mins)
Debrief
Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: mindful movement ie. walking, physical exercise, mindful movement

MBSR All Day Class Agenda

Welcome, guidelines for the day: silence, no eye contact, self-care, availability of teachers etc.
Sitting Meditation: focus on awareness of breathing
Guided Yoga, with option of ending with short body scan
Slow walking meditation: with introductory guidance
Sitting Meditation: less guidance, more silence

Brief talk, teaching story, poem, drawing out theme such as mindfulness skills across multiple situations in life, cultivating a sense of presence from moment-to-moment, and being open to any experience, whether evaluated as pleasant, unpleasant, or neutral, as an opportunity to practice mindful attention
Lunch instructions - Silent Lunch, mindful walking, self-care
Mountain or Lake Meditation
Slow/fast walking exercise with specific verbal guidance – repeated instructions for noticing, in movement and stillness, various mind-body experiences. Emphasize options for meeting needs as they arise, and the possibility for moving in and out of the exercise
Loving Kindness meditation, ending in stillness
Optional ending practices
Short sittings alternated with short walking, sitting anywhere when change occurs
Mindful walking, gazing out window, stopping and noticing one thing, followed by an open awareness meditation
Dissolving the silence by whispering in pairs
Group Discussion and Dialogue
Closing ceremony

Week 7

In-class meditation with guided instructions (10 mins)
Debrief
Mindfulness of Activities of Daily Living (ADL) ie. cooking, shopping,
Discussion of last week's Home Practice
Mindfulness and Stress, Anxiety, and Depression: the importance of being present in the moment vs. role of default mental activity in mental health problems
In-class meditation with guided instructions (15 mins)
Debrief
Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Noticing stress response, default mode and returning attention to present
Informal practice: Mindful communication, eating or physical exercises

Week 8

In-class meditation with guided instructions (10 mins)
Debrief
Discussion of last week's Home Practice
Mindfulness and Emotion Management
In-class "Working with distractions"
The last hour will be a recorded focus group
Debrief
Home Practice: Formal practice of the Body Scan (2 x 20 mins OR Breath meditations daily)
Informal practice: Mindful communication, eating, walking or physical exercises

1-Month Follow-Up (Focus Group)

Consent Form to Participate in a Research Study

Study Title: 8-Week Mindfulness-Based Stress Reduction (MBSR) Program

Principal Investigator: Todd Tran (PhD Student), OT Reg (Ont) and Dr. Catherine Donnelly

Funder: Canadian Centre for Brain Aging and Health Innovation

---

Consent

This consent form will give you information in order for you make an informed decision to participate in this research study or not. You do not have to decide today whether or not you will participate in the study. Before you decide, you can talk to anyone you feel comfortable with about the research.

The informed decision is a voluntary agreement to participate in this research study. It is not merely a form that is signed but is a process, in which you will have an understanding of the research and its risks described below before agreeing (or not) to participate.

Please ask me to stop as we go through the information if you have any questions and I will take time to explain. If you have questions later, you can ask them of me and also the research associates throughout the research study to answer any of your questions as well. Please take as much time as you need in order to understand and to read through this document in order to make an informed decision to participate (or not) in this research study.

Introduction

I am the Principal Investigator and also a PhD student at Queen's University in the school of Rehabilitation Therapy; Aging and Health Stream and this study is part of my program. You are invited to participate in a research study, an 8-Week Mindfulness-Based Stress Reduction (MBSR) Program for older adults 60+ years and older living with subjective cognitive decline (SCD) or with mild cognitive impairments (MCIs) at Women's College Hospital (WCH), Family Health Centre in partnership with Queen's University. We are looking for a small number of 30 to 40 participants to be involved in this study.

For ease of understanding, the term **mindfulness** is defined as:

"Paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally" "Bringing one's complete attention to the present experience on a moment-to-moment basis"

What is the purpose of this research study?

The aim of this study is to look at the feasibility of carrying out a mindfulness program that may benefit older adults 60+ years and older living with mild memory issues, on a Family Health Team. First, the study will

assess feasibility outcomes (e.g. participant's experiences, use of technology and acceptability with the overall experience in the MBSR program). Second, studies in the past 25 years have seen that MBSR can be used to reduce anxiety, low mood, perceived stress along with enhancing emotional well-being and quality-of-life. Thus, this study is to see if MBSR can be used to help with emotional well-being for those living with SCD or MCI to cope with memory problems. Third, the study will also look at how MBSR may influence your perceived satisfaction on functional performance on every-day tasks. Lastly, if you agree to participate, you will be asked to be part of a focus group (at around Week 12) to explore your experience of being in the MBSR program. We will ask you questions around your overall experience within the program (e.g. satisfaction, value, barriers and facilitators). Closer to the date, we will ask you again for your informed consent to participate in this focus group. You do not have to decide now, but you will get an opportunity to decide in the future between Week-6 and Week-12. We will contact you again at that point in time.

What will happen in this study?
If you decide to participate, you will be enrolled in an 8-Week MBSR Program (with a follow-up session four weeks after participating in the program). We will randomly assign the groups to you, to either Group 1 (to start within a few weeks) or Group 2 (at a future date). The group you are assigned to will not be known, until you consent to the study. Unfortunately, you will not be able to choose your group. However, it is important to note that, regardless of your group allocation, we will be asking you to complete some questionnaires at different time points. If you are assigned to Group 1, we will also ask you to participate in a focus group at the end of the program that will consist of 1.5 hour in duration. Group 1 participants will be invited to an audio-recorded focus group, facilitated by an assessor that is not part of the study. The purpose of the focus group is to get feedback about participant's overall experience within the group. Group 2 will not be involved in a focus group.

The MBSR program is provided to a group of older adults 60+ years and older with mild memory issues and will consist of mindfulness practices including: sitting and lying down meditations, gentle mindful movement (yoga)), learning about mindful eating, and mindful everyday routines.

The research team would like to access your medical chart at WCH for purposes of research to confirm only the following: your health history, co-morbidities and medications. You have the option to opt out of this if you would like:

- ☐ Yes, I consent to allow the research team to have access to my medical records at WCH
- ☐ No, I do not wish the research team to have access to my medical records at WCH

You will also be provided with a study mini-iPAD (if you do not have one of your own), and you are able to keep it during the study timeframe only (for the duration of the study). All mini-iPADs will have an identification sticker attached and will correspond with your participant ID number.

Clear instructions will be given on the care (ie. charging it, taking care of the device) throughout the sessions. However, if the device becomes damaged, loss, stolen (beyond your control), you are not responsible for replacing it. However, based on the number of participants and iPADs, if available we would provide you with a replacement iPAD. It will be understood at the end of the study, the iPADs must be returned.
As part of the research, you will be required to complete some surveys (pencil and paper questionnaires) initially during the Intake Assessment session at Week 1, again at the end of the program at Week 8, and the follow-up session at Week 12, which we will hold ~ 1 month after completion of the MBSR course.

The screening session will be approximately 60 minutes in length to make sure you are eligible for the study. The screening session will entail completing a cognitive screen, and a depression scale. If your score is not within the criteria of the study, you will not be considered eligible. However, if you are not eligible, we will give you some community resources, or you may also follow-up with your family physician, to talk to them about your score(s).

All the data that we collect from you over the sessions will be kept strictly confidential and will **not** be added to your medical chart.

Length of Study
Excluding the session of pre-screening for eligibility, the length of the study will be **11 sessions**, consisting of: i. Orientation (3 hours), ii. The 8-week MBSR program (3 hours per week), iii. An all-day Saturday retreat (6 hours), and iv. A follow-up session held about 1 month after the program (1.5 hours – focus group) and post-surveys. Approximately, a three month commitment.

The weekly sessions will be as follows:

- They will be held on Thursday afternoons from 1:30 pm to 4:30. You are able to take a break at any time during the sessions and accessible washrooms are close by.
- There will be an initial intake and screening session (if you are deemed to be eligible), and the program will then run for 8-Weeks with (an all day Saturday session) and one follow-up session at Week 12 (four weeks after the completion of the program).
- A copy of the 8-Week program agenda is also attached to this form for you to read
- We are hoping that the group will be made up of anywhere from 15-20 participants, all genders
- We will be asking you to provide some information on the following topics as part of completing the pencil and paper questionnaires: anxiety and mood rating scales along with quality-of-life measures and questions around your basic day-to-day activities that you do routinely around your home and outside of your home
- You will be given a mini-iPAD to borrow for the duration of the study to use (to play audio files for mindfulness practices)

What are the possible harms of taking part in this study?
To participate in the study, you must be under the care of a physician, and you will be asked to provide us with an emergency contact for us to contact in case of emergency.

Name of Emergency Contact: _____

Relationship: _____

There may be unforeseeable harms that may arise, you may have a short or long-term concerns that may interfere with your ability to participate and be involved in the program. The study requires an investment of your time as it will be a 3-month commitment, if assigned either into Group 1 (in a few weeks) **or** Group 2 (at a future date). Some questions may make you feel upset or distressed but, you can opt out, take a break or discontinue participation for any reason whenever you feel the need to. If you experience any emotional distress, we will connect you with a social worker on the Family Health Team (FHT).

If you experience any difficulties, challenges or ability to follow and keep up with the pace during the 8-Week Program, there will be staff that may be able to assist and support you as there is a team of occupational therapists involved in this research study.

- Staff members or Research Assistant (RA) will give you reminder phone calls for each session if you provide consent for us to do so, and if you're unable to come to any of the session(s), a follow-up phone call will be provided to give you the homework, and to inform you of what was missed. Again this will only be done if you provide consent for us to phone you (see page 6 for consent).

- Technical support on using the mini-iPAD will be provided on-site during the weekly sessions

- Staff will answer any of your questions and address any of your concerns along the way

- We will establish group norms, e.g., making sure that we abide by WCH scent-free policy, keeping whatever is discussed within the group is kept private and confidential thus, creating a safe environment for participants to feel free to speak and share their experiences. We also encourage people to get up and move around if they need to, allowing for people to take breaks when they need to, etc.

- We will provide support and accommodation(s) to you for any of the activities, e.g., supporting people to lie down, sit and/or stand if they chose based on their health condition, throughout the study.

What are the possible benefits of participating in this study?
As a participant, you may or may not experience any benefits as every participant is different. There is no guarantee that the intervention will have an effect. However, research has shown that some people who practice mindfulness experience improvements in anxiety, mood, perceived stress, emotional well-being and quality-of-life. This is why we are doing the research – in order to determine if there is a potential benefit for those living with cognitive impairments.

What happens if I decide not to take part in this research study?
Your participation in this study is completely voluntary.
Your decision to take part or not in this research study will not have an impact on your medical care. You will continue to have the same access of routine care you are currently receiving now.

Do I have the right to withdraw?
You can withdraw from this study at any time by contacting the Principal Investigator (Todd Tran). If you withdraw your participation, your data provided to date may still be used as part of the study. And we will collect your iPad.

Compensation
You will be provided with a $5 Metro Gift Card at each session. The gift card is given at each session by a staff member and your signature is be required.

Confidentiality
We respect your privacy and will do our outmost to keep all information about yourself collected or obtained confidential. Only the research team members will have access to this information. The research study staff,

the WCH Research Ethics Board, Queen's committee members and employees of the sponsor or funder of the study may look at your personal information only for purposes related with this study. The research team and those mentioned are the only people authorized to view your research data only under the supervision of the Principal Investigator and will be obligated to protect your privacy and not disclose your personal information. None of your personal information will be made public unless necessary by the law. If the research results are published, your identity will remain confidential. The risk of identifying you from the study data is negligible, however it can never be completely eliminated. The study data will be kept in a secure location for ten years, then destroyed.

It is important to note that as staff members, we are very serious about confidentiality, however, we cannot guarantee that other participants in the group will maintain confidentiality (if you were to discuss anything in a group or one-on-one to other participants). We will, however, convey the importance of maintaining confidentiality throughout the 8-Week program as this is something we would request from all participants in the study.

If I have questions or problems, whom should I contact?
If you have any questions, please feel free to contact the PI:

Todd Tran PhD (cand), MScCH, OT Reg (Ont),
Occupational Therapist in Family Practice and Foot Care Centre
416-323-6525
Todd.Tran@wchospital.ca

If you have questions or concerns about your experience as a research participant, you can contact the Chair of the Research Ethics Board at Women's College Hospital, Dr. Nancy Walton, at 416-351-3732, extension 2325. The Research Ethics Board are a group of people who are not involved in this study and who have ethical oversight of research activities.

Participant

Participant/Substitute decision-maker
By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal health information, medical record (if applicable), and research study data as explained in this form
- I have agreed to participate in this study or agree to allow the person I am responsible for to participate in this study
- (If applicable) I understand that my family doctor will be informed of my participation in this research study
- (if applicable) This informed consent document will be placed in my medical records

☐ I have consent to participating in this study

_____	_____	_____
Name of participant/ (Print)	Signature	Date

Person obtaining consent
By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

_____	_____	_____
Name of Person obtaining Consent (print)	Signature	Date

I acknowledge my responsibility for the care and well-being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

Name: _____

Signature: _____

Date: _____

Please indicate if you give consent for us to contact you by phone (for reminder calls or to provide you with the homework if you were to missed a class), and for us to leave a voicemail or/and email as another way to communicate with you

☐ Yes, I consent to allow the research team to call me if necessary and to leave a voicemail and/or contact me by e-mail

Phone number: _( )_____ E-mail: _____

☐ No, I do not consent the research team to phone or e-mail me for the duration of the study

Confirming Consent for Focus Group – (between Week-6 to Week-12)

☐ I consent to participate in a focus group

☐ No, I do not consent to participate in a focus group

Name of participant (Print)	Signature	Date

Person obtaining consent
By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

Name of Person obtaining Consent (print)	Signature	Date

Our 8-Week Mindfulness-Based Stress Reduction MBSR Program will be as follows:

77 Grenville St.
Family Practice: Room 202
3.0 hours in duration (with a break)
There will always be staff members at each session

Agenda:

Week 1

Guidelines of the Program
Outline the principles and process of the Program with the participants and their companion
Completing intake surveys
Introductions (participants, companion and the team of six occupational therapists)
What is Mindfulness
Discussion around Memory and dementia and the importance of Mindfulness practice
Q & A period
Introducing the concept of Formal and Informal Mindfulness practices
Handing out the iPad Mini and showing participants and their companion how to use it
In-class mindfulness practice – the Body Scan meditation 10 mins
Debrief
Home practice: Formal practice Body Scan meditation 10 minutes 2x/day

Week 2

Collecting surveys or completing surveys if not done
Introductions again if any new participants joining the group
Education around the importance of Mindfulness practice and tying it to Memory
In-class informal mindfulness practice with guided instructions ie. mindful eating
Debrief
Discussion around homework from last week (any barriers or challenges)
Discussion around difficulty with technology use etc…
In-class formal practice Body Scan 10 mins
Debrief
Home practice: Formal practice of the Body Scan meditation and 10 mins x/day and
Informal practice in daily life ie. mindful eating

Week 3

In-class Breath meditation with guided instructions emphasizing present-moment, curiosity, open mind, wandering mind etc.. (10 mins)
Debrief
Discussion around technology use, other apps on the iPad Mini participants can learn and use ie. camera, setting up WiFi, FaceTime, etc..
Discussion around Memory strategies (visual, audio cues, reminders etc..)
In-class Breath meditation (5 mins)
Home practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: Eating

