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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

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5 An occupational therapy-led Mindfulness-Based Stress Reduction for older adults living
6 with subjective cognitive decline or mild cognitive impairment in primary care: A
7 feasibility randomized control trial (RCT) protocol
8

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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 its 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 \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) 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.

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2
3 Monitoring of adherence would include (i) attendance records (ii) home practice log (iii)
4 iPad (log-in, frequency, duration) and (iii) field notes from clinicians in regards to the level of
5 participation and engagement and group process.
6

7
8 Any participants who experience emotional issues (e.g. increased anxiety, low mood)
9 during the group is referred to other health-care professionals on the FHT (e.g. Social Worker)
10 for psychosocial support.
11

12 The control group or usual care is the comparison group and will receive MBSR three
13 months after the intervention group is completed.
14

15 MBSR Fidelity

16
17
18 The *training fidelity* is significant as the teacher's embodiment of mindfulness is central
19 to the participant's learning within the 8-week curriculum. To examine program efficacy, the
20 Qualified MBSR teacher will have adhered to the intervention integrity [32]. Additionally, the
21 implementation of the MBSR curriculum will follow the teacher training protocol and also the
22 Mindfulness-Based Interventions Teaching Assessment Criteria (MBI: TAC), a tool that assesses
23 mindfulness-based teaching fidelity.
24

25 Outcome Measures

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28 Demographic data is collected at baseline (age, education, income, physical activity, etc.) along
29 with primary and secondary outcome measures.
30

31 Quantitative Data

32
33
34 The *primary outcome* will be changed scores on perceived satisfaction with functional
35 performance as measured by the *Canadian Occupational Performance Measure (COPM)*; [33].
36

37 *Secondary outcomes* will measure change with mood, anxiety, perceived stress, mindfulness,
38 Quality-of-Life and acceptance, which include:
39

- 40 1. Patient Health Questionnaire-9 (PHQ-9); [34, 35]
- 41 2. Geriatric Anxiety Inventory (GAI); [36]
- 42 3. Perceived Stress Scale (PSS); [37]
- 43 4. Cognitive and Affective Mindfulness Scale-Revised (CAMS-R); [38]
- 44 5. Quality of Life-Alzheimer's Disease (QoL-AD); [39]
- 45 6. Acceptance and Action Questionnaire (AAQ-II); [40]
- 46
- 47

48 Time of Outcome Measures

49
50
51 Outcome measures will be assessed at baseline (Time 1: Week 1) on completion of the
52 intervention at (Time 2: Week-8) and one-month post-intervention follow-up (Time 3: Week-
53 12). See **Figure 2**
54

55 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)

1
2
3 The survey has 13-items covering domains (e.g. health, mood, living situation, memory, money
4 etc.) [46]. It demonstrates good test-retest reliability. Has excellent inter-rater reliability with
5 Cohen's kappa values >0.70 and internal consistency is also high with Cronbach's alpha
6 coefficient of 0.82 [39].
7

8 9 *Acceptance and Action Questionnaire-II (AAQ-II)*

10
11 AAQ-II measures psychological flexibility and inflexibility [47]. It has shown that
12 psychological flexibility—broadly defined—is a prominent factor in understanding
13 psychological health [48]. AAQ-II demonstrates good test-retest reliability with alpha co-
14 efficient at 3-months at 0.81 and 12-months at 0.79 [47].
15

16 17 ***Feasibility Outcome Measures:***

18
19 As a feasibility study, the overarching purpose is to determine whether MBSR is
20 worthwhile for a definitive larger clinical trial for community-dwelling older adults living with
21 SCD or MCI. As such, the following feasibility measures will be taken to evaluate its
22 *acceptability*. The Principal Investigator (PI) and clinicians will collect all data during the period
23 of the intervention.
24

25
26 Acceptability will be evaluated by:

- 27
28 i. Recruitment rate: defined as feasible for a future study if 30-40 participants are
29 recruited within three to four months (May to August 2019), similar to other
30 feasibility studies [49].
31
- 32
33 ii. Retention rate: will be deemed feasible if at least 66% of participants complete six or
34 more of the nine sessions as well as a follow-up assessment at T3.
35
- 36
37 iii. Adherence rate: deemed adequate adherence for a future study if participants
38 complete 3 log-ins per week and practice homework for at least 1.5 hr per week
39 (duration), which would be deemed moderate adherence rate at 51-79 [50, 51]. The
40 treatment adherence rate is determined by the number of sessions completed in full
41 (180 minutes).
42
- 43
44 iv. Acceptability of using iPad as a tool for practice delivery is determined by (i) using
45 field notes by clinicians, (ii) research team will document any participants that may
46 need to switch to traditional low technology such as CDs or e-mail link for the
47 homework practices during duration of the 8-Weeks, and (iii) focus groups at follow-
48 up at the end of 8-Weeks (T2) of their perceived value and benefits of using
49 technology.
50
- 51
52 v. Satisfaction with the MBSR program will be assessed by the overall experience of the
53 8-Week intervention by surveys, e.g., field notes, research meeting notes, interviews
54 with clinicians (T3-Week-12) and participant focus groups (T2-Week-8). The
55 satisfaction of the program will include length (number of weeks), difficulty (e.g.
56 pacing, workload or other challenges), and session duration (e.g. too short, too long).
57
58
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Figure 2
Time Frame of Measurements (Participant Timelines)