Week 4

In-class Breath meditation with guided instructions emphasizing present-moment, curiosity, open mind, wandering mind etc.. (10 mins)
Debrief
Discussion of last week's Home Practice
Sleep and it's affect on Brain health
Mental Exercises (cross word puzzles, Sudoku, spot the differences, etc..
Debrief
In class meditation (5 mins)
Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: eating
Emphasize that Mindfulness can be done anywhere, anytime

Week 5

In-class mindful listening meditation with guided instructions (10 mins)
Debrief
Discussion of last week's home practice
Application of mindfulness and Activities of Daily Living (ADL), communications (talking and listening)
In-class mindfulness exercises with guided instructions ie. Communicating with Awareness
Debrief
In-class Breath meditation with guided instructions emphasizing present-moment, curiosity, open mind, wandering mind etc.. (10 mins)
Home practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: Mindful communication

Week 6

In-class mindfulness meditation with guided instructions (10 mins)
Debrief
Discussion of last week's Home Practice
Application of mindfulness and Activities of Daily Living (ADL), medication management/adherence and (strategies)
Introduction of Mindful Walking (10 mins)
Debrief
Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Informal practice: mindful movement ie. walking, physical exercise, mindful movement

MBSR All Day Class Agenda

Welcome, guidelines for the day: silence, no eye contact, self-care, availability of teachers etc.
Sitting Meditation: focus on awareness of breathing
Guided Yoga, with option of ending with short body scan
Slow walking meditation: with introductory guidance
Sitting Meditation: less guidance, more silence
Brief talk, teaching story, poem, drawing out theme such as mindfulness skills across multiple situations in life, cultivating a sense of presence from moment-to-moment, and being open to any experience, whether evaluated as pleasant, unpleasant, or neutral, as an opportunity to practice mindful attention
Lunch instructions - Silent Lunch, mindful walking, self-care

Mountain or Lake Meditation
Slow/fast walking exercise with specific verbal guidance – repeated instructions for noticing, in movement and stillness, various mind-body experiences. Emphasize options for meeting needs as they arise, and the possibility for moving in and out of the exercise
Loving Kindness meditation, ending in stillness
Optional ending practices
Short sittings alternated with short walking, sitting anywhere when change occurs
Mindful walking, gazing out window, stopping and noticing one thing, followed by an open awareness meditation
Dissolving the silence by whispering in pairs
Group Discussion and Dialogue
Closing ceremony

Week 7

In-class meditation with guided instructions (10 mins)
Debrief
Mindfulness of Activities of Daily Living (ADL) ie. cooking, shopping,
Discussion of last week's Home Practice
Mindfulness and Stress, Anxiety, and Depression: the importance of being present in the moment vs. role of default mental activity in mental health problems
In-class meditation with guided instructions (15 mins)
Debrief
Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
Noticing stress response, default mode and returning attention to present
Informal practice: Mindful communication, eating or physical exercises

Week 8

In-class meditation with guided instructions (10 mins)
Debrief
Discussion of last week's Home Practice
Mindfulness and Emotion Management
In-class "Working with distractions"
The last hour will be a recorded focus group
Debrief
Home Practice: Formal practice of the Body Scan (2 x 20 mins OR Breath meditations daily)
Informal practice: Mindful communication, eating, walking or physical exercises

1-Month Follow-Up (Evaluation and Focus-Group, if agreeable to participate)

BMJ Open

An occupational therapist-led mindfulness-based stress reduction for older adults living with subjective cognitive decline or mild cognitive impairment in primary care: a feasibility randomized control trial protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035299.R1
Article Type:	Protocol
Date Submitted by the Author:	28-Jan-2020
Complete List of Authors:	Tran, Todd; Women's College Hospital, Family Practice; Queen's University, Aging and Health Donnelly, Catherine; Queen's University Faculty of Health Sciences, Rehabilitation Therapy Nalder, Emily; University of Toronto, Occupational Science and Occupational Therapy; March of Dimes Canada, Trothen, Tracy; Queen's University Faculty of Health Sciences Finlayson, Marcia ; Queen's University, School of Rehabilitation Therapy
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	PRIMARY CARE, MENTAL HEALTH, Anxiety disorders < PSYCHIATRY, Delirium & cognitive disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Old age psychiatry < PSYCHIATRY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

An occupational therapist-led Mindfulness-Based Stress Reduction for older adults living with subjective cognitive decline or mild cognitive impairment in primary care: A feasibility randomized control trial protocol

Keywords: mindfulness, occupational therapy, subjective cognitive decline, mild cognitive impairment, primary care, interprofessional primary care

Protocol Version: January, 27th, 2020 version 4.0

Authorship (my research team – are the only people to have access to research data)

(1) Todd Tran; Principal Investigator; *Occupational Therapist, PhD (cand);* **Todd.Tran@wchospital.ca**
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada

Clinical Site: Women's College Hospital
76 Grenville St.
Toronto, Ontario, M5S 1B2, Canada
1-416-301-5881

(2) Catherine Donnelly; *Associate Professor*; **Catherine.Donnelly@Queensu.ca**
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-533-6385

(3) Emily Nalder; *Assistant Professor;* **Emily.Nalder@utoronto.ca**
University of Toronto
Department of Occupational Science & Occupational Therapy
500 University Ave., Toronto, ON, M5G 1V7, Canada
1-416-978-5937

(4) Tracy Trothen; *Professor;* **Tracy.Trothen@Queensu.ca**
Queen's University

Jointly appointed to the School of Rehabilitation Therapy
and School of Religion (Theological Hall)
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada

1-613-273-8438

(5) Marcia Finlayson; *Professor, Director of School of Rehabilitation Therapy, Vice Dean of Health Sciences;* **Marcia.Finlayson@Queensu.ca**
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-533-2576

Competing Interest: There is no competing interest to declare as there is no financial interest; however, this is Principal Investigator's doctoral dissertation. The co-authors are Ph.D. committee members involved in overseeing study in its entirety, from data management to data monitoring, which is independent of the funders and has no competing interests. The committee and supervisor will be conducting the interim results and will make the final decision to terminate the trial at any point in time if deemed appropriate. Thus, auditing will also be done weekly with support from the supervisor, independent from the funders. Funding sources had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Word count: (approximately 4000 words)

Funding:

Centre for Ageing & Brain Health Innovation
3560 Bathurst Street
Toronto, ON
M6A 2E1 Canada

And

VHA Home HealthCare
30 Soudan Avenue, Suite 600
Toronto, ON
M4S 1V6

Abstract

Introduction: Community-dwelling older adults living with subjective cognitive decline (SCD) or mild cognitive impairment (MCI) may experience decreased efficiency in their overall functional performance. This decreased cognitive efficiency may result in anxiety, low mood, perceived stress, and decreased emotional well-being and quality-of-life. These psychological symptoms may further exacerbate cognitive decline.

Exploring non-pharmacological interventions such as mindfulness within primary care is vital in enabling individuals to develop strategies to manage cognitive impairment or psychological symptoms. Mindfulness-Based Stress Reduction (MBSR) is an 8-week program that is beneficial in alleviating psychological symptoms; however, its impact on perceived satisfaction on overall functional performance with this population has not been evaluated. The primary objective of this study is to explore the feasibility of conducting an RCT of an occupational therapist-led MBSR program within primary care.

Methods: Convergent mixed-methods, randomized control feasibility trial with 40 participants from an interprofessional primary care team in Toronto, Ontario. Participants are randomized into the 8-week MBSR group or wait-list control will be compared at baseline, post-intervention and four-weeks follow-up. The primary aim is to determine the feasibility of the intervention with this population and setting. The secondary aim is to examine perceived satisfaction with functional performance as measured by the Canadian Occupational Performance Measure (COPM). Secondary clinical outcomes include psychological symptoms.

Analysis: Investigators will analyze the quantitative and qualitative data strands separately. Descriptive statistics, focus group and interviews will then be merged and further analyzed to best understand the feasibility and preliminary clinical outcomes from the study.

Ethics and dissemination: The study is approved by Women's College Hospital (2017-0056-E), and Queen's University, Kingston, Ontario (6026418). This study is registered at Clinicaltrials.gov (NCT03867474). The study will follow Standard Protocol Items: Recommendations for Interventional Trials. The results will be published in peer-reviewed academic journals and disseminated to patient organizations and media.

Strengths and limitations of this study

- The study will provide valuable data on feasibility and clinical outcomes to determine whether occupational therapist-led MBSR is appropriate for a larger clinical trial
- The first study to use the COPM to evaluate perceived satisfaction on functional performance with community-dwelling older individuals living with SCD or MCI within an interprofessional primary care context
- The only study to explore the qualitative perspective of both participants and health care providers in terms of barriers, enablers and facilitators of implementing and delivering the MBSR program within a primary care setting

- The study is innovative in exploring the acceptability of a tablet computer as a method of intervention delivery and data collection with this population

- The lack of an attention control comparison group and the small sample size is a study limitation

Introduction

By 2036, approximately one-in-four Canadians will be 65 years and over (1), and an estimated one-third of community-dwelling older adults will experience memory complaints (2). The earliest sign of memory impairment is subjective cognitive decline (SCD), a self-reported decline in cognition without "objective evidence," characterized by increasing compensatory cognitive efforts and subtle cognitive decline (3). If SCD is to decline further, the next stage is mild cognitive impairment (MCI), with 10 - 20% of older adults developing MCI by age 65 (4). MCI is clinically characterized as: (i) concern raised by the individual or an informant, or clinician, (ii) cognitive impairment in one or more cognitive domains relative normative data for that individual, and (iii) preservation of functional independence (5, 6).

There is a large body of evidence that demonstrates that those living with memory complaints face a decline in performance of everyday tasks, most notably in complex instrumental activities-of-daily living (iADLs) (7). These functional changes result in a general sense of decreased satisfaction and discontentment with their overall functional performance (8).

Living with SCD or receiving a diagnosis of MCI is usually life-altering and has been found to have a negative impact on an individual's emotional health and well-being (9), with an increased risk of depression and anxiety disorders (10). There is limited evidence that supports the use of pharmacologic interventions to improve concomitant anxiety disorders (11) and depression among those living with cognitive impairment (12). Medications may increase the risk of adverse side-effects, especially for those with multiple comorbidities, including drug complications (13) and falls (14). Exploring non-pharmacologic interventions to mitigate psychosocial factors and to support functional performance is critical (10, 15). Successful adaptive coping strategies to improve depression and anxiety symptoms in this population are essential to prevent and/or delay further cognitive decline (10).

Evidence from the past 20 years suggests that mindfulness meditation, such as Mindfulness-Based Stress Reduction (MBSR), could benefit those living with SCD and MCI (16, 17). MBSR may be neuroprotective against cognitive decline as it has been found to produce brain changes along with decreased cognitive complaints and increased memory self-efficacy (17). Furthermore, a small proof-of-concept study identified that MBSR is feasible with older adults living with MCI and that it may positively affect QoL and well-being (16). This study will build on these proof-of-concept and pilot studies as MBSR has demonstrated mental health benefits, including the reduction of emotional distress and worry (18, 19).

Other studies have demonstrated that mindfulness helps older adults with loneliness, depression, anxiety, and sleep problems (19-23) in general community settings and secondary care, e.g., neurology clinics. However, primary care providers are often the first point of contact

when older adults and their families are concerned about cognitive problems (24). There is an increasing emphasis on interprofessional primary care teams or patient medical homes to address the challenges of an ageing population. Currently, no studies to date have examined the feasibility of MBSR for those living with SCD or MCI receiving care from interprofessional primary care teams. A growing number of occupational therapists working in primary care teams are ideally positioned to support individuals with SCD and MCI through their expertise in understanding the impact of cognitive impairment on daily function. Examining effective interventions such as an occupational therapist-led, MBSR for individuals at the early stages of cognitive changes is critical to support ageing-in-place (25).

The overarching purpose is to determine whether occupational therapist-led MBSR in primary care is appropriate for a larger clinical trial in the future. The study has two aims:

Primary Aim:

To explore the feasibility of conducting an RCT of an occupational therapist-led, 8-week MBSR program in an interprofessional primary care setting. The following objectives will assess feasibility outcomes:

1a. Assess participant recruitment, intervention adherence, and study retention (Quantitative)
1b. Explore the acceptability of using tablet computer technology to support intervention, delivery and data collection in the MBSR program (Qualitative)
1c. Explore the perspectives of participants and healthcare providers concerning satisfaction (e.g., the intervention and its' delivery), perceived value, and barriers and facilitators of implementation of the MBSR program in a primary care setting (Qualitative)

Secondary Aim:

To evaluate the effect sizes of satisfaction on functional performance as a primary clinical outcome and psychological symptoms as secondary clinical outcomes in individuals with SCD or MCI completing an 8-week MBSR program in an interprofessional primary care setting. (Quantitative)

Methods

This study will use a convergent mixed-methods, single-blind RCT with two parallel groups and will follow SPIRIT reporting (26) guidelines for randomized feasibility trials. See Trial Design **(See Figures 1 and 2)**. There will be three assessment time points: Baseline (Time-1) at week-0, on completion of the intervention (Time-2) at week-8, and one-month post-intervention follow-up (Time-3) at week-12.

Study Setting

The study will take place at an interprofessional primary care clinic in the province of Ontario, Canada. Interprofessional team members include occupational therapy, physiotherapy, nursing, pharmacy, social work, and dietetics. There are approximately 18,000 rostered patients with the clinic.

Eligibility Criteria

To qualify for the study, participants will be screened using the Montreal Cognitive Assessment (MoCA), with a score of 22 or greater and a Geriatric Depression Scale (GDS) score of 6 or lower to be eligible to participate in the study. Scores of greater than 7 on the GDS and lower than 22 on the MoCA will warrant further assessment with their family physician and will be excluded from the study. The inclusion and exclusion criteria are:

Inclusion Criteria:

(1) Age $\geq$ 60 years
(2) English fluency
(3) Living independently (non-assisted living, e.g. retirement or any long-term care facility; self-report)
(4) Have a self-reported SCD or an MCI diagnosis in their chart
(5) Must be a patient with the interprofessional primary care clinic

Exclusion Criteria:

(1) History of prior participation in any MBSR or other mindfulness-based interventions in the past or having 2-3 times per week or more of either mindfulness or yoga practice
(2) Current history of significant medical (e.g. cancer), neurological (e.g. brain injury) or psychiatric condition (e.g. depression with 6 or greater on the GDS), active psychosis, bereavement that significantly impacts on mood, i.e. depression
(3) Alcoholism or other substance abuse
(4) Participating in other cognitive or memory training programs in the community or is involved in another research study

Intervention/Treatment (MBSR) Group

Participants randomized to the intervention arm will participate in an 8-week MBSR program established in 1979 by Kabat-Zinn (27). Four occupational therapists, also Qualified-MBSR teachers, will be involved in the delivery of the intervention group. The traditional MBSR curriculum usually have two teachers, but due to the unique population with cognitive impairment and the use of tablet computers, having two additional MBSR teachers will be beneficial to assist with any issues that may arise, including technological issues or memory challenges. The group will be 3-hours in duration (with a 15-minute break) for 8-weeks, along with an orientation and one all-day retreat. Sessions will consist of: lying down (body scan), sitting (focusing on the breath), and mindful movement (yoga and walking). Daily home practice will be given to be performed for 30 to 45 minutes outside of class.

We will distribute a tablet computer to each participant to access the Application (App), Insight Timer (28), for the duration of the study. Insight Timer contains guided meditation homework practices, with homework accessed by logging directly into Insight Timer. All homework data will be downloaded at the end of the 8-week program. In addition to the App, all participants will be asked to record their home practice using pen and paper weekly logs as a

backup provided by the research team. If participants have difficulty with using tablets, additional support will be provided during or after class. If any participant does not have access to Wi-Fi, we will provide them with CDs for ease of adherence for their guided homework practices, and homework will be tracked exclusively using pencil and paper sheets. Similarly, if participants have difficulty with using tablet computers, switching to CDs will be offered as an alternative low technology option.

Monitoring of adherence will include (i) attendance records (ii) home practice logs (iii) tablet computer use (login, frequency, duration) and (iii) field notes from Qualified-MBSR teachers in regards to the level of participation, engagement and group process.

Any participants who experience emotional issues (e.g. increased anxiety, low mood) during the group will be referred to other health-care professionals on the interprofessional primary care team (e.g. social worker, consultant psychiatrists) for psychological support.

The control group (usual care) will be identical to the intervention group and will be offered the MBSR program three months after the intervention group.

Assessment of Intervention (MBSR) Treatment Fidelity

This study will use Gearing et al. (29) four major (intervention) fidelity components: *Design, Training, Delivery* and *Receipt*. The *design fidelity* of this feasibility RCT is to follow an existing eight-week protocol of MBSR following the authorized curriculum guide from the University of Massachusetts, Medical School, Center for Mindfulness in Medicine, Health Care and Society. Design fidelity will be met by ensuring: a fixed number and length of sessions, following the scripted manual for the course, including external monitoring by the research team recording any protocol deviations based on the population, monitoring of the home practice logs.

The *training fidelity* is significant as the teacher's embodiment of mindfulness is central to the participant's learning within the 8-week curriculum. To maintain training fidelity, three facilitators are Qualified-MBSR teachers who have undergone training at the University of Massachusetts, Medical School; one facilitator has equivalent MBSR-qualifications from a different institution in Toronto, Canada using the same standardized MBSR treatment manuals. All qualified-MBSR Teachers have over three years of facilitating MBSR groups. Training fidelity will be met by: teachers meeting regularly to debrief, using the same teachers for the duration of the 8-weeks, and lastly, participant focus group inquiring about the curriculum will be used.

Delivery fidelity is the implementation of the MBSR curriculum by following both the MBSR curriculum protocol from the University of Massachusetts, Medical School and the Mindfulness-Based Interventions Teaching Assessment Criteria (MBI:TAC); a tool that assesses mindfulness-based teaching integrity that will be used as a guide to support the delivery of the MBSR curriculum. Delivery fidelity will also be measured by: participant focus group reflection of the teachers' embodiment of mindfulness practice, attendance, and intervention handouts provided for all participants along with tablet computers or CDs with home practice recordings.

Lastly, *receipt fidelity* will be achieved by attendance during the 8-week program, in conjunction with logins and doing the home practices on participant's computer tablets. Additionally, receipt fidelity will be met by: the collection of participant's weekly handwritten home practice log sheets and inquiry discussions during the weekly sessions. This demonstrates that participants are practicing the skills during the study period and are engaged and adherent to the program. However, any missing attendance or drop-outs will be followed-up with a telephone call.

Primary AIM: Feasibility Outcome Measures

As a feasibility study, the overarching purpose is to determine whether MBSR is worthwhile for a definitive larger clinical trial for community-dwelling older adults living with SCD or MCI in an interprofessional primary care setting.

Objective 1a: Feasibility Measures

i. Recruitment rate: will be defined as feasible for a future study if 30-40 participants are recruited within three to four months (May to August 2019), similar to other feasibility studies (30).

ii. Retention rate: will be deemed feasible if at least 75-80% of participants complete six or more of the nine sessions as well as a follow-up assessment at T3 based on other feasibility studies.

iii. Adherence rate: will be deemed to have adequate adherence for a future study if participants complete three logins per week and practice homework for at least 1.5 hours per week (duration), which would be deemed moderate adherence rate at 51-79 (29, 31). The treatment adherence rate is determined by the number of sessions completed in full (180 minutes).

Objective 1b: Acceptability of technology

iv. Acceptability of using a tablet computer as a tool for home practice delivery will be determined through. (i) field notes by Qualified-MBSR teachers documenting group participation, (ii) number of participants that switch from computer tablets to low technology for the homework practices during the duration of the 8-weeks, and (iii) focus groups at follow-up at the end of 8-weeks (T2) examining perceived value and benefits of using technology.

Objective 1c: Satisfaction with the MBSR program

v. The overall experience of the 8-week intervention will be evaluated by field notes, mid-way participants surveys, interviews with Qualified-MBSR teachers (T3-week-12) and participant focus groups (T2-week-8). The dimensions of satisfaction with the program will include length (number of weeks), difficulty (e.g. pacing, workload or other challenges), and session duration (e.g. too short, too long).

Secondary AIM: Clinical Outcome Measures

Demographic data will be collected at baseline (e.g. age, education, income, physical activity, etc.) along with primary and secondary clinical outcome measures.

Quantitative Data

The *primary clinical outcome* will be the average change scores on the perceived satisfaction with functional performance as measured by the *Canadian Occupational Performance Measure (COPM);* (32).

Secondary clinical outcomes will include mood, anxiety, perceived stress, mindfulness traits, QoL and acceptance, as shown:

1. Patient Health Questionnaire-9 (PHQ-9); (33, 34)
2. Geriatric Anxiety Inventory (GAI); (35)
3. Perceived Stress Scale (PSS); (36)
4. Cognitive and Affective Mindfulness Scale-Revised (CAMS-R); (37)
5. Quality of Life-Alzheimer's Disease (QoL-AD); (38)
6. Acceptance and Action Questionnaire (AAQ-II); (39)

Time of Outcome Measures

Outcome measures will be assessed at baseline (Time-1: week-1) on completion of the intervention at (Time-2: week-8) and one-month post-intervention follow-up (Time-3: week-12). **See Table 1**

Clinical Outcome Measures:

Primary Outcome

Canadian Occupational Performance Measure

The COPM is an individualized, client-centred outcome measure. Through a semi-structured interview, individuals identify areas of difficulty in the performance of everyday activities and satisfaction with their performance. Maximum of five activities can be identified, and each is rated on a 10-point scale for self-perceived performance and satisfaction for their functional performance. COPM demonstrates strong test-retest reliability for both the performance and satisfaction scores when tested a week apart (40) and has demonstrated good responsiveness (41). A change of at least 3 points or more is recommended to distinguish between older adults who report a clinically significant change compared to those who do not (42).

Secondary Outcome

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a self-administered tool that scores each of the 9 DSM-IV criteria as '0' (not at all) to '3' (nearly every day), giving a total score of 27 (33). PHQ-9 represents a

reasonable alternative to the Geriatric Depression Scale with older adults in primary care settings (33, 34). The internal reliability of the PHQ-9 is excellent, with a Cronbach's of 0.89 in a PHQ-9 Primary Care Study, with excellent test-retest reliability. PHQ-9 has a sensitivity of 88% and a specificity of 88% for use in a population with major depression (33).

Geriatric Anxiety Inventory (GAI)

The GAI consists of 20 'Agree/Disagree' items designed to assess typical common anxiety symptoms for the last week (35). GAI was developed specifically for community-dwelling older adults. The GAI has high internal consistency ($\alpha = .76$), as well as high inter-rater ($r = .89$) and test-retest ($r = .86$) reliability (35).

Perceived Stress Scale (PSS)

PSS is an assessment of the global appraisal of stress (36). The 10-item questionnaire examines stress of respondents using a 4-point scale (0-Never to 4-Very Often). The PSS has acceptable psychometric properties, with satisfactory test-retest reliability criterion assessed at >0.70 (43).

The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)

CAMS-R is a brief comprehensive measure designed to capture mindfulness based on Jon Kabat-Zinn's definition of mindfulness (37). The CAMS-R is a 10-item questionnaire with a 4-point scale (1 –Rarely to 4 -Almost Always) s and has demonstrated internal consistency reliability with Cronbach's alpha ranges from 0.61 to 0.81. The CAMS-R has also demonstrated concurrent validity with moderate to large correlation with other measures of mindfulness (r = 0.51 to 0.67) (37).

Quality-of-Life in Alzheimer's Disease (QoL-AD)

The QoL-AD is a 13-item questionnaire covering multiple domains including health, mood, living situation, memory, and money (44). The measure has demonstrated good test-retest reliability and strong inter-rater reliability with Cohen's kappa values >0.70. Internal consistency is also high with a Cronbach's alpha coefficient of 0.82 (38).

Acceptance and Action Questionnaire-II (AAQ-II)

The AAQ-II is a 7-item questionnaire that measures psychological flexibility-inflexibility and experiential avoidance (45). The measure has shown that psychological flexibility is a prominent factor in understanding psychological health (46). The AAQ-II has an alpha coefficient of 0.84 and demonstrates good test-retest reliability at 3-months at 0.81 and 12-months at 0.79 (45).

Table 1

Timeframe of Measurements for participants in MBSR Intervention

Measures Taken		**(Time 1)**							**(Time 2)**	**(Time 3)**
Item	0-week	1-week	2-week	3-week	4-week	5-week	6-week	7-week	8-week (Post-MBSR)	12-week (Follow-Up)
Screening										
(MoCA and GDS)	X									
Feasibility Measures		X	X	X	X	X	X	X	X	X
Qualitative Measures										
Focus Group (Participants)									X	
Interview with MBSR teachers										X
Evaluations (Participants)					X				X	
Weekly Research Meeting Notes		X	X	X	X	X	X	X	X	
Weekly Field Notes		X	X	X	X	X	X	X	X	
Quantitative Measures										
COPM (Satisfaction / Performance)		X							X	X
PHQ-9 (Mood)		X							X	X
GAI (Anxiety)		X							X	X
CAMS-R (Mindfulness)		X							X	X
PSS (Stress)		X							X	X
QoL-AD (Quality-of-Life)	X							X	X	
AAQ-II (Acceptance)		X							X	X

Sample Size

The goal is to recruit approximately 40 participants (e.g. 20 MBSR and 20 wait-list controls) to fit comfortably in a room. This number is feasible in the practice context and will enable examination of study objectives. To achieve this goal, 48 participants from the interprofessional primary care team will be recruited to account for an expected 20% attrition rate based on other feasibility studies (30, 47).

Recruitment

Participants will be recruited within the interprofessional primary care clinic. Posters will be placed in the waiting area, clinic and physician consult rooms and other interdisciplinary primary care providers may also inform potential participants about the study. Interested participants will be instructed to call the principle investigator (PI) who will explain the purpose of the research and study activities. If interested, participants will be scheduled for an intake assessment to screen for study eligibility. If eligible, the informed consent process will be reviewed with the individual, written consent obtained, and then randomization into one of the two groups will be completed.

Treatment allocation and randomization

A block size design of four will be used to balance participants in the control or intervention groups. The block size design of four will randomly allocate two participants in the control and two in the intervention group resulting in six different possible block combinations, ideal for this feasibility study with a sample size of 40 participants. A research staff member, not

involved in the trial, will design and prepare the randomization sequence in sealed opaque envelopes to ensure allocation concealment for distribution. All research staff, including the PI, will be blinded to the randomization list. At screening, if participants are eligible, the PI (first author) will obtain informed consent, assign participants a study number and collect baseline data. Last, a randomization envelope with the same study number of the participant will be opened, and allocation will be to one of the two treatment groups (48), intervention (Group 1) or a wait-list control (Group 2). The wait-list control group will receive the MBSR intervention three months later when the experimental group is completed.

Blinding

The PI will assess baseline outcome measures for eligible participants at T1-week-1. A blinded independent assessor will evaluate post-intervention at T2-week-8 and at T3-week-12, to minimize bias. The wait-list control (Group 2) is assessed at T2-week-8 and T3-week-12, along with the intervention (Group 1). To minimize unblinding, a research volunteer will provide reminder calls for the participants' assessment date and time and will remind them not to disclose which group they are in during their assessment. Also, the independent assessor will again instruct all participants not to disclose which group they are in prior to their assessment. Due to the nature of the population with cognitive impairment, some participants may disclose their group unintentionally to the assessor. If unblinding occurs, it will be documented which participant disclosed, and it will be noted in the analysis. The Qualified-MBSR teachers delivering the intervention cannot be blinded to the group allocation as they are providing the intervention being tested. Similarly, unblinding may occur if participants guess which group they are in (e.g. intervention or control) however, participants are unable to confirm until after the study is completed.

Data Management

The technical support department at the interprofessional primary care clinic will encrypt all computer tablets before distributing them to the intervention participants. The independent assessor will be in charge of data management including and data entry. All original hard copies of the study data, including questionnaires, teacher notes will be kept under lock and key in a secure location within the clinic. The PI will be responsible for overseeing the entire study and ensure timelines are met, data is cleaned, accurate and any missing values are identified. The committee from Queen's University and the University of Toronto will service the role of data monitoring committee (DMC) as part of PI's Ph.D. research program.

Qualitative data will be collected from both MBSR teachers and participants. MBSR teacher data will include weekly field notes and weekly meeting notes. A research assistant will conduct semi-structured interviews with each MBSR teacher at the completion of the intervention. Qualitative participant data will include open-ended feedback surveys at week-4 (mid-point) and week-8 (program completion) and a focus group that will be conducted at the end of the MBSR program. A research assistant will conduct a focus group using a guided script that will be an hour in duration. The focus group will explore satisfaction (e.g. intervention and delivery), acceptability, perceived value, barriers and facilitators of the 8-week occupational therapist-led MBSR program in primary care.

Qualitative Analysis

Participant focus group and individual MBSR teacher interviews will be audio-recorded and transcribed verbatim. All transcripts will be de-identified and pseudonyms will be given to each of the participants. Transcripts will be read and re-read by both the PI and the research team. An inductive process of sorting, initial coding and grouping the data into broad topic-oriented categories, which is refined into fewer analytical themes, will be used (49). Critical discussion with the research staff of emerging themes will occur throughout the analysis process. The qualitative software package NVivo 11 (QSR International) will be used to support the analysis.

To enhance trustworthiness, member checking will be used as a strategy (50). Peer debriefing, triangulation, and an audit trail will be used to clarify interpretations of the data that may identify possible sources of bias. Each of these strategies will enhance trustworthiness to ensure dependability, credibility and transferability in the qualitative analysis (51).

Quantitative Analysis

The primary and secondary outcome measures will be analyzed by the PI using IBM Statistical Package for Social Sciences software (SPSS). A biostatistician will be consulted to provide an arms-length review of the analysis. Every attempt to minimize missing data will be implemented; however, the research team will use intent-to-treat (ITT), an approach that includes every participant. The ITT analysis will preserve the same sample size and reduce type I error. As a feasibility study with a small sample size, missing data is dealt with by using the last observation carried forward (LOCF) method, where the last available measurement for each participant at the point before withdrawal from the study, is retained and used in the analysis. In a future larger study, researchers will undertake a more sophisticated approach to allow additional factors to account for attrition (52).