Timeframe of Measurements for participants in MBSR Intervention

Measures Taken Item	(Time 1)					(Time 2)				(Time 3)
	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	X	X
Qualitative Measures										
Focus Group (Participants)									X	
Interview with Clinicians Evaluations (Participants)					X				X	X
Weekly Research Meeting Notes	X	X	X	X	X	X	X	X	X	
Weekly Field Notes	X	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-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

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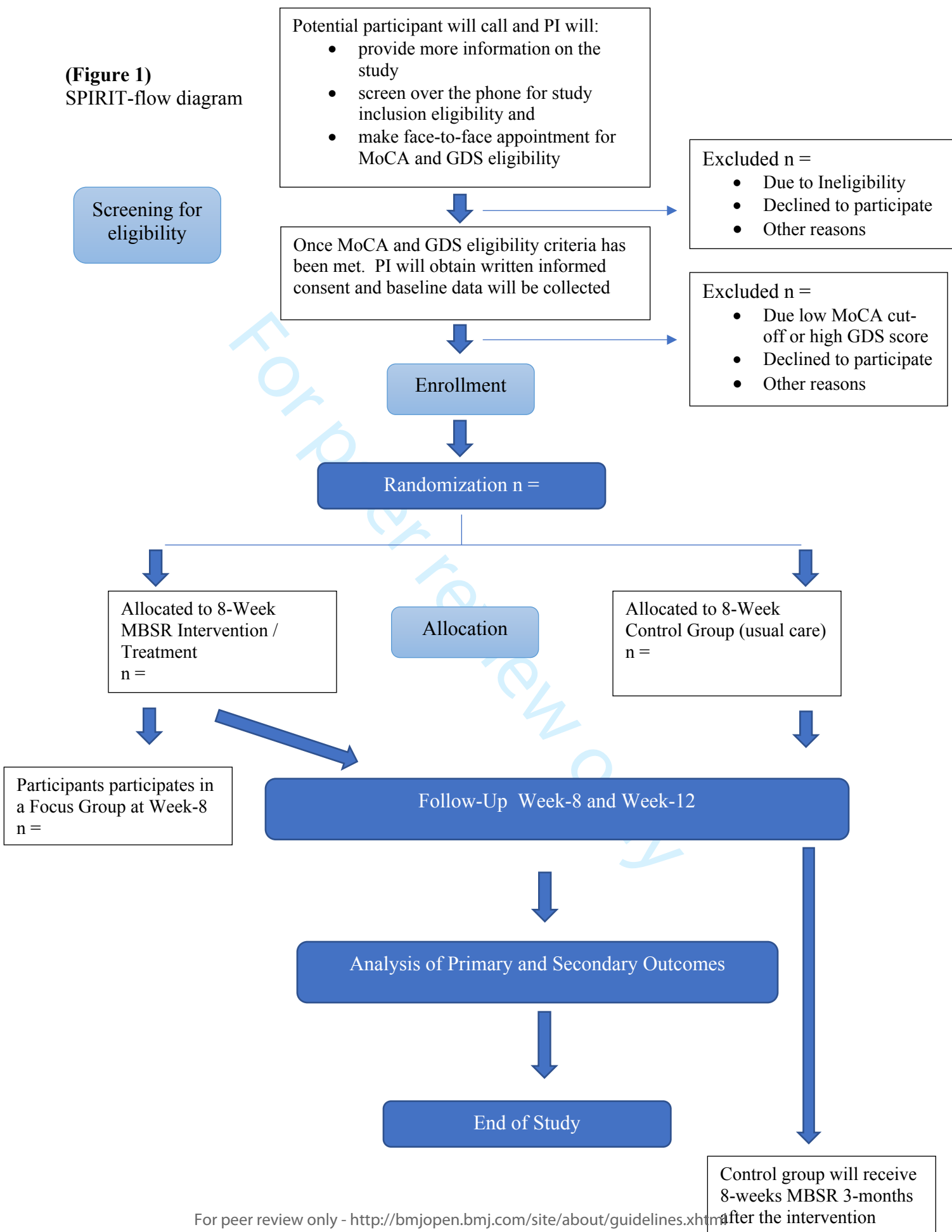
19 **Blinding**

20
21 The PI will assess baseline outcome measures for eligible participants at T1-Week-1. A
22 blinded independent assessor will evaluate post-MBSR at T2-Week-8 and at T3-Week-12, to
23 minimize bias. The wait-list control (Group 2) is assessed at T2-Week-8 and T3-Week-12,
24 along with the intervention (Group 1). The study occupational therapists delivering the
25 intervention will not be blinded to the group allocation as they are providing the intervention
26 being tested.
27
28

29 **Data Management**

30
31 The PI and research assistant will perform data checking, diagnosing errors, and editing
32 suspected errors or abnormalities. Participants' data will be de-identified and will be identified
33 only by a study ID number. A master log (saved on hospital site internal server) with personal
34 identifiers will be kept and stored separately from the study data. All iPads are encrypted and
35 have no participants' information other than their ID number.
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(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. *Peer 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.