Baseline differences between the two groups will be tested using two-sample t-tests for normal distribution variables using the Shapiro-Wilk test and chi-squared tests for categorical variables. Determining differences in clinical outcomes is not the object of this study. However, comparisons will be undertaken to investigate the estimates of the treatment effects for these potential clinical outcomes. Baseline at T1-week-1 to T2-week-8 and T1-week-1 to T3-week-12 will be analyzed relative to change from baseline using one-way repeated analysis of variance (ANOVA) for each participant and outcome measure. However, if there are any differences between the two groups, an analysis of covariance (ANCOVA) will be performed and adjustments will be made for baseline scores, as appropriate e.g. age, sex and education as possible confounders. For clinical outcome data, results will be reported as between-group mean, SD, change scores, and treatment effects with a confidence interval (CI) at 95%. Significance levels and Cohen's *d* effect sizes will be reported at 95% CI (53). Similarly, feasibility and acceptability outcomes will be analyzed using descriptive statistics (e.g. adherence, attrition, frequency and duration logins) of intervention at baseline and the post-intervention outcome will be undertaken.

(*Insight Timer - App metrics*):

The number of login (frequency) and length of home practice (duration) are extracted by the following: days, weeks, months and total hours overall for the duration of the MBSR program. Descriptive statistics, including paired-sample *t*-tests or Wilcoxon, signed rank tests, is conducted to compare pre-post change scores on outcomes.

Benefits of Participants

This protocol has been designed to explore the feasibility of conducting an RCT to determine whether an 8-week MBSR program is feasible for a future larger clinical trial. There is growing recognition that interprofessional primary care teams are able to better support individuals with complex health conditions as compared to physician care alone. This study will be the first to explore the feasibility of an occupational therapist-led MBSR program and provide valuable insights as to how MBSR can be best delivered with this population. In addition, this study will provide details to better implement this intervention with the use of technology, such as computer tablets to deliver the MBSR program. Last, findings from this trial, if successful, will lay the foundation for a larger clinical trial. This study will highlight the possible benefits of MBSR and evaluation as a way to support psychological symptoms for those living with early memory issues within interprofessional primary care context.

Patient and public involvement

Patients and public members were not invited to provide feedback on the study design and the conduct of carrying out the study. The main results of the study will be disseminated to participants either through a letter or a face-to-face meeting if interested with respect to their results from baseline and end-of-study assessments.

References

1. Canada Year Book. Seniors 2011 [Available from: https://www150.statcan.gc.ca/n1/pub/11-402-x/2011000/chap/seniors-aines/seniors-aines-eng.htm.
2. Zuniga KE, Mackenzie MJ, Kramer A, McAuley E. Subjective memory impairment and well-being in community-dwelling older adults. Psychogeriatrics. 2016;16(1):20-6.
3. Jessen F, Amariglio RE, van Boxtel M, Breteler M, Ceccaldi M, Chételat G, et al. A conceptual framework for research on subjective cognitive decline in preclinical Alzheimer's disease. Alzheimer's & Dementia: The Journal of the Alzheimer's Association. 2014;10(6):844-52.
4. Langa KM, Levine DA. The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review. JAMA. 2014;312(23):2551-61.
5. Petersen RC, Caracciolo B, Brayne C, Gauthier S, Jelic V, Fratiglioni L, et al. Mild cognitive impairment: a concept in evolution. Journal of Internal Medicine. 2014;275(3):214-28.
6. American Psychiatric A, American Psychiatric Association DSMTF. Diagnostic and statistical manual of mental disorders: DSM-5. 5th ed. Washington, D.C: American Psychiatric Association; 2013.
7. Belchior P, Korner-Bitensky N, Holmes M, Robert A. Identification and assessment of functional performance in mild cognitive impairment: A survey of occupational therapy practices. Australian Occupational Therapy Journal. 2015;62(3):187-96.
8. De Vriendt P, Gorus E, Cornelis E, Velghe A, Petrovic M, Mets T. The process of decline in advanced activities of daily living: a qualitative explorative study in mild cognitive impairment. International Psychogeriatrics. 2012;24(6):1-13.
9. Joosten-Weyn Banningh EWA, Vernooy-Dassen MJFJ, Olde Rikkert MGM, Teunisse JPWM. Mild cognitive impairment: coping with an uncertain label. International Journal of Geriatric Psychiatry. 2008;23(2):148-54.
10. Regan B, Varanelli L. Adjustment, depression, and anxiety in mild cognitive impairment and early dementia: a systematic review of psychological intervention studies. International psychogeriatrics / IPA. 2013;25(12):1963.
11. Andreescu C, Varon D. New Research on Anxiety Disorders in the Elderly and an Update on Evidence-Based Treatments. Current Psychiatry Reports. 2015;17(7):1-7.
12. Sepehry AA, Lee PE, Hsiung GYR, Beattie BL, Jacova C. Effect of selective serotonin reuptake inhibitors in Alzheimer's disease with comorbid depression: a meta-analysis of depression and cognitive outcomes. Drugs & ageing. 2012;29(10):793.
13. Kok RM, Reynolds CF. Management of Depression in Older Adults: A Review. JAMA. 2017;317(20):2114-22.
14. Dhalwani NN, Fahami R, Sathanapally H, Seidu S, Davies MJ, Khunti K. Association between polypharmacy and falls in older adults: a longitudinal study from England. BMJ Open. 2017;7(10):e016358-e.
15. Moniz-Cook E. Psychosocial interventions through memory clinics. Nursing & Residential Care. 2011;13(4):189-92.
16. Wells RE, Kerr CE, Wolkin J, Dossett M, Davis RB, Walsh J, et al. Meditation for Adults with Mild Cognitive Impairment: A Pilot Randomized Trial. Journal of the American Geriatrics Society. 2013;61(4):642-5.

17. Smart CM, Segalowitz SJ, Mulligan BP, Koudys J, Gawryluk JR. Mindfulness Training for Older Adults with Subjective Cognitive Decline: Results from a Pilot Randomized Controlled Trial. Journal of Alzheimer's disease 2016;52(2):757.
18. Smoski MJ, McClintock A, Keeling L. Mindfulness Training for Emotional and Cognitive Health in Late Life. Current Behavioral Neuroscience Reports. 2016;3(4):301-7.
19. Geiger PJ, Boggero IA, Brake CA, Caldera CA, Combs HL, Peters JR, et al. Mindfulness-Based Interventions for Older Adults: a Review of the Effects on Physical and Emotional Well-Being. Mindfulness. 2016;7(2):296-307.
20. Creswell JD, Irwin MR, Burklund LJ, Lieberman MD, Arevalo JMG, Ma J, et al. Mindfulness-Based Stress Reduction training reduces loneliness and pro-inflammatory gene expression in older adults: A small randomized controlled trial. Brain, Behavior, and Immunity. 2012;26(7):1095-101.
21. Splevins K, Smith A, Simpson J. Do improvements in emotional distress correlate with becoming more mindful? A study of older adults. Ageing & Mental Health. 2009;13(3):328-35.
22. Black DS, O'Reilly GA, Olmstead R, Breen EC, Irwin MR. Mindfulness Meditation and Improvement in Sleep Quality and Daytime Impairment Among Older Adults With Sleep Disturbances: A Randomized Clinical Trial. JAMA Internal Medicine. 2015;175(4):494-501.
23. Foulk MA, Ingersoll-Dayton B, Kavanagh J, Robinson E, Kales HC. Mindfulness-Based Cognitive Therapy With Older Adults: An Exploratory Study. Journal of Gerontological Social Work. 2014;57(5):498-520.
24. Knopman DS, Petersen RC. Mild cognitive impairment and mild dementia: a clinical perspective. Mayo Clinic proceedings. 2014;89(10):1452-9.
25. Ciro CA. Maximizing ADL Performance to Facilitate Ageing in Place for People with Dementia. Nursing Clinics of North America. 2014;49(2):157-69.
26. Chan A-W, Tetzlaff J, Altman D, Laupacis A, Gøtzsche P, Krleza-Jeric K, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Annals of Internal Medicine. 2013;153(3):200-7.
27. Kabat-Zinn J, University of Massachusetts Medical Center/Worcester. Stress Reduction C. Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness. Delta trade pbk. reissue, 15th anniversary ed. New York, N.Y: Delta Trade Paperbacks; 2009.
28. Timer I. Insight Timer (version 2019) [Mobile Application Software] Retreived from https://insighttimer.com. 2019.
29. Gearing RE, El-Bassel N, Ghesquiere A, Baldwin S, Gillies J, Ngeow E. Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. Clinical Psychology Review. 2011;31(1):79-88.
30. Aguirre E, Stott J, Charlesworth G, Noone D, Payne J, Patel M, et al. Mindfulness-Based Cognitive Therapy (MBCT) programme for depression in people with early stages of dementia: study protocol for a randomised controlled feasibility study. 2017;3.
31. Perepletchikova F, Kazdin AE. Treatment Integrity and Therapeutic Change: Issues and Research Recommendations. Clinical Psychology: Science and Practice. 2005;12(4):365-83.
32. Law M, Canadian Association of Occupational T. Canadian Occupational Performance Measure. 4th ed. Ottawa, Ont: Canadian Association of Occupational Therapists; 2005.
33. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. 2001;16(9):606-13.

34. Phelan E, Williams B, Meeker K, Bonn K, Frederick J, Logerfo J, et al. A study of the diagnostic accuracy of the PHQ-9 in primary care elderly. BMC family practice. 2010;11(1):63-.
35. Pachana NA, Byrne GJ, Siddle H, Koloski N, Harley E, Arnold E. Development and validation of the Geriatric Anxiety Inventory. International Psychogeriatrics. 2007;19(1):103-14.
36. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. Journal of Health and Social Behavior. 1983;24(4):385-96.
37. Feldman G, Hayes A, Kumar S, Greeson J, Laurenceau J-P. Mindfulness and Emotion Regulation: The Development and Initial Validation of the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R). Journal of Psychopathology and Behavioral Assessment. 2007;29(3):177-90.
38. Logsdon RG, Gibbons LE, Teri L, McCurry SM. QUALITY OF LIFE IN ALZHEIMER'S DISEASE: LONGITUDINAL PERSPECTIVES. The Gerontologist. 1999;39:164.
39. Hayes SC, Strosahl K, Wilson KG, Bissett RT, Pistorello J, Toarmino D, et al. Measuring experiential avoidance: A preliminary test of a working model. The Psychological Record. 2004;54(4):553-78.
40. Carswell A, McColl MA, Baptiste S, Law M, Polatajko H, Pollock N. The Canadian Occupational Performance Measure: A Research and Clinical Literature Review. Canadian Journal of Occupational Therapy. 2004;71(4):210-22.
41. Donnelly C, Carswell A. Individualized Outcome Measures: A Review of the Literature. Canadian Journal of Occupational Therapy. 2002;69(2):84-94.
42. Tuntland H, Aaslund MK, Langeland E, Espehaug B, Kjeken I. Psychometric properties of the Canadian Occupational Performance Measure in home-dwelling older adults.(ORIGINAL RESEARCH). Journal of Multidisciplinary Healthcare. 2016;9(1):411.
43. Lee E-H. Review of the Psychometric Evidence of the Perceived Stress Scale. Asian Nursing Research. 2012;6(4):121-7.
44. Logsdon RG, Gibbons, L.E. McCurry, S.,M., Teri, L. Quality of Life in Alzheimer's Disease: Patient and Caregiver Reports Journal of Mental Health and Ageing. 1999;5(1):21-32.
45. Bond FW, Hayes SC, Baer RA, Carpenter KM, Guenole N, Orcutt HK, et al. Preliminary Psychometric Properties of the Acceptance and Action Questionnaire–II: A Revised Measure of Psychological Inflexibility and Experiential Avoidance. Behavior Therapy. 2011;42(4):676-88.
46. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and Commitment Therapy: Model, processes and outcomes. Behaviour Research and Therapy. 2006;44(1):1-25.
47. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
48. Altman DG. Avoiding bias in trials in which allocation ratio is varied. Journal of the Royal Society of Medicine. 2018;111(4):143-4.
49. Clarke V, Braun V. Thematic analysis. The Journal of Positive Psychology. 2017;12(3):297-8.
50. Connelly LM. Trustworthiness in Qualitative Research. Medsurg nursing : official journal of the Academy of Medical-Surgical Nurses. 2016;25(6):435.
51. Hadi MA, José Closs S. Ensuring rigour and trustworthiness of qualitative research in clinical pharmacy. International Journal of Clinical Pharmacy. 2016;38(3):641-6.
52. Wong WK, Boscardin WJ, Postlethwaite AE, Furst DE. Handling missing data issues in clinical trials for rheumatic diseases. Contemporary Clinical Trials. 2011;32(1):1-9.

53. Evans A. Using basic statistics in the behavioral and social sciences. Fifth ed. Thousand Oaks, California: SAGE Publications, Inc; 2014.

Data Statement:
Technical appendix, statistical code, and dataset available from the Dryad repository, DOI:

Author Contribution Statement:

Todd Tran (Principal Investigator, Occupational Therapist and Ph.D. Candidate)
I came up with the conception of the design of the study, along with conducting and will be responsible for the reporting of the study. I am also responsible for achieving the overall timelines and wrote this manuscript.

Catherine Donnelly Ph.D. (Associate Professor)
Catherine is heavily involved in this study by providing supervision, planning, conducting and instrumental in providing feedback on this manuscript. This manuscript would not have been written without many hours of contribution.

Emily Nalder Ph.D. (Assistant Professor)
Emily provided support at the inception of the design of the study design and also provided instrumental feedback, both verbal and written, on this manuscript. This manuscript would not have in the state it would be without her valuable comments and clinical support.

Tracy Trothen Th.D. (Professor who provided written guidance)
Tracy provided valuable feedback around the ethics of running such a trial by providing valuable comments and feedback at the conception and design of the current study.

Marcia Finlayson Ph.D. (Professor who provided substantial feedback)
Marcia provided insightful comments and feedback on this manuscript from the inception of the idea to the design and implementation of this study. Marcia is an experienced researcher that provided a tremendous amount of guidance to allow for this study to be viable and for it to be replicable.