1
2
3 T1-week-1 to T2-week-8 and T1-week-1 to T3-week-12 mean change scores and SD will be
4 conducted using paired *t*-test or ANOVA, calculated for normally distributed data, and Cohen's
5 *d* effect sizes and confidence intervals are used as it provides an estimate of the strength of the
6 treatment or relationship [57]. Effect sizes will be calculated to determine baseline and post-
7 intervention outcome variable values.
8
9

10 Similarly, feasibility outcomes will be analyzed using descriptive statistics of intervention
11 (e.g. acceptability), at baseline and post-intervention outcome.
12

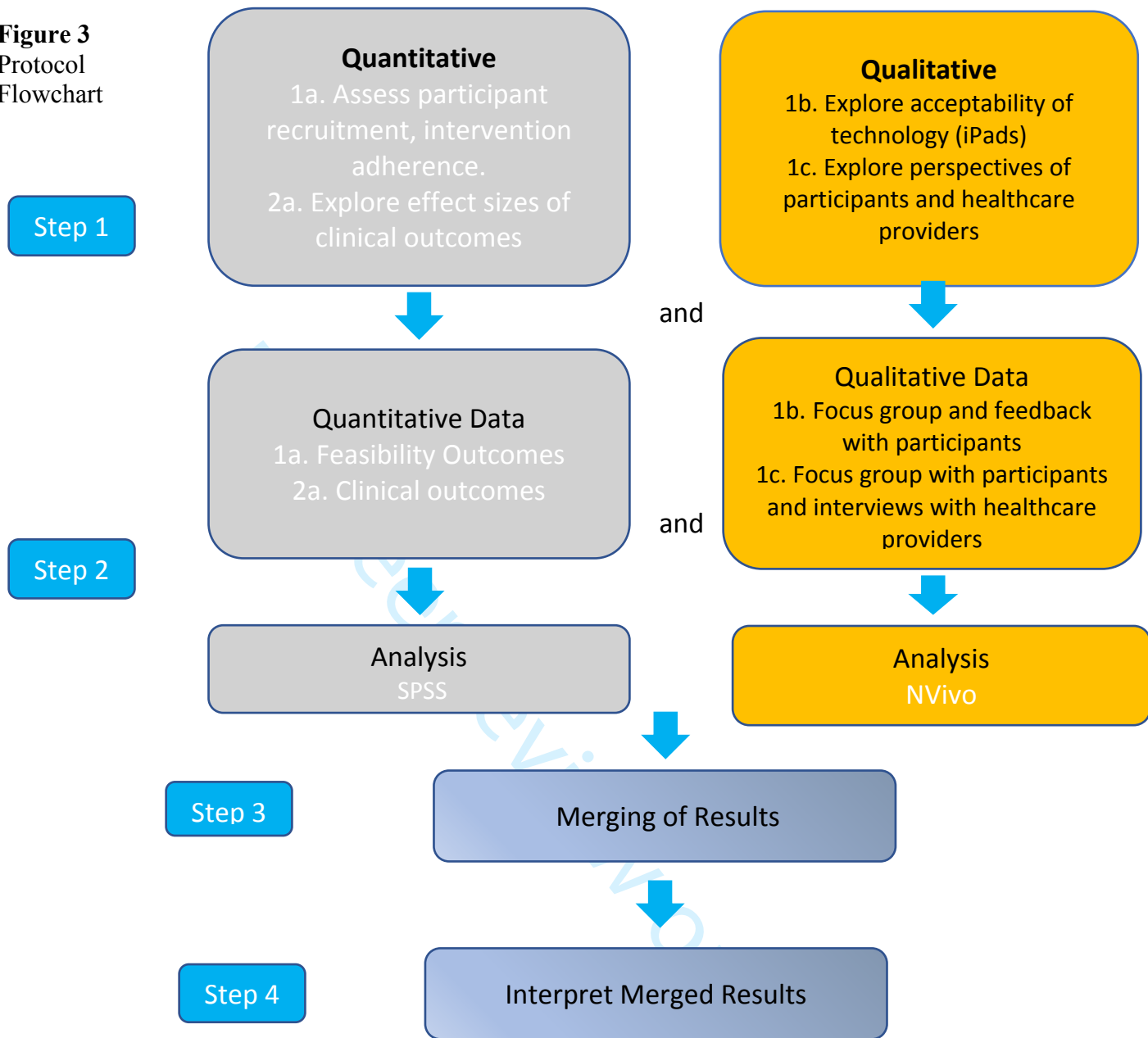
13 (*Insight Timer - App metrics*):

14 Both logged in time (frequency), length of homework practice (duration) is extracted by the
15 following (days, weeks, months and total hours overall for the duration of the MBSR program).
16 Descriptive statistics including paired-sample *t*-tests or Wilcoxon signed rank tests, is conducted
17 to compare pre-post change scores on outcomes.
18
19

20 **Conclusion**

21
22 This protocol has been designed to explore the feasibility of conducting RCT to
23 determine pre-clinical outcomes and whether an 8-Week MBSR program is feasible for a future
24 larger clinical trial. As there are limited evidence-based approaches in primary care to support
25 those living with SCD or MCI, preliminary results from this study may provide insight into the
26 management of this unique population. There is growing recognition for team-based care, and
27 this study is the first to explore an occupational therapy-led MBSR program within
28 interprofessional primary care teams or patient medical homes. This study will provide
29 acceptability and satisfaction of using technology such as iPads to deliver the MBSR program
30 within a primary care setting. Last, findings from this trial will offer feasibility challenges that
31 can be potentially avoided in a future clinical trial.
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Figure 3
Protocol
Flowchart