Acknowledgements (non-authors):

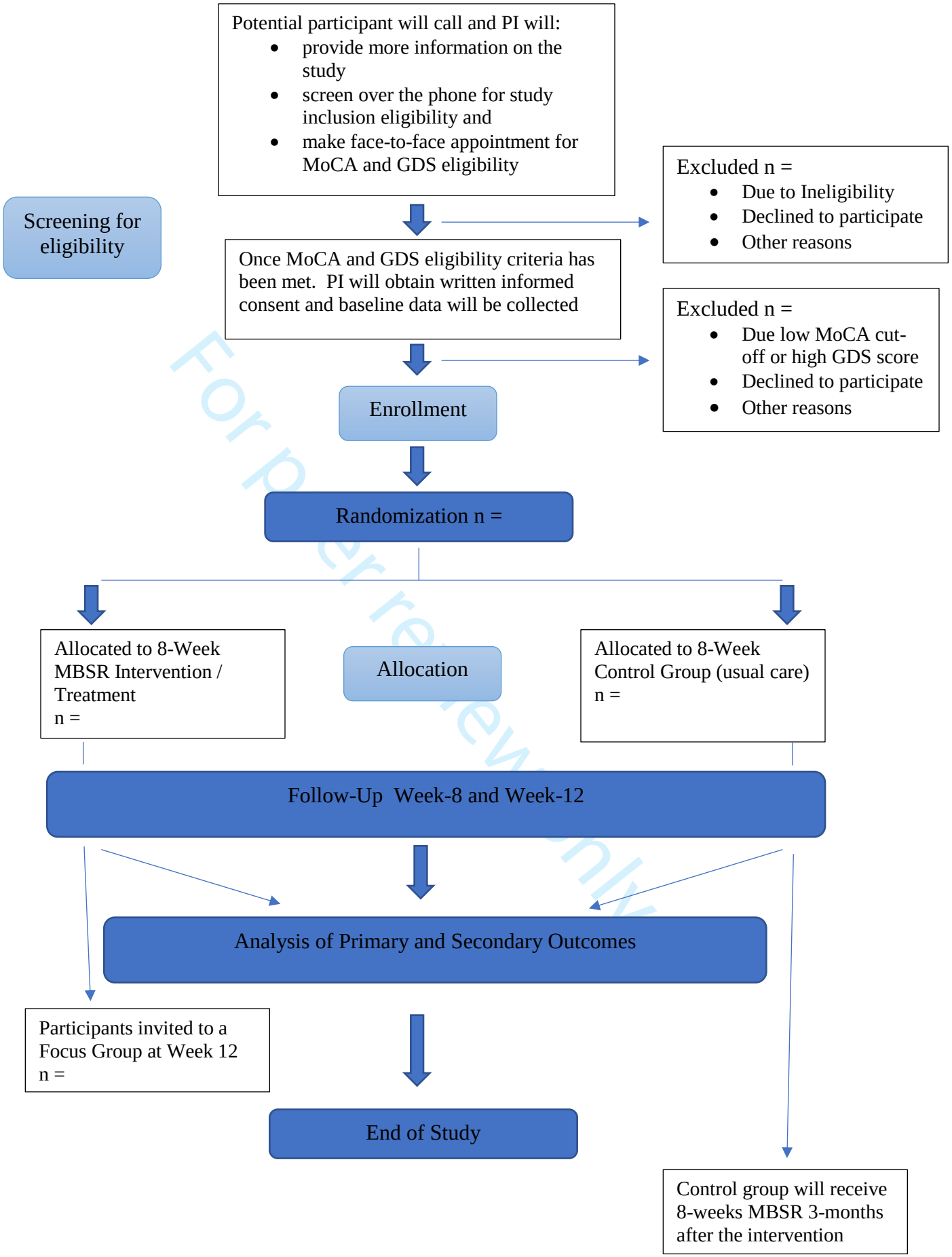
Kareena Gurbaxani
Jaisa Sulit
Mubeenaa Rahman
Virginia Vander Hyden
Sarah Scheffe
Ken Callaghan
Dr. Ruth Heisey
Susan Hum

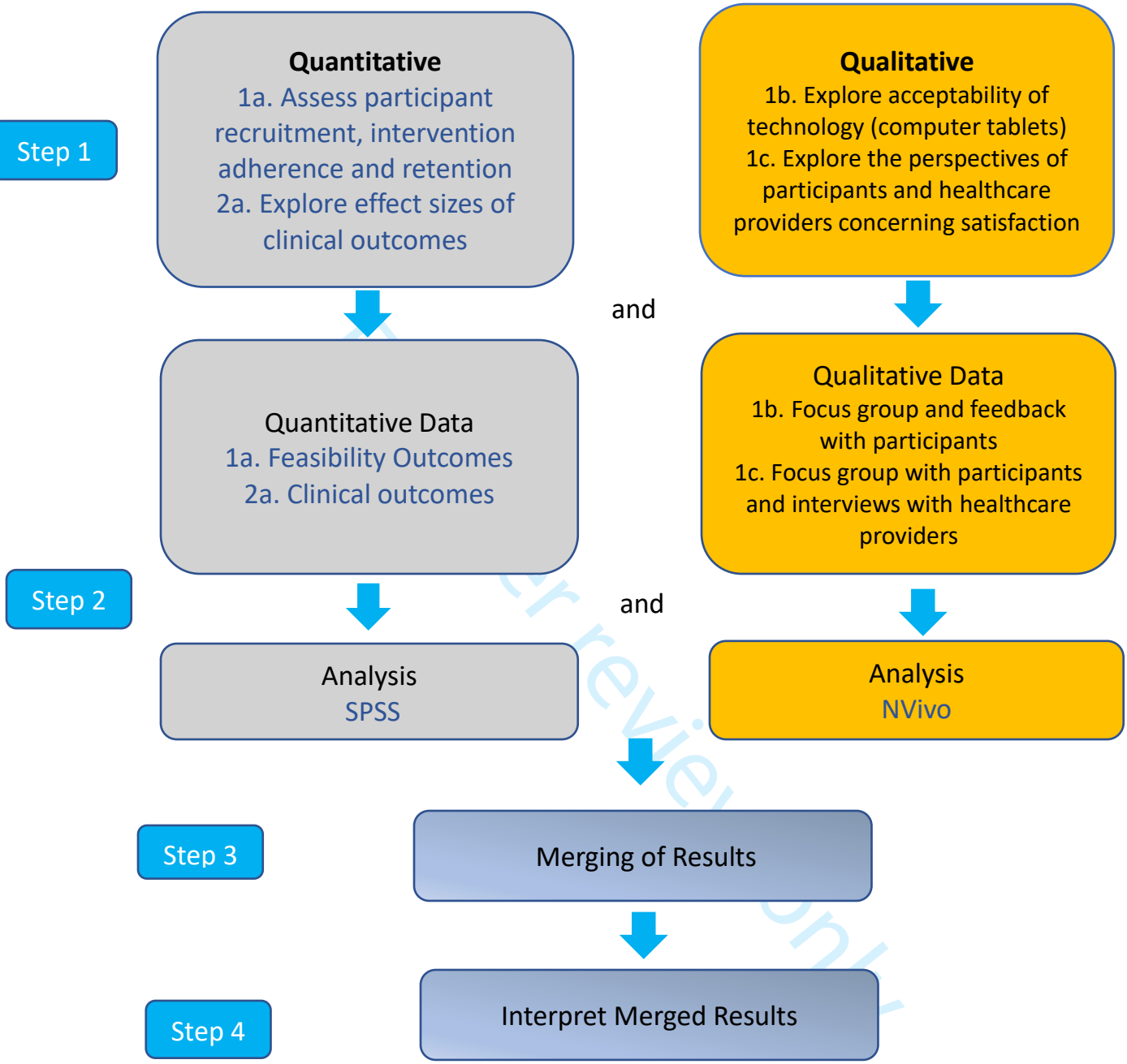
Figure legend/caption (in the following order):

1. **Table 1.** "Timeframe of Measurement for participants in MBSR Intervention" (*to be placed around page 11 before sample size section or to your discretion*)
   Abbreviations: MBSR, Mindfulness-Based Stress Reduction; MoCA, Montreal Cognitive Assessment; GDS, Geriatric Depression Scale; COPM, Canadian Occupational Performance Measure; PHQ-9, Patient Health Questionnaire; GAI, Geriatric Anxiety Inventory; CAMS-R, The Cognitive and Affective Mindfulness Scale-Revised; PSS. Perceived Stress Scale; QoL-AD, Quality-of-Life in Alzheimer's Disease; AAQ-II, Acceptance and Action Questionnaire

2. **Figure 1.** "SPIRIT-flow diagram of participants through the study" (*anywhere after Blinding section*)

3. **Figure 2.** "Protocol Flowchart" (*to be at the end of the paper before the Benefits of Participants section?)*
4.





BMJ Open

An occupational therapist-led mindfulness-based stress reduction for older adults living with subjective cognitive decline or mild cognitive impairment in primary care: a feasibility randomized control trial protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2019-035299.R2
Article Type:	Protocol
Date Submitted by the Author:	31-Mar-2020
Complete List of Authors:	Tran, Todd; Women's College Hospital, Family Practice; Queen's University, Aging and Health Donnelly, Catherine; Queen's University Faculty of Health Sciences, Rehabilitation Therapy Nalder, Emily; University of Toronto, Occupational Science and Occupational Therapy; March of Dimes Canada, Trothen, Tracy; Queen's University Faculty of Health Sciences Finlayson, Marcia ; Queen's University, School of Rehabilitation Therapy
Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Evidence based practice
Keywords:	PRIMARY CARE, MENTAL HEALTH, Anxiety disorders < PSYCHIATRY, Delirium & cognitive disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Old age psychiatry < PSYCHIATRY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

An occupational therapist-led Mindfulness-Based Stress Reduction for older adults living with subjective cognitive decline or mild cognitive impairment in primary care: A feasibility randomized control trial protocol

Keywords: mindfulness, occupational therapy, subjective cognitive decline, mild cognitive impairment, primary care, interprofessional primary care

Protocol Version: March 30th, 2020 version 5.0

Authorship (my research team – are the only people to have access to research data)

(1) Todd Tran; Principal Investigator; *Occupational Therapist, PhD (cand);* Todd.Tran@wchospital.ca (corresponding author)
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada

Clinical Site: Women's College Hospital
76 Grenville St.
Toronto, Ontario, M5S 1B2, Canada
1-416-301-5881

(2) Catherine Donnelly; *Associate Professor*; Catherine.Donnelly@Queensu.ca
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-533-6385

(3) Emily Nalder; *Assistant Professor;* Emily.Nalder@utoronto.ca
University of Toronto
Department of Occupational Science & Occupational Therapy
500 University Ave., Toronto, ON, M5G 1V7, Canada
1-416-978-5937

(4) Tracy Trothen; *Professor;* Tracy.Trothen@Queensu.ca
Queen's University

Jointly appointed to the School of Rehabilitation Therapy
and School of Religion (Theological Hall)
Louise D. Acton Building

31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-273-8438

(5) Marcia Finlayson; *Professor, Director of School of Rehabilitation Therapy, Vice Dean of Health Sciences;* **Marcia.Finlayson@Queensu.ca**
Queen's University
School of Rehabilitation Therapy
Louise D. Acton Building
31 George Street, Kingston, Ontario, K7L 3N6, Canada
1-613-533-2576

Competing Interest: There is no competing interest to declare as there is no financial interest; however, this is Principal Investigator's doctoral dissertation. The co-authors are Ph.D. committee members involved in overseeing study in its entirety, from data management to data monitoring, which is independent of the funders and has no competing interests. The committee and supervisor will be conducting the interim results and will make the final decision to terminate the trial at any point in time if deemed appropriate. Thus, auditing will also be done weekly with support from the supervisor, independent from the funders. Funding sources had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.

Word count: (approximately 4000 words)

Funding:

Centre for Ageing & Brain Health Innovation
3560 Bathurst Street
Toronto, ON
M6A 2E1 Canada

And

VHA Home HealthCare
30 Soudan Avenue, Suite 600
Toronto, ON
M4S 1V6

Abstract

Introduction: Community-dwelling older adults living with subjective cognitive decline (SCD) or mild cognitive impairment (MCI) may experience decreased efficiency in their overall functional performance. This decreased cognitive efficiency may result in anxiety, low mood, perceived stress, and decreased emotional well-being and quality-of-life. These psychological symptoms may further exacerbate cognitive decline.

Exploring non-pharmacological interventions such as mindfulness within primary care is vital in enabling individuals to develop strategies to manage cognitive impairment or psychological symptoms. Mindfulness-Based Stress Reduction (MBSR) is an 8-week program that is beneficial in alleviating psychological symptoms; however, its impact on perceived satisfaction on overall functional performance with this population has not been evaluated. The primary objective of this study is to explore the feasibility of conducting an RCT of an occupational therapist-led MBSR program within primary care.

Methods: Convergent mixed-methods, randomized control feasibility trial with 40 participants from an interprofessional primary care team in Toronto, Ontario. Participants are randomized into the 8-week MBSR group or wait-list control will be compared at baseline, post-intervention and four-weeks follow-up. The primary aim is to determine the feasibility of the intervention with this population and setting. The secondary aim is to examine perceived satisfaction with functional performance as measured by the Canadian Occupational Performance Measure (COPM). Secondary clinical outcomes include psychological symptoms.

Analysis: Investigators will analyze the quantitative and qualitative data strands separately. Descriptive statistics, focus group and interviews will then be merged and further analyzed to best understand the feasibility and preliminary clinical outcomes from the study.

Ethics and dissemination: The study is approved by Women's College Hospital (2017-0056-E), and Queen's University, Kingston, Ontario (6026418). This study is registered at Clinicaltrials.gov (NCT03867474). The study will follow Standard Protocol Items: Recommendations for Interventional Trials. The results will be published in peer-reviewed academic journals and disseminated to patient organizations and media.

Strengths and limitations of this study

- The study will provide valuable data on feasibility and clinical outcomes to determine whether occupational therapist-led MBSR is appropriate for a larger clinical trial
- The first study to use the COPM to evaluate perceived satisfaction on functional performance with community-dwelling older individuals living with SCD or MCI within an interprofessional primary care context
- The only study to explore the qualitative perspective of both participants and health care providers in terms of barriers, enablers and facilitators of implementing and delivering the MBSR program within a primary care setting

- The study is innovative in exploring the acceptability of a tablet computer as a method of intervention delivery and data collection with this population

- The lack of an attention control comparison group and the small sample size is a study limitation

Introduction

By 2036, approximately one-in-four Canadians will be 65 years and over (1), and an estimated one-third of community-dwelling older adults will experience memory complaints (2). The earliest sign of memory impairment is subjective cognitive decline (SCD), a self-reported decline in cognition without "objective evidence," characterized by increasing compensatory cognitive efforts and subtle cognitive decline (3). If SCD is to decline further, the next stage is mild cognitive impairment (MCI), with 10 - 20% of older adults developing MCI by age 65 (4). MCI is clinically characterized as: (i) concern raised by the individual or an informant, or clinician, (ii) cognitive impairment in one or more cognitive domains relative normative data for that individual, and (iii) preservation of functional independence (5, 6).

There is a large body of evidence that demonstrates that those living with memory complaints face a decline in performance of everyday tasks, most notably in complex instrumental activities-of-daily living (iADLs) (7). These functional changes result in a general sense of decreased satisfaction and discontentment with their overall functional performance (8).

Living with SCD or receiving a diagnosis of MCI is usually life-altering and has been found to have a negative impact on an individual's emotional health and well-being (9), with an increased risk of depression and anxiety disorders (10). There is limited evidence that supports the use of pharmacologic interventions to improve concomitant anxiety disorders (11) and depression among those living with cognitive impairment (12). Medications may increase the risk of adverse side-effects, especially for those with multiple comorbidities, including drug complications (13) and falls (14). Exploring non-pharmacologic interventions to mitigate psychosocial factors and to support functional performance is critical (10, 15). Successful adaptive coping strategies to improve depression and anxiety symptoms in this population are essential to prevent and/or delay further cognitive decline (10).

Evidence from the past 20 years suggests that mindfulness meditation, such as Mindfulness-Based Stress Reduction (MBSR), could benefit those living with SCD and MCI (16, 17). MBSR may be neuroprotective against cognitive decline as it has been found to produce brain changes along with decreased cognitive complaints and increased memory self-efficacy (17). Furthermore, a small proof-of-concept study identified that MBSR is feasible with older adults living with MCI and that it may positively affect QoL and well-being (16). This study will build on these proof-of-concept and pilot studies as MBSR has demonstrated mental health benefits, including the reduction of emotional distress and worry (18, 19).

Other studies have demonstrated that mindfulness helps older adults with loneliness, depression, anxiety, and sleep problems (19-23) in general community settings and secondary care, e.g., neurology clinics. However, primary care providers are often the first point of contact

when older adults and their families are concerned about cognitive problems (24). There is an increasing emphasis on interprofessional primary care teams or patient medical homes to address the challenges of an ageing population. Currently, no studies to date have examined the feasibility of MBSR for those living with SCD or MCI receiving care from interprofessional primary care teams. A growing number of occupational therapists working in primary care teams are ideally positioned to support individuals with SCD and MCI through their expertise in understanding the impact of cognitive impairment on daily function. Examining effective interventions such as an occupational therapist-led, MBSR for individuals at the early stages of cognitive changes is critical to support ageing-in-place (25).

The overarching purpose is to determine whether occupational therapist-led MBSR in primary care is appropriate for a larger clinical trial in the future. The study has two aims:

Primary Aim:

To explore the feasibility of conducting an RCT of an occupational therapist-led, 8-week MBSR program in an interprofessional primary care setting. The following objectives will assess feasibility outcomes:

1a. Assess participant recruitment, intervention adherence, and study retention (Quantitative)
1b. Explore the acceptability of using tablet computer technology to support intervention, delivery and data collection in the MBSR program (Qualitative)
1c. Explore the perspectives of participants and healthcare providers concerning satisfaction (e.g., the intervention and its' delivery), perceived value, and barriers and facilitators of implementation of the MBSR program in a primary care setting (Qualitative)

Secondary Aim:

To evaluate the effect sizes of satisfaction on functional performance as a primary clinical outcome and psychological symptoms as secondary clinical outcomes in individuals with SCD or MCI completing an 8-week MBSR program in an interprofessional primary care setting. (Quantitative)

Methods

This study will use a convergent mixed-methods, single-blind RCT with two parallel groups and will follow SPIRIT reporting (26) guidelines for randomized feasibility trials. See Trial Design **(See Figures 1 and 2)**. There will be three assessment time points: Baseline (Time-1) at week-0, on completion of the intervention (Time-2) at week-8, and one-month post-intervention follow-up (Time-3) at week-12.

Study Setting

The study will take place at an interprofessional primary care clinic in the province of Ontario, Canada. Interprofessional team members include occupational therapy, physiotherapy, nursing, pharmacy, social work, and dietetics. There are approximately 18,000 rostered patients with the clinic.

Eligibility Criteria

To qualify for the study, participants will be screened using the Montreal Cognitive Assessment (MoCA), with a score of 22 or greater and a Geriatric Depression Scale (GDS) score of 6 or lower to be eligible to participate in the study. Scores of greater than 7 on the GDS and lower than 22 on the MoCA will warrant further assessment with their family physician and will be excluded from the study. The inclusion and exclusion criteria are:

Inclusion Criteria:

(1) Age $\geq$ 60 years
(2) English fluency
(3) Living independently (non-assisted living, e.g. retirement or any long-term care facility; self-report)
(4) Have a self-reported SCD or an MCI diagnosis in their chart
(5) Must be a patient with the interprofessional primary care clinic

Exclusion Criteria:

(1) History of prior participation in any MBSR or other mindfulness-based interventions in the past or having 2-3 times per week or more of either mindfulness or yoga practice
(2) Current history of significant medical (e.g. cancer), neurological (e.g. brain injury) or psychiatric condition (e.g. depression with 6 or greater on the GDS), active psychosis, bereavement that significantly impacts on mood, i.e. depression
(3) Alcoholism or other substance abuse
(4) Participating in other cognitive or memory training programs in the community or is involved in another research study

Intervention/Treatment (MBSR) Group

Participants randomized to the intervention arm will participate in an 8-week MBSR program established in 1979 by Kabat-Zinn (27). Four occupational therapists, also Qualified-MBSR teachers, will be involved in the delivery of the intervention group. The traditional MBSR curriculum usually has two teachers, but due to the unique population with cognitive impairment and the use of tablet computers, having two additional MBSR teachers will be beneficial to assist with any issues that may arise, including technological issues or memory challenges. The group will be 3-hours in duration (with a 15-minute break) for 8-weeks, along with an orientation and one all-day retreat. Sessions will consist of: lying down (body scan), sitting (focusing on the breath), and mindful movement (yoga and walking). Daily home practice will be given to be performed for 30 to 45 minutes outside of class.

We will distribute a tablet computer (mini-iPad 3 model) to each participant to access the Application (App), Insight Timer (28), for the duration of the study. Insight Timer contains guided meditation homework practices, with homework accessed by logging directly into Insight Timer. All homework data will be downloaded at the end of the 8-week program. In addition to the App, all participants will be asked to record their home practice using pen and paper weekly

logs as a backup provided by the research team. If participants have difficulty with using tablets, additional support will be provided during or after class. If any participant does not have access to Wi-Fi, we will provide them with CDs for ease of adherence for their guided homework practices, and homework will be tracked exclusively using pencil and paper sheets. Similarly, if participants have difficulty with using tablet computers, switching to CDs will be offered as an alternative low technology option.

Monitoring of adherence will include (i) attendance records (ii) home practice logs (iii) tablet computer use (login, frequency, duration) and (iii) field notes from Qualified-MBSR teachers in regards to the level of participation, engagement and group process.

Any participants who experience emotional issues (e.g. increased anxiety, low mood) during the group will be referred to other health-care professionals on the interprofessional primary care team (e.g. social worker, consultant psychiatrists) for psychological support.

The control group (usual care) will be identical to the intervention group and will be offered the MBSR program three months after the intervention group.

Assessment of Intervention (MBSR) Treatment Fidelity

This study will use Gearing et al. (29) four major (intervention) fidelity components: *Design, Training, Delivery* and *Receipt*. The *design fidelity* of this feasibility RCT is to follow an existing eight-week protocol of MBSR following the authorized curriculum guide from the University of Massachusetts, Medical School, Center for Mindfulness in Medicine, Health Care and Society. Design fidelity will be met by ensuring: a fixed number and length of sessions, following the scripted manual for the course, including external monitoring by the research team, recording any protocol deviations based on the population, monitoring of the home practice logs.

The *training fidelity* is significant as the teacher's embodiment of mindfulness is central to the participant's learning within the 8-week curriculum. To maintain training fidelity, three facilitators are Qualified-MBSR teachers who have undergone training at the University of Massachusetts, Medical School; one facilitator has equivalent MBSR-qualifications from a different institution in Toronto, Canada using the same standardized MBSR treatment manuals. All qualified-MBSR Teachers have over three years of facilitating MBSR groups. Training fidelity will be met by: teachers meeting regularly to debrief, using the same teachers for the duration of the 8-weeks, and lastly, participant focus group inquiring about the curriculum will be used.

Delivery fidelity is the implementation of the MBSR curriculum by following both the MBSR curriculum protocol from the University of Massachusetts, Medical School and the Mindfulness-Based Interventions Teaching Assessment Criteria (MBI:TAC); a tool that assesses mindfulness-based teaching integrity that will be used as a guide to support the delivery of the MBSR curriculum. Delivery fidelity will also be measured by: participant focus group reflection of the teachers' embodiment of mindfulness practice, attendance, and intervention handouts provided for all participants along with tablet computers or CDs with home practice recordings.

Lastly, *receipt fidelity* will be achieved by attendance during the 8-week program, in conjunction with log-ins and doing the home practices on participant's computer tablets. Additionally, receipt fidelity will be met by: the collection of participant's weekly handwritten home practice log sheets and inquiry discussions during the weekly sessions. This demonstrates that participants are practicing the skills during the study period and are engaged and adherent to the program. However, any missing attendance or drop-outs will be followed-up with a telephone call.

Primary AIM: Feasibility Outcome Measures

As a feasibility study, the overarching purpose is to determine whether MBSR is worthwhile for a definitive larger clinical trial for community-dwelling older adults living with SCD or MCI in an interprofessional primary care setting.

Objective 1a: Feasibility Measures

i. Recruitment rate: will be defined as feasible for a future study if 30-40 participants are recruited within three to four months (May to August 2019), similar to other feasibility studies (30).

ii. Retention rate: will be deemed feasible if at least 75-80% of participants complete six or more of the nine sessions as well as a follow-up assessment at T3 based on other feasibility studies.

iii. Adherence rate: will be deemed to have adequate adherence for a future study if participants complete three logins per week and practice homework for at least 1.5 hours per week (duration), which would be deemed moderate adherence rate at 51-79 (29, 31). The treatment adherence rate is determined by the number of sessions completed in full (180 minutes).

Objective 1b: Acceptability of technology

iv. Acceptability of using a tablet computer as a tool for home practice delivery will be determined through. (i) field notes by Qualified-MBSR teachers documenting group participation, (ii) number of participants that switch from computer tablets to low technology for the homework practices during the duration of the 8-weeks, and (iii) focus groups at follow-up at the end of 8-weeks (T2) examining perceived value and benefits of using technology.

Objective 1c: Satisfaction with the MBSR program

v. The overall experience of the 8-week intervention will be evaluated by field notes, mid-way participants surveys, interviews with Qualified-MBSR teachers (T3-week-12) and participant focus groups (T2-week-8). The dimensions of satisfaction with the program will include length (number of weeks), difficulty (e.g. pacing, workload or other challenges), and session duration (e.g. too short, too long).

Secondary AIM: Clinical Outcome Measures

Demographic data will be collected at baseline (e.g. age, education, income, physical activity, etc.) along with primary and secondary clinical outcome measures.

Quantitative Data

The *primary clinical outcome* will be the average change scores on the perceived satisfaction with functional performance as measured by the *Canadian Occupational Performance Measure (COPM);* (32).

Secondary clinical outcomes will include mood, anxiety, perceived stress, mindfulness traits, QoL and acceptance, as shown:

1. Patient Health Questionnaire-9 (PHQ-9); (33, 34)
2. Geriatric Anxiety Inventory (GAI); (35)
3. Perceived Stress Scale (PSS); (36)
4. Cognitive and Affective Mindfulness Scale-Revised (CAMS-R); (37)
5. Quality of Life-Alzheimer's Disease (QoL-AD); (38)
6. Acceptance and Action Questionnaire (AAQ-II); (39)

Time of Outcome Measures

Outcome measures will be assessed at baseline (Time-1: week-1) on completion of the intervention at (Time-2: week-8) and one-month post-intervention follow-up (Time-3: week-12). **See Table 1**

Clinical Outcome Measures:

Primary Outcome

Canadian Occupational Performance Measure

The COPM is an individualized, client-centred outcome measure. Through a semi-structured interview, individuals identify areas of difficulty in the performance of everyday activities and satisfaction with their performance. Maximum of five activities can be identified, and each is rated on a 10-point scale for self-perceived performance and satisfaction for their functional performance. COPM demonstrates strong test-retest reliability for both the performance and satisfaction scores when tested a week apart (40) and has demonstrated good responsiveness (41). A change of at least 3 points or more is recommended to distinguish between older adults who report a clinically significant change compared to those who do not (42).

Secondary Outcome

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a self-administered tool that scores each of the 9 DSM-IV criteria as '0' (not at all) to '3' (nearly every day), giving a total score of 27 (33). PHQ-9 represents a reasonable alternative to the Geriatric Depression Scale with older adults in primary care settings (33, 34). The internal reliability of the PHQ-9 is excellent, with a Cronbach's of 0.89 in a PHQ-9 Primary Care Study, with excellent test-retest reliability. PHQ-9 has a sensitivity of 88% and a specificity of 88% for use in a population with major depression (33).

Geriatric Anxiety Inventory (GAI)

The GAI consists of 20 'Agree/Disagree' items designed to assess typical common anxiety symptoms for the last week (35). GAI was developed specifically for community-dwelling older adults. The GAI has high internal consistency (α = .76), as well as high inter-rater (r = .89) and test-retest (r = .86) reliability (35).

Perceived Stress Scale (PSS)

PSS is an assessment of the global appraisal of stress (36). The 10-item questionnaire examines stress of respondents using a 4-point scale (0-Never to 4-Very Often). The PSS has acceptable psychometric properties, with satisfactory test-retest reliability criterion assessed at >0.70 (43).

The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)

CAMS-R is a brief comprehensive measure designed to capture mindfulness based on Jon Kabat-Zinn's definition of mindfulness (37). The CAMS-R is a 10-item questionnaire with a 4-point scale (1 –Rarely to 4 -Almost Always) s and has demonstrated internal consistency reliability with Cronbach's alpha ranges from 0.61 to 0.81. The CAMS-R has also demonstrated concurrent validity with moderate to large correlation with other measures of mindfulness (r = 0.51 to 0.67) (37).

Quality-of-Life in Alzheimer's Disease (QoL-AD)

The QoL-AD is a 13-item questionnaire covering multiple domains including health, mood, living situation, memory, and money (44). The measure has demonstrated good test-retest reliability and strong inter-rater reliability with Cohen's kappa values >0.70. Internal consistency is also high with a Cronbach's alpha coefficient of 0.82 (38).

Acceptance and Action Questionnaire-II (AAQ-II)

The AAQ-II is a 7-item questionnaire that measures psychological flexibility-inflexibility and experiential avoidance (45). The measure has shown that psychological flexibility is a prominent factor in understanding psychological health (46). The AAQ-II has an alpha coefficient of 0.84 and demonstrates good test-retest reliability at 3-months at 0.81 and 12-months at 0.79 (45).

login**Table 1**

Timeframe of Measurements for participants in MBSR Intervention

Measures Taken	(Time 1)							(Time 2)	(Time 3)
Item	0-week	1-week	2-week	3-week	4-week	5-week	6-week	7-week	8-week (Post-MBSR)	12-week (Follow-Up)
Screening										
(MoCA and GDS)	X									
Feasibility Measures		X	X	X	X	X	X	X	X	X
Qualitative Measures										
Focus Group (Participants)									X	
Interview with MBSR teachers										X
Evaluations (Participants)					X				X	
Weekly Research Meeting Notes		X	X	X	X	X	X	X	X	
Weekly Field Notes		X	X	X	X	X	X	X	X	
Quantitative Measures										
COPM (Satisfaction / Performance)		X							X	X
PHQ-9 (Mood)		X							X	X
GAI (Anxiety)		X							X	X
CAMS-R (Mindfulness)		X							X	X
PSS (Stress)		X							X	X
QoL-AD (Quality-of-Life)	X							X	X	
AAQ-II (Acceptance)		X							X	X

Sample Size

The goal is to recruit approximately 40 participants (e.g. 20 MBSR and 20 wait-list controls) to fit comfortably in a room. This number is feasible in the practice context and will enable examination of study objectives. To achieve this goal, 48 participants from the interprofessional primary care team will be recruited to account for an expected 20% attrition rate based on other feasibility studies (30, 47).