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20
21
22 Author Statement:

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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 SPIRIT reporting 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

1	Trial registration	#2a	Trial identifier and registry name. If not yet	3
2			registered, name of intended registry	
3				
4				
5				
6	Trial registration:	#2b	All items from the World Health Organization	n/a
7	data set		Trial Registration Data Set	
8				
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12	Protocol version	#3	Date and version identifier	1
13				
14				
15	Funding	#4	Sources and types of financial, material, and	2
16			other support	
17				
18				
19				
20	Roles and	#5a	Names, affiliations, and roles of protocol	1-2
21	responsibilities:		contributors	
22				
23	contributorship			
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28	Roles and	#5b	Name and contact information for the trial	2
29	responsibilities:		sponsor	
30				
31	sponsor contact			
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33	information			
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38	Roles and	#5c	Role of study sponsor and funders, if any, in	2
39	responsibilities:		study design; collection, management,	
40			analysis, and interpretation of data; writing of	
41	sponsor and funder		the report; and the decision to submit the	
42			report for publication, including whether they	
43			will have ultimate authority over any of these	
44			activities	
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1	Roles and	#5d	Composition, roles, and responsibilities of the	1-2
2				
3	responsibilities:		coordinating centre, steering committee,	
4				
5	committees		endpoint adjudication committee, data	
6				
7				
8			management team, and other individuals or	
9				
10			groups overseeing the trial, if applicable (see	
11				
12			Item 21a for data monitoring committee)	
13				
14				
15	Introduction			
16				
17				
18	Background and	#6a	Description of research question and	4-5
19				
20	rationale		justification for undertaking the trial, including	
21				
22			summary of relevant studies (published and	
23				
24			unpublished) examining benefits and harms for	
25				
26			each intervention	
27				
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31	Background and	#6b	Explanation for choice of comparators	3,7
32				
33	rationale: choice of			
34				
35	comparators			
36				
37				
38	Objectives	#7	Specific objectives or hypotheses	5
39				
40				
41	Trial design	#8	Description of trial design including type of trial	5, 12
42				
43			(eg, parallel group, crossover, factorial, single	
44				
45			group), allocation ratio, and framework (eg,	
46				
47			superiority, equivalence, non-inferiority,	
48				
49			exploratory)	
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54	Methods:			
55				
56	Participants,			
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1 **interventions, and**
 2
 3 **outcomes**
 4

5			
6	Study setting	#9	Description of study settings (eg, community
7			clinic, academic hospital) and list of countries
8			where data will be collected. Reference to
9			where list of study sites can be obtained
10			
11			
12			
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14			
15			
16	Eligibility criteria	#10	Inclusion and exclusion criteria for participants.
17			If applicable, eligibility criteria for study centres
18			and individuals who will perform the
19			interventions (eg, surgeons, psychotherapists)
20			
21			
22			
23			
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25	Interventions:	#11a	Interventions for each group with sufficient
26			detail to allow replication, including how and
27	description		when they will be administered
28			
29			
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31			
32			
33	Interventions:	#11b	Criteria for discontinuing or modifying allocated
34			interventions for a given trial participant (eg,
35	modifications		drug dose change in response to harms,
36			participant request, or improving / worsening
37			disease)
38			
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45	Interventions:	#11c	Strategies to improve adherence to
46			intervention protocols, and any procedures for
47	adherence		monitoring adherence (eg, drug tablet return;
48			laboratory tests)
49			
50			
51			
52			
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55	Interventions:	#11d	Relevant concomitant care and interventions
56			that are permitted or prohibited during the trial
57	concomitant care		
58			
59			
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1	Outcomes	#12	Primary, secondary, and other outcomes,	8-10
2				
3				
4			including the specific measurement variable	
5				
6			(eg, systolic blood pressure), analysis metric	
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8			(eg, change from baseline, final value, time to	
9				
10			event), method of aggregation (eg, median,	
11				
12			proportion), and time point for each outcome.	
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15			Explanation of the clinical relevance of chosen	
16				
17			efficacy and harm outcomes is strongly	
18				
19			recommended	
20				
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22	Participant timeline	#13	Time schedule of enrolment, interventions	10
23				
24			(including any run-ins and washouts),	
25				
26			assessments, and visits for participants. A	
27				
28			schematic diagram is highly recommended	
29				
30			(see Figure)	
31				
32				
33				
34	Sample size	#14	Estimated number of participants needed to	10
35				
36			achieve study objectives and how it was	
37				
38			determined, including clinical and statistical	
39				
40			assumptions supporting any sample size	
41			calculations	
42				
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46	Recruitment	#15	Strategies for achieving adequate participant	10
47				
48			enrolment to reach target sample size	
49				
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Methods:

Assignment of

1 interventions (for
2
3 controlled trials)
4

5	Allocation:	#16a	Method of generating the allocation sequence	11
6	sequence		(eg, computer-generated random numbers),	
7	generation		and list of any factors for stratification. To	
8			reduce predictability of a random sequence,	
9			details of any planned restriction (eg, blocking)	
10			should be provided in a separate document	
11			that is unavailable to those who enrol	
12			participants or assign interventions	
13				
14	Allocation	#16b	Mechanism of implementing the allocation	11
15	concealment		sequence (eg, central telephone; sequentially	
16	mechanism		numbered, opaque, sealed envelopes),	
17			describing any steps to conceal the sequence	
18			until interventions are assigned	
19				
20	Allocation:	#16c	Who will generate the allocation sequence,	11
21	implementation		who will enrol participants, and who will assign	
22			participants to interventions	
23				
24	Blinding (masking)	#17a	Who will be blinded after assignment to	11
25			interventions (eg, trial participants, care	
26			providers, outcome assessors, data analysts),	
27			and how	
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1	Blinding (masking):	#17b	If blinded, circumstances under which	n/a
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3	emergency		unblinding is permissible, and procedure for	
4				
5	unblinding		revealing a participant's allocated intervention	
6				
7			during the trial	
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11	Methods: Data			
12				
13	collection,			
14				
15	management, and			
16				
17	analysis			
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21	Data collection plan	#18a	Plans for assessment and collection of	6, 10 (8-9)
22			outcome, baseline, and other trial data,	
23				
24			including any related processes to promote	
25				
26			data quality (eg, duplicate measurements,	
27				
28			training of assessors) and a description of	
29				
30			study instruments (eg, questionnaires,	
31				
32			laboratory tests) along with their reliability and	
33				
34			validity, if known. Reference to where data	
35				
36			collection forms can be found, if not in the	
37				
38			protocol	
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44	Data collection	#18b	Plans to promote participant retention and	6, 13
45				
46	plan: retention		complete follow-up, including list of any	
47				
48			outcome data to be collected for participants	
49				
50			who discontinue or deviate from intervention	
51				
52			protocols	
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1	Data management	#19	Plans for data entry, coding, security, and	2,11,13
2			storage, including any related processes to	
3			promote data quality (eg, double data entry;	
4			range checks for data values). Reference to	
5			where details of data management procedures	
6			can be found, if not in the protocol	
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15	Statistics:	#20a	Statistical methods for analysing primary and	13-14
16	outcomes		secondary outcomes. Reference to where	
17			other details of the statistical analysis plan can	
18			be found, if not in the protocol	
19				
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25	Statistics: additional	#20b	Methods for any additional analyses (eg,	n/a
26	analyses		subgroup and adjusted analyses)	
27				
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31	Statistics: analysis	#20c	Definition of analysis population relating to	13
32	population and		protocol non-adherence (eg, as randomised	
33	missing data		analysis), and any statistical methods to	
34			handle missing data (eg, multiple imputation)	
35				
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41	Methods:			
42				
43	Monitoring			
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46	Data monitoring:	#21a	Composition of data monitoring committee	1 (my committee
47	formal committee		(DMC); summary of its role and reporting	members are
48			structure; statement of whether it is	involved as I'm a
49			independent from the sponsor and competing	PhD student)
50			interests; and reference to where further	
51			details about its charter can be found, if not in	
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1		the protocol. Alternatively, an explanation of	
2			
3		why a DMC is not needed	
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5			
6	Data monitoring:	#21b Description of any interim analyses and	1 (PI, and only my
7			
8	interim analysis	stopping guidelines, including who will have	committee members)
9			
10		access to these interim results and make the	
11			
12		final decision to terminate the trial	
13			
14			
15			
16	Harms	#22 Plans for collecting, assessing, reporting, and	7 (field notes)
17			
18		managing solicited and spontaneously	
19			
20		reported adverse events and other unintended	
21			
22		effects of trial interventions or trial conduct	
23			
24			
25			
26	Auditing	#23 Frequency and procedures for auditing trial	n/a
27			
28		conduct, if any, and whether the process will	
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30		be independent from investigators and the	
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32		sponsor	
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36	Ethics and		
37			
38	dissemination		
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41	Research ethics	#24 Plans for seeking research ethics committee /	3
42			
43	approval	institutional review board (REC / IRB) approval	
44			
45			
46	Protocol	#25 Plans for communicating important protocol	n/a
47			
48	amendments	modifications (eg, changes to eligibility criteria,	
49			
50		outcomes, analyses) to relevant parties (eg,	
51			
52		investigators, REC / IRBs, trial participants,	
53			
54		trial registries, journals, regulators)	
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1	Consent or assent	#26a	Who will obtain informed consent or assent	10
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4			from potential trial participants or authorised	
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6			surrogates, and how (see Item 32)	
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8				
9	Consent or assent:	#26b	Additional consent provisions for collection and	n/a
10				
11	ancillary studies		use of participant data and biological	
12				
13			specimens in ancillary studies, if applicable	
14				
15				
16	Confidentiality	#27	How personal information about potential and	13 (de-identification)
17				
18			enrolled participants will be collected, shared,	
19				
20			and maintained in order to protect	
21				
22			confidentiality before, during, and after the trial	
23				
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25				
26	Declaration of	#28	Financial and other competing interests for	1
27				
28	interests		principal investigators for the overall trial and	
29				
30			each study site	
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34	Data access	#29	Statement of who will have access to the final	1 (only my
35				committee members)
36			trial dataset, and disclosure of contractual	
37				
38			agreements that limit such access for	
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40			investigators	
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44	Ancillary and post	#30	Provisions, if any, for ancillary and post-trial	n/a
45				
46	trial care		care, and for compensation to those who suffer	
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48			harm from trial participation	
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51	Dissemination	#31a	Plans for investigators and sponsor to	3
52				
53	policy: trial results		communicate trial results to participants,	
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55			healthcare professionals, the public, and other	
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relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