Recruitment

Participants will be recruited within the interprofessional primary care clinic. Posters will be placed in the waiting area, clinic and physician consult rooms and other interdisciplinary primary care providers may also inform potential participants about the study. Interested participants will be instructed to call the principle investigator (PI) who will explain the purpose of the research and study activities. If interested, participants will be scheduled for an intake assessment to screen for study eligibility. If eligible, the informed consent process will be reviewed with the individual, written consent obtained, and then randomization into one of the two groups will be completed.

Treatment allocation and randomization

A block size design of four will be used to balance participants in the control or intervention groups. The block size design of four will randomly allocate two participants in the

control and two in the intervention group resulting in six different possible block combinations, ideal for this feasibility study with a sample size of 40 participants. A research staff member, not involved in the trial, will design and prepare the randomization sequence in sealed opaque envelopes to ensure allocation concealment for distribution. All research staff, including the PI, will be blinded to the randomization list. At screening, if participants are eligible, the PI (first author) will obtain informed consent, assign participants a study number and collect baseline data. Last, a randomization envelope with the same study number of the participant will be opened, and allocation will be to one of the two treatment groups (48), intervention (Group 1) or a wait-list control (Group 2). The wait-list control group will receive the MBSR intervention three months later when the experimental group is completed.

Blinding

The PI will assess baseline outcome measures for eligible participants at T1-week-1. A blinded independent assessor will evaluate post-intervention at T2-week-8 and at T3-week-12, to minimize bias. The wait-list control (Group 2) is assessed at T2-week-8 and T3-week-12, along with the intervention (Group 1). To minimize unblinding, a research volunteer will provide reminder calls for the participants' assessment date and time and will remind them not to disclose which group they are in during their assessment. Also, the independent assessor will again instruct all participants not to disclose which group they are in prior to their assessment. Due to the nature of the population with cognitive impairment, some participants may disclose their group unintentionally to the assessor. If unblinding occurs, it will be documented which participant disclosed, and it will be noted in the analysis. The Qualified-MBSR teachers delivering the intervention cannot be blinded to the group allocation as they are providing the intervention being tested. Similarly, unblinding may occur if participants guess which group they are in (e.g. intervention or control) however, participants are unable to confirm until after the study is completed.

Data Management

The technical support department at the interprofessional primary care clinic will encrypt all computer tablets before distributing them to the intervention participants. The independent assessor will be in charge of data management including and data entry. All original hard copies of the study data, including questionnaires, teacher notes will be kept under lock and key in a secure location within the clinic. The PI will be responsible for overseeing the entire study and ensure timelines are met, data is cleaned, accurate and any missing values are identified. The committee from Queen's University and the University of Toronto will service the role of data monitoring committee (DMC) as part of PI's Ph.D. research program.

Qualitative data will be collected from both MBSR teachers and participants. MBSR teacher data will include weekly field notes and weekly meeting notes. A research assistant will conduct semi-structured interviews with each MBSR teacher at the completion of the intervention. Qualitative participant data will include open-ended feedback surveys at week-4 (mid-point) and week-8 (program completion) and a focus group that will be conducted at the end of the MBSR program. A research assistant will conduct a focus group using a guided script that will be an hour in duration. The focus group will explore satisfaction (e.g. intervention and

delivery), acceptability, perceived value, barriers and facilitators of the 8-week occupational therapist-led MBSR program in primary care.

Qualitative Analysis

Participant focus group and individual MBSR teacher interviews will be audio-recorded and transcribed verbatim. All transcripts will be de-identified and pseudonyms will be given to each of the participants. Transcripts will be read and re-read by both the PI and the research team. An inductive process of sorting, initial coding and grouping the data into broad topic-oriented categories, which is refined into fewer analytical themes, will be used (49). Critical discussion with the research staff of emerging themes will occur throughout the analysis process. The qualitative software package NVivo 11 (QSR International) will be used to support the analysis.

To enhance trustworthiness, member checking will be used as a strategy (50). Peer debriefing, triangulation, and an audit trail will be used to clarify interpretations of the data that may identify possible sources of bias. Each of these strategies will enhance trustworthiness to ensure dependability, credibility and transferability in the qualitative analysis (51).

Quantitative Analysis

The primary and secondary outcome measures will be analyzed by the PI using IBM Statistical Package for Social Sciences software (SPSS). A biostatistician will be consulted to provide an arms-length review of the analysis. Every attempt to minimize missing data will be implemented; however, the research team will use intent-to-treat (ITT), an approach that includes every participant. The ITT analysis will preserve the same sample size and reduce type I error. As a feasibility study with a small sample size, missing data is dealt with by using the last observation carried forward (LOCF) method, where the last available measurement for each participant at the point before withdrawal from the study, is retained and used in the analysis. In a future larger study, researchers will undertake a more sophisticated approach to allow additional factors to account for attrition (52).

Baseline differences between the two groups will be tested using two-sample t-tests for normal distribution variables using the Shapiro-Wilk test and chi-squared tests for categorical variables. Determining differences in clinical outcomes is not the object of this study. However, comparisons will be undertaken to investigate the estimates of the treatment effects for these potential clinical outcomes. Baseline at T1-week-1 to T2-week-8 and T1-week-1 to T3-week-12 will be analyzed relative to change from baseline using one-way repeated analysis of variance (ANOVA) for each participant and outcome measure. However, if there are any differences between the two groups, an analysis of covariance (ANCOVA) will be performed and adjustments will be made for baseline scores, as appropriate e.g. age, sex and education as possible confounders. For clinical outcome data, results will be reported as between-group mean, SD, change scores, and treatment effects with a confidence interval (CI) at 95%. Significance levels and Cohen's *d* effect sizes will be reported at 95% CI (53). Similarly, feasibility and acceptability outcomes will be analyzed using descriptive statistics (e.g. adherence, attrition, frequency and duration logins) of intervention at baseline and the post-intervention outcome will be undertaken.

(*Insight Timer - App metrics*):

The number of login (frequency) and length of home practice (duration) are extracted by the following: days, weeks, months and total hours overall for the duration of the MBSR program. Descriptive statistics, including paired-sample *t*-tests or Wilcoxon, signed rank tests, is conducted to compare pre-post change scores on outcomes.

Benefits of Participants

This protocol has been designed to explore the feasibility of conducting an RCT to determine whether an 8-week MBSR program is feasible for a future larger clinical trial. There is growing recognition that interprofessional primary care teams are able to better support individuals with complex health conditions as compared to physician care alone. This study will be the first to explore the feasibility of an occupational therapist-led MBSR program and provide valuable insights as to how MBSR can be best delivered with this population. In addition, this study will provide details to better implement this intervention with the use of technology, such as computer tablets to deliver the MBSR program. Last, findings from this trial, if successful, will lay the foundation for a larger clinical trial. This study will highlight the possible benefits of MBSR and evaluation as a way to support psychological symptoms for those living with early memory issues within interprofessional primary care context.

Patient and public involvement

Patients and public members were not invited to provide feedback on the study design and the conduct of carrying out the study. The main results of the study will be disseminated to participants either through a letter or a face-to-face meeting if interested with respect to their results from baseline and end-of-study assessments.

Ethics and Dissemination

Ethics permission has been granted by local and national registries. The findings of the study will be published in peer-reviewed journals and disseminated to patient organizations, national and international conferences and through socia media.

and

References

1. Canada Year Book. Seniors 2011 [Available from: https://www150.statcan.gc.ca/n1/pub/11-402-x/2011000/chap/seniors-aines/seniors-aines-eng.htm.
2. Zuniga KE, Mackenzie MJ, Kramer A, McAuley E. Subjective memory impairment and well-being in community-dwelling older adults. Psychogeriatrics. 2016;16(1):20-6.
3. Jessen F, Amariglio RE, van Boxtel M, Breteler M, Ceccaldi M, Chételat G, et al. A conceptual framework for research on subjective cognitive decline in preclinical Alzheimer's disease. Alzheimer's & Dementia: The Journal of the Alzheimer's Association. 2014;10(6):844-52.
4. Langa KM, Levine DA. The Diagnosis and Management of Mild Cognitive Impairment: A Clinical Review. JAMA. 2014;312(23):2551-61.
5. Petersen RC, Caracciolo B, Brayne C, Gauthier S, Jelic V, Fratiglioni L, et al. Mild cognitive impairment: a concept in evolution. Journal of Internal Medicine. 2014;275(3):214-28.
6. American Psychiatric A, American Psychiatric Association DSMTF. Diagnostic and statistical manual of mental disorders: DSM-5. 5th ed. Washington, D.C: American Psychiatric Association; 2013.
7. Belchior P, Korner-Bitensky N, Holmes M, Robert A. Identification and assessment of functional performance in mild cognitive impairment: A survey of occupational therapy practices. Australian Occupational Therapy Journal. 2015;62(3):187-96.
8. De Vriendt P, Gorus E, Cornelis E, Velghe A, Petrovic M, Mets T. The process of decline in advanced activities of daily living: a qualitative explorative study in mild cognitive impairment. International Psychogeriatrics. 2012;24(6):1-13.
9. Joosten-Weyn Banningh EWA, Vernooy-Dassen MJFJ, Olde Rikkert MGM, Teunisse JPWM. Mild cognitive impairment: coping with an uncertain label. International Journal of Geriatric Psychiatry. 2008;23(2):148-54.
10. Regan B, Varanelli L. Adjustment, depression, and anxiety in mild cognitive impairment and early dementia: a systematic review of psychological intervention studies. International psychogeriatrics / IPA. 2013;25(12):1963.
11. Andreescu C, Varon D. New Research on Anxiety Disorders in the Elderly and an Update on Evidence-Based Treatments. Current Psychiatry Reports. 2015;17(7):1-7.
12. Sepehry AA, Lee PE, Hsiung GYR, Beattie BL, Jacova C. Effect of selective serotonin reuptake inhibitors in Alzheimer's disease with comorbid depression: a meta-analysis of depression and cognitive outcomes. Drugs & ageing. 2012;29(10):793.
13. Kok RM, Reynolds CF. Management of Depression in Older Adults: A Review. JAMA. 2017;317(20):2114-22.
14. Dhalwani NN, Fahami R, Sathanapally H, Seidu S, Davies MJ, Khunti K. Association between polypharmacy and falls in older adults: a longitudinal study from England. BMJ Open. 2017;7(10):e016358-e.
15. Moniz-Cook E. Psychosocial interventions through memory clinics. Nursing & Residential Care. 2011;13(4):189-92.
16. Wells RE, Kerr CE, Wolkin J, Dossett M, Davis RB, Walsh J, et al. Meditation for Adults with Mild Cognitive Impairment: A Pilot Randomized Trial. Journal of the American Geriatrics Society. 2013;61(4):642-5.

17. Smart CM, Segalowitz SJ, Mulligan BP, Koudys J, Gawryluk JR. Mindfulness Training for Older Adults with Subjective Cognitive Decline: Results from a Pilot Randomized Controlled Trial. Journal of Alzheimer's disease 2016;52(2):757.
18. Smoski MJ, McClintock A, Keeling L. Mindfulness Training for Emotional and Cognitive Health in Late Life. Current Behavioral Neuroscience Reports. 2016;3(4):301-7.
19. Geiger PJ, Boggero IA, Brake CA, Caldera CA, Combs HL, Peters JR, et al. Mindfulness-Based Interventions for Older Adults: a Review of the Effects on Physical and Emotional Well-Being. Mindfulness. 2016;7(2):296-307.
20. Creswell JD, Irwin MR, Burklund LJ, Lieberman MD, Arevalo JMG, Ma J, et al. Mindfulness-Based Stress Reduction training reduces loneliness and pro-inflammatory gene expression in older adults: A small randomized controlled trial. Brain, Behavior, and Immunity. 2012;26(7):1095-101.
21. Splevins K, Smith A, Simpson J. Do improvements in emotional distress correlate with becoming more mindful? A study of older adults. Ageing & Mental Health. 2009;13(3):328-35.
22. Black DS, O'Reilly GA, Olmstead R, Breen EC, Irwin MR. Mindfulness Meditation and Improvement in Sleep Quality and Daytime Impairment Among Older Adults With Sleep Disturbances: A Randomized Clinical Trial. JAMA Internal Medicine. 2015;175(4):494-501.
23. Foulk MA, Ingersoll-Dayton B, Kavanagh J, Robinson E, Kales HC. Mindfulness-Based Cognitive Therapy With Older Adults: An Exploratory Study. Journal of Gerontological Social Work. 2014;57(5):498-520.
24. Knopman DS, Petersen RC. Mild cognitive impairment and mild dementia: a clinical perspective. Mayo Clinic proceedings. 2014;89(10):1452-9.
25. Ciro CA. Maximizing ADL Performance to Facilitate Ageing in Place for People with Dementia. Nursing Clinics of North America. 2014;49(2):157-69.
26. Chan A-W, Tetzlaff J, Altman D, Laupacis A, Gøtzsche P, Krleza-Jeric K, et al. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. Annals of Internal Medicine. 2013;153(3):200-7.
27. Kabat-Zinn J, University of Massachusetts Medical Center/Worcester. Stress Reduction C. Full catastrophe living: using the wisdom of your body and mind to face stress, pain, and illness. Delta trade pbk. reissue, 15th anniversary ed. New York, N.Y: Delta Trade Paperbacks; 2009.
28. Timer I. Insight Timer (version 2019) [Mobile Application Software] Retreived from https://insighttimer.com. 2019.
29. Gearing RE, El-Bassel N, Ghesquiere A, Baldwin S, Gillies J, Ngeow E. Major ingredients of fidelity: A review and scientific guide to improving quality of intervention research implementation. Clinical Psychology Review. 2011;31(1):79-88.
30. Aguirre E, Stott J, Charlesworth G, Noone D, Payne J, Patel M, et al. Mindfulness-Based Cognitive Therapy (MBCT) programme for depression in people with early stages of dementia: study protocol for a randomised controlled feasibility study. 2017;3.
31. Perepletchikova F, Kazdin AE. Treatment Integrity and Therapeutic Change: Issues and Research Recommendations. Clinical Psychology: Science and Practice. 2005;12(4):365-83.
32. Law M, Canadian Association of Occupational T. Canadian Occupational Performance Measure. 4th ed. Ottawa, Ont: Canadian Association of Occupational Therapists; 2005.
33. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. 2001;16(9):606-13.