10	Dissemination	#31b	Authorship eligibility guidelines and any	1 (it will be me the
11	policy: authorship		intended use of professional writers	PhD Student)
16	Dissemination	#31c	Plans, if any, for granting public access to the	3 (pre-results on
17	policy: reproducible		full protocol, participant-level dataset, and	clinicaltrials.gov)
18	research		statistical code	

Appendices

26	Informed consent	#32	Model consent form and other related	20
27	materials		documentation given to participants and	
28			authorised surrogates	
34	Biological	#33	Plans for collection, laboratory evaluation, and	n/a
35	specimens		storage of biological specimens for genetic or	
36			molecular analysis in the current trial and for	
37			future use in ancillary studies, if applicable	

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)

- 1 • 27: 13 (de-identification)
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- 3
- 4 • 29: 1 (only my committee members)
- 5
- 6
- 7 • 31b: 1 (it will be me the PhD Student)
- 8
- 9
- 10 • 31c: 3 (pre-results on clinicaltrials.gov) The SPIRIT checklist is distributed under the terms of the
- 11 Creative Commons Attribution License CC-BY-ND 3.0. This checklist was completed on 21.
- 12 October 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in
- 13 collaboration with [Penelope.ai](#)
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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. If 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 utmost 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

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- 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
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- I have consented to participating in this study

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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: _____

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3 **Confirming Consent for Focus Group – (between Week-6 to Week-12)**
4

- 5 I consent to participate in an interview with a Research Assistant
6
7 No, I do not consent to participate in a focus group
8
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11 _____
12 Name of participant

11 _____
12 Signature

11 _____
12 Date

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14 Person obtaining consent

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16 By signing this form, I confirm that:

- 17
18 • This study and its purpose has been explained to the participant named above
19 • All questions asked by the participant have been answered
20 • I will give a copy of this signed and dated document to the participant
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25 _____
26 Name of Person obtaining
27 Consent (print)

25 _____
26 Signature

25 _____
26 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

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3 Brief talk, teaching story, poem, drawing out theme such as mindfulness skills across multiple
4 situations in life, cultivating a sense of presence from moment-to-moment, and being open to
5 any experience, whether evaluated as pleasant, unpleasant, or neutral, as an opportunity to
6 practice mindful attention
7 Lunch instructions - Silent Lunch, mindful walking, self-care
8 Mountain or Lake Meditation
9 Slow/fast walking exercise with specific verbal guidance – repeated instructions for noticing, in
10 movement and stillness, various mind-body experiences. Emphasize options for meeting needs
11 as they arise, and the possibility for moving in and out of the exercise
12 Loving Kindness meditation, ending in stillness
13 Optional ending practices
14 Short sittings alternated with short walking, sitting anywhere when change occurs
15 Mindful walking, gazing out window, stopping and noticing one thing, followed by an open
16 awareness meditation
17 Dissolving the silence by whispering in pairs
18 Group Discussion and Dialogue
19 Closing ceremony
20
21

22 **Week 7**

23 In-class meditation with guided instructions (10 mins)
24 Debrief
25 Mindfulness of Activities of Daily Living (ADL) ie. cooking, shopping,
26 Discussion of last week's Home Practice
27 Mindfulness and Stress, Anxiety, and Depression: the importance of being present in the
28 moment vs. role of default mental activity in mental health problems
29 In-class meditation with guided instructions (15 mins)
30 Debrief
31 Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)
32 Noticing stress response, default mode and returning attention to present
33 Informal practice: Mindful communication, eating or physical exercises
34
35

36 **Week 8**

37 In-class meditation with guided instructions (10 mins)
38 Debrief
39 Discussion of last week's Home Practice
40 Mindfulness and Emotion Management
41 In-class "Working with distractions"
42 The last hour will be a recorded focus group
43 Debrief
44 Home Practice: Formal practice of the Body Scan (2 x 20 mins OR Breath meditations daily)
45 Informal practice: Mindful communication, eating, walking or physical exercises
46

47 **1-Month Follow-Up (Focus Group)**

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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

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7 assess feasibility outcomes (e.g. participant's experiences, use of technology and acceptability with the
8 overall experience in the MBSR program). Second, studies in the past 25 years have seen that MBSR can be
9 used to reduce anxiety, low mood, perceived stress along with enhancing emotional well-being and quality-of-
10 life. Thus, this study is to see if MBSR can be used to help with emotional well-being for those living with
11 SCD or MCI to cope with memory problems. Third, the study will also look at how MBSR may influence your
12 perceived satisfaction on functional performance on every-day tasks. Lastly, if you agree to participate, you
13 will be asked to be part of a focus group (at around Week 12) to explore your experience of being in the
14 MBSR program. We will ask you questions around your overall experience within the program (e.g.
15 satisfaction, value, barriers and facilitators). Closer to the date, we will ask you again for your informed
16 consent to participate in this focus group. You do not have to decide now, but you will get an opportunity to
17 decide in the future between Week-6 and Week-12. We will contact you again at that point in time.
18

19 **What will happen in this study?**

20 If you decide to participate, you will be enrolled in an 8-Week MBSR Program (with a follow-up session four
21 weeks after participating in the program). We will randomly assign the groups to you, to either Group 1 (to
22 start within a few weeks) or Group 2 (at a future date). The group you are assigned to will not be known, until
23 you consent to the study. Unfortunately, you will not be able to choose your group. However, it is important
24 to note that, regardless of your group allocation, we will be asking you to complete some questionnaires at
25 different time points. If you are assigned to Group 1, we will also ask you to participate in a focus group at the
26 end of the program that will consist of 1.5 hour in duration. Group 1 participants will be invited to an audio-
27 recorded focus group, facilitated by an assessor that is not part of the study. The purpose of the focus group
28 is to get feedback about participant's overall experience within the group. Group 2 will not be involved in a
29 focus group.
30

31
32 The MBSR program is provided to a group of older adults 60+ years and older with mild memory issues and
33 will consist of mindfulness practices including: sitting and lying down meditations, gentle mindful movement
34 (yoga), learning about mindful eating, and mindful everyday routines.
35

36 The research team would like to access your medical chart at WCH for purposes of research to confirm only
37 the following: your health history, co-morbidities and medications. You have the option to opt out of this if you
38 would like:
39

- 40 Yes, I consent to allow the research team to have access to my medical records at WCH
41
42 No, I do not wish the research team to have access to my medical records at WCH
43

44 You will also be provided with a study mini-iPAD (if you do not have one of your own), and you are able to
45 keep it during the study timeframe only (for the duration of the study). All mini-iPADs will have an
46 identification sticker attached and will correspond with your participant ID number.
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49 Clear instructions will be given on the care (ie. charging it, taking care of the device) throughout the sessions.
50 However, if the device becomes damaged, loss, stolen (beyond your control), you are not responsible for
51 replacing it. However, based on the number of participants and iPADS, if available we would provide you with
52 a replacement iPad. It will be understood at the end of the study, the iPADS must be returned.

53 As part of the research, you will be required to complete some surveys (pencil and paper questionnaires)
54 initially during the Intake Assessment session at Week 1, again at the end of the program at Week 8, and the
55 follow-up session at Week 12, which we will hold ~ 1 month after completion of the MBSR course.
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8 The screening session will be approximately 60 minutes in length to make sure you are eligible for the study.
9 The screening session will entail completing a cognitive screen, and a depression scale. If your score is not
10 within the criteria of the study, you will not be considered eligible. However, if you are not eligible, we will give
11 you some community resources, or you may also follow-up with your family physician, to talk to them about
12 your score(s).

13
14 All the data that we collect from you over the sessions will be kept strictly confidential and will **not** be added to
15 your medical chart.

16 17 **Length of Study**

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

22
23 The weekly sessions will be as follows:

- 24
25 • They will be held on Thursday afternoons from 1:30 pm to 4:30. You are able to take a break at any
26 time during the sessions and accessible washrooms are close by.
- 27
28 • There will be an initial intake and screening session (if you are deemed to be eligible), and the
29 program will then run for 8-Weeks with (an all day Saturday session) and one follow-up session at
30 Week 12 (four weeks after the completion of the program).
- 31
32 • A copy of the 8-Week program agenda is also attached to this form for you to read
- 33
34 • We are hoping that the group will be made up of anywhere from 15-20 participants, all genders
- 35
36 • We will be asking you to provide some information on the following topics as part of completing the
37 pencil and paper questionnaires: anxiety and mood rating scales along with quality-of-life measures
38 and questions around your basic day-to-day activities that you do routinely around your home and
39 outside of your home
- 40
41 • You will be given a mini-iPAD to borrow for the duration of the study to use (to play audio files for
42 mindfulness practices)

43 44 **What are the possible harms of taking part in this study?**

45 To participate in the study, you must be under the care of a physician, and you will be asked to provide us
46 with an emergency contact for us to contact in case of emergency.

47 Name of Emergency Contact: _____

48 Relationship: _____

49
50 There may be unforeseeable harms that may arise, you may have a short or long-term concerns that may
51 interfere with your ability to participate and be involved in the program. The study requires an investment of
52 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
53 future date). Some questions may make you feel upset or distressed but, you can opt out, take a break or
54 discontinue participation for any reason whenever you feel the need to. If you experience any emotional
55 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,

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

15
16 It is important to note that as staff members, we are very serious about confidentiality, however, we cannot
17 guarantee that other participants in the group will maintain confidentiality (if you were to discuss anything in a
18 group or one-on-one to other participants). We will, however, convey the importance of maintaining
19 confidentiality throughout the 8-Week program as this is something we would request from all participants in
20 the study.

21 22 **If I have questions or problems, whom should I contact?**

23 If you have any questions, please feel free to contact the PI:

24
25 Todd Tran PhD (cand), MScCH, OT Reg (Ont),
26 Occupational Therapist in Family Practice and Foot Care Centre
27 416-323-6525
28 Todd.Tran@wchospital.ca

29
30
31 If you have questions or concerns about your experience as a research participant, you can contact the Chair
32 of the Research Ethics Board at Women's College Hospital, Dr. Nancy Walton, at 416-351-3732, extension
33 2325. The Research Ethics Board are a group of people who are not involved in this study and who have
34 ethical oversight of research activities.

35 36 **Participant**

37
38 Participant/Substitute decision-maker

39 By signing this form, I confirm that:

- 40
41
- 42 • This research study has been fully explained to me and all of my questions answered to my
43 satisfaction
 - 44 • I understand the requirements of participating in this research study
 - 45 • I have been informed of the risks and benefits, if any, of participating in this research study
 - 46 • I have been informed of any alternatives to participating in this research study
 - 47 • I have been informed of the rights of research participants
 - 48 • I have read each page of this form
 - 49 • I authorize access to my personal health information, medical record (if applicable), and research
50 study data as explained in this form
 - 51 • I have agreed to participate in this study or agree to allow the person I am responsible for to
52 participate in this study
 - 53 • (If applicable) I understand that my family doctor will be informed of my participation in this research
54 study
 - 55 • (if applicable) This informed consent document will be placed in my medical records
- 56
57

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: _____

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7 No, I do not consent the research team to phone or e-mail me for the duration of the study
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13 **Confirming Consent for Focus Group – (between Week-6 to Week-12)**
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15

- 16 I consent to participate in a focus group
17
18 No, I do not consent to participate in a focus group
19
20
21
22

23 _____
24 Name of participant
25 (Print)

23 _____
24 Signature

23 _____
24 Date

26 Person obtaining consent

27 By signing this form, I confirm that:

- 28
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30
 - 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
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36 _____
37 Name of Person obtaining
38 Consent (print)

36 _____
37 Signature

36 _____
37 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

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7 **Mountain or Lake Meditation**

8 Slow/fast walking exercise with specific verbal guidance – repeated instructions for noticing, in movement and
9 stillness, various mind-body experiences. Emphasize options for meeting needs as they arise, and the
10 possibility for moving in and out of the exercise

11 Loving Kindness meditation, ending in stillness

12 Optional ending practices

13 Short sittings alternated with short walking, sitting anywhere when change occurs

14 Mindful walking, gazing out window, stopping and noticing one thing, followed by an open awareness
15 meditation

16 Dissolving the silence by whispering in pairs

17 Group Discussion and Dialogue

18 Closing ceremony
19

20 **Week 7**

21 In-class meditation with guided instructions (10 mins)

22 Debrief

23 Mindfulness of Activities of Daily Living (ADL) ie. cooking, shopping,

24 Discussion of last week's Home Practice

25 Mindfulness and Stress, Anxiety, and Depression: the importance of being present in the moment vs. role
26 of default mental activity in mental health problems

27 In-class meditation with guided instructions (15 mins)

28 Debrief

29 Home Practice: Formal practice of the Body Scan (2 x 10 mins OR Breath meditations daily)

30 Noticing stress response, default mode and returning attention to present

31 Informal practice: Mindful communication, eating or physical exercises
32
33

34 **Week 8**

35 In-class meditation with guided instructions (10 mins)

36 Debrief

37 Discussion of last week's Home Practice

38 Mindfulness and Emotion Management

39 In-class "Working with distractions"

40 The last hour will be a recorded focus group

41 Debrief

42 Home Practice: Formal practice of the Body Scan (2 x 20 mins OR Breath meditations daily)

43 Informal practice: Mindful communication, eating, walking or physical exercises
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46 **1-Month Follow-Up (Evaluation and Focus-Group, if agreeable to participate)**
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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:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-035299.R1
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Date Submitted by the Author:	28-Jan-2020
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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

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5 An occupational therapist-led Mindfulness-Based Stress Reduction for older adults living
6 with subjective cognitive decline or mild cognitive impairment in primary care: A
7 feasibility randomized control trial protocol
8

9
10 Keywords: mindfulness, occupational therapy, subjective cognitive decline, mild
11 cognitive impairment, primary care, interprofessional primary care
12

13
14 Protocol Version: January, 27th, 2020 version 4.0
15

16 **Authorship (my research team – are the only people to have access to research data)**
17

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16

17
18 Competing Interest: There is no competing interest to declare as there is no financial interest;
19 however, this is Principal Investigator's doctoral dissertation. The co-authors are Ph.D.
20 committee members involved in overseeing study in its entirety, from data management to data
21 monitoring, which is independent of the funders and has no competing interests. The committee
22 and supervisor will be conducting the interim results and will make the final decision to
23 terminate the trial at any point in time if deemed appropriate. Thus, auditing will also be done
24 weekly with support from the supervisor, independent from the funders. Funding sources had no
25 role in the design of this study and will not have any role during its execution, analyses,
26 interpretation of the data, or decision to submit results.
27
28

29 **Word count:** (approximately 4000 words)
30
31

32 **Funding:**

33
34 Centre for Ageing & Brain Health Innovation
35 3560 Bathurst Street
36 Toronto, ON
37 M6A 2E1