34. Phelan E, Williams B, Meeker K, Bonn K, Frederick J, Logerfo J, et al. A study of the diagnostic accuracy of the PHQ-9 in primary care elderly. BMC family practice. 2010;11(1):63-.
35. Pachana NA, Byrne GJ, Siddle H, Koloski N, Harley E, Arnold E. Development and validation of the Geriatric Anxiety Inventory. International Psychogeriatrics. 2007;19(1):103-14.
36. Cohen S, Kamarck T, Mermelstein R. A Global Measure of Perceived Stress. Journal of Health and Social Behavior. 1983;24(4):385-96.
37. Feldman G, Hayes A, Kumar S, Greeson J, Laurenceau J-P. Mindfulness and Emotion Regulation: The Development and Initial Validation of the Cognitive and Affective Mindfulness Scale-Revised (CAMS-R). Journal of Psychopathology and Behavioral Assessment. 2007;29(3):177-90.
38. Logsdon RG, Gibbons LE, Teri L, McCurry SM. QUALITY OF LIFE IN ALZHEIMER'S DISEASE: LONGITUDINAL PERSPECTIVES. The Gerontologist. 1999;39:164.
39. Hayes SC, Strosahl K, Wilson KG, Bissett RT, Pistorello J, Toarmino D, et al. Measuring experiential avoidance: A preliminary test of a working model. The Psychological Record. 2004;54(4):553-78.
40. Carswell A, McColl MA, Baptiste S, Law M, Polatajko H, Pollock N. The Canadian Occupational Performance Measure: A Research and Clinical Literature Review. Canadian Journal of Occupational Therapy. 2004;71(4):210-22.
41. Donnelly C, Carswell A. Individualized Outcome Measures: A Review of the Literature. Canadian Journal of Occupational Therapy. 2002;69(2):84-94.
42. Tuntland H, Aaslund MK, Langeland E, Espehaug B, Kjeken I. Psychometric properties of the Canadian Occupational Performance Measure in home-dwelling older adults.(ORIGINAL RESEARCH). Journal of Multidisciplinary Healthcare. 2016;9(1):411.
43. Lee E-H. Review of the Psychometric Evidence of the Perceived Stress Scale. Asian Nursing Research. 2012;6(4):121-7.
44. Logsdon RG, Gibbons, L.E. McCurry, S.,M., Teri, L. Quality of Life in Alzheimer's Disease: Patient and Caregiver Reports Journal of Mental Health and Ageing. 1999;5(1):21-32.
45. Bond FW, Hayes SC, Baer RA, Carpenter KM, Guenole N, Orcutt HK, et al. Preliminary Psychometric Properties of the Acceptance and Action Questionnaire–II: A Revised Measure of Psychological Inflexibility and Experiential Avoidance. Behavior Therapy. 2011;42(4):676-88.
46. Hayes SC, Luoma JB, Bond FW, Masuda A, Lillis J. Acceptance and Commitment Therapy: Model, processes and outcomes. Behaviour Research and Therapy. 2006;44(1):1-25.
47. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. BMJ. 2016;355:i5239.
48. Altman DG. Avoiding bias in trials in which allocation ratio is varied. Journal of the Royal Society of Medicine. 2018;111(4):143-4.
49. Clarke V, Braun V. Thematic analysis. The Journal of Positive Psychology. 2017;12(3):297-8.
50. Connelly LM. Trustworthiness in Qualitative Research. Medsurg nursing : official journal of the Academy of Medical-Surgical Nurses. 2016;25(6):435.
51. Hadi MA, José Closs S. Ensuring rigour and trustworthiness of qualitative research in clinical pharmacy. International Journal of Clinical Pharmacy. 2016;38(3):641-6.
52. Wong WK, Boscardin WJ, Postlethwaite AE, Furst DE. Handling missing data issues in clinical trials for rheumatic diseases. Contemporary Clinical Trials. 2011;32(1):1-9.

53. Evans A. Using basic statistics in the behavioral and social sciences. Fifth ed. Thousand Oaks, California: SAGE Publications, Inc; 2014.

Data Statement:
Technical appendix, statistical code, and dataset available from the Dryad repository, DOI:

Author Contribution Statement:

Todd Tran (Principal Investigator, Occupational Therapist and Ph.D. Candidate)
I came up with the conception of the design of the study, along with conducting and will be responsible for the reporting of the study. I am also responsible for achieving the overall timelines and wrote this manuscript.

Catherine Donnelly Ph.D. (Associate Professor)
Catherine is heavily involved in this study by providing supervision, planning, conducting and instrumental in providing feedback on this manuscript. This manuscript would not have been written without many hours of contribution.

Emily Nalder Ph.D. (Assistant Professor)
Emily provided support at the inception of the design of the study design and also provided instrumental feedback, both verbal and written, on this manuscript. This study would not have in the state it would be without her valuable comments and clinical support.

Tracy Trothen Th.D. (Professor who provided written guidance)
Tracy provided valuable feedback around the ethics of running such a trial by providing valuable comments and feedback at the conception and design of the study.

Marcia Finlayson Ph.D. (Professor who provided substantial feedback)
Marcia provided insightful comments and feedback on this manuscript from the inception of the idea to the design and implementation of this study. Marcia is an experienced researcher that provided a tremendous amount of guidance to allow for this study to be viable and for it to be replicable.

Acknowledgements (non-authors):

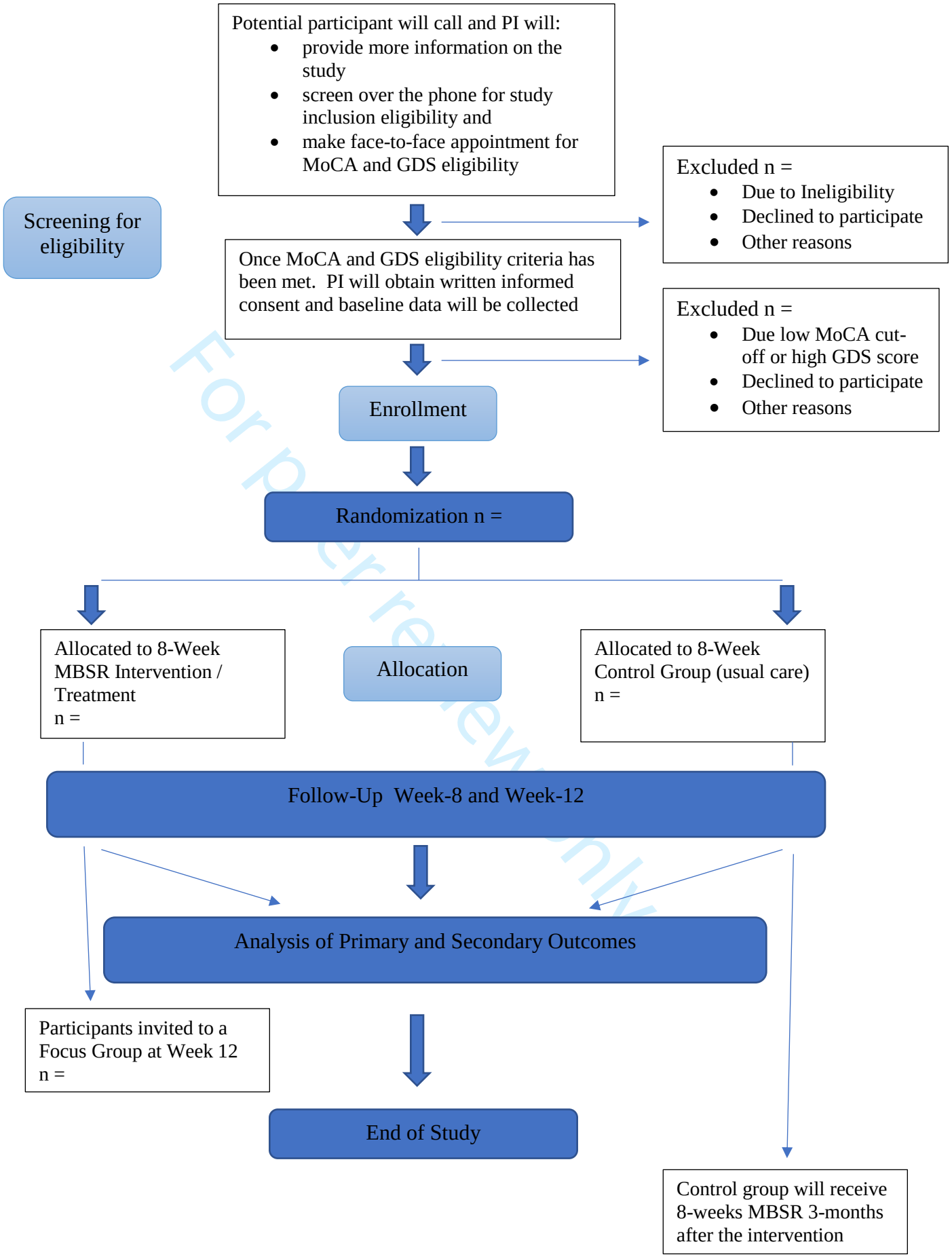
Kareena Gurbaxani
Jaisa Sulit
Mubeenaa Rahman
Virginia Vander Hyden
Sarah Scheffe
Ken Callaghan
Dr. Ruth Heisey
Susan Hum

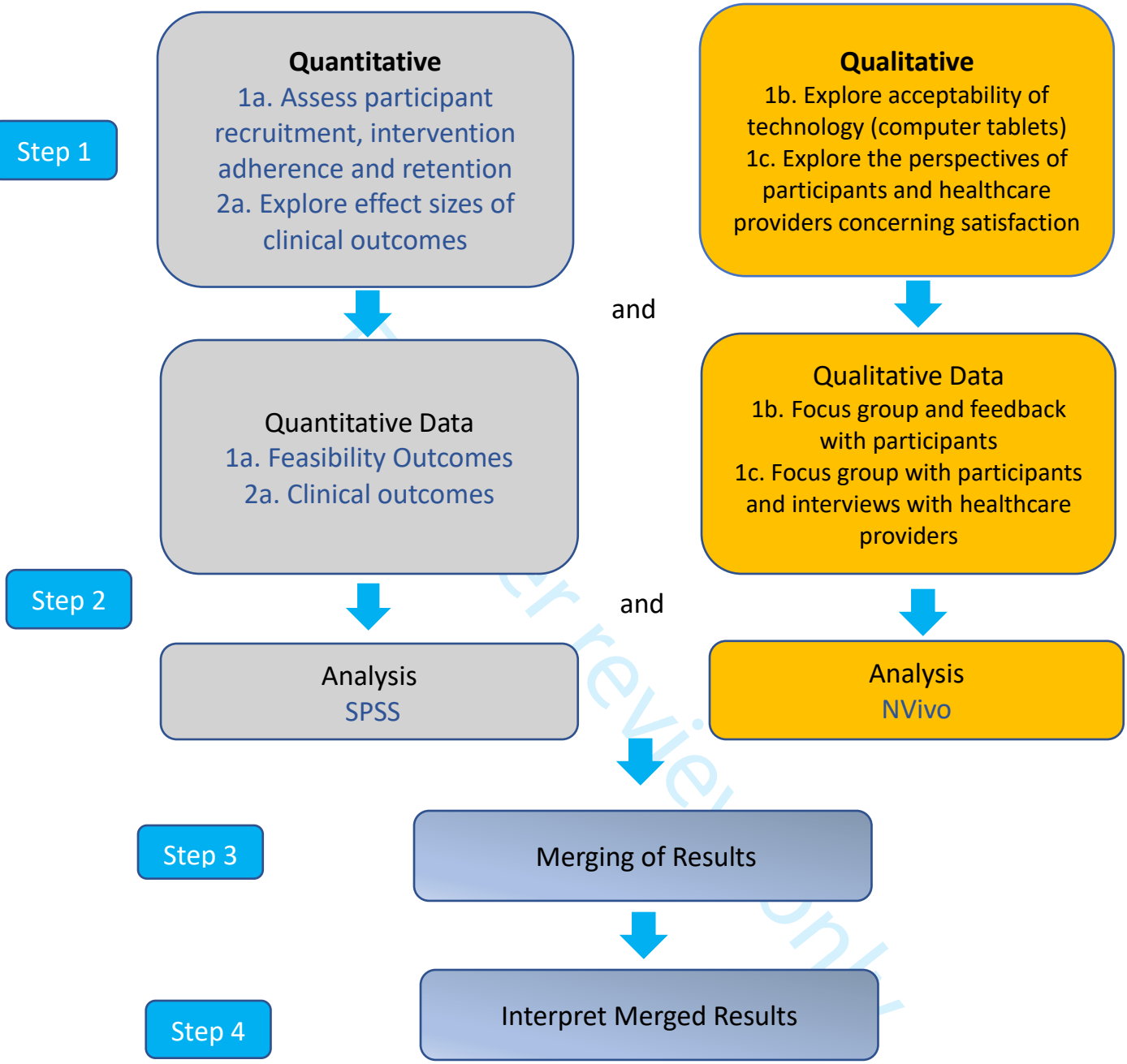
Figure legend/caption (in the following order):

1. **Table 1.** "Timeframe of Measurement for participants in MBSR Intervention" (*to be placed around page 11 before sample size section or to your discretion*)
   Abbreviations: MBSR, Mindfulness-Based Stress Reduction; MoCA, Montreal Cognitive Assessment; GDS, Geriatric Depression Scale; COPM, Canadian Occupational Performance Measure; PHQ-9, Patient Health Questionnaire; GAI, Geriatric Anxiety Inventory; CAMS-R, The Cognitive and Affective Mindfulness Scale-Revised; PSS. Perceived Stress Scale; QoL-AD, Quality-of-Life in Alzheimer's Disease; AAQ-II, Acceptance and Action Questionnaire

2. **Figure 1.** "SPIRIT-flow diagram of participants through the study" (*anywhere after Blinding section*)

3. **Figure 2.** "Protocol Flowchart" (*to be at the end of the paper before the Benefits of Participants section?)*





Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Gøtzsche PC, Krleža-Jerić K, Hróbjartsson A, Mann H, Dickersin K, Berlin J, Doré C, Parulekar W, Summerskill W, Groves T, Schulz K, Sox H, Rockhold FW, Rennie D, Moher D. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-207

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1

Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a
Protocol version	#3	Date and version identifier	1
Funding	#4	Sources and types of financial, material, and other support	2
Roles and responsibilities: contributorship	#5a	Names, affiliations, and roles of protocol contributors	1,19
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	2
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2

Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	2, 19
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	7
Objectives	#7	Specific objectives or hypotheses	5
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	5

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	6
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	7

Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	8
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	11

Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	11
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	11, 12

Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Allocation: implementation	#16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	12
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	12
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data,	12

		including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	12
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the	13

		statistical analysis plan can be found, if not in the protocol	
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	13
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	13
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	1 (Queens University & University of Toronto committee members who are not inovled directy in the study but are at an arm's length only to provide guidance)
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results	1 (Queens University & University of Toronto committee members will be

		and make the final decision to terminate the trial	notified with the PI's final decision to terminate the trial if required)
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	7 (field notes)
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	12
Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	3, 14
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	If such an amendment is required, it will be agreed upon by the committee and resubmission for Ethics will be made

Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	12
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13 (de-identification)
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	1
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	1 (only my research team)
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	3, 14
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	19 (no interntion use of professional writers)
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	3 (*Data sharing statement No later than 2 year after the collection of the 1-year feasibility and clinical outcomes, we will deliver a completely deidentified data set to an appropriate data archive for sharing purposes.*)
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	(See attached consent form)

Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

Notes:

- 31c: 3 (pre-results on clinicaltrials.gov) The SPIRIT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY-ND 3.0. This checklist was completed on 21. October 2019 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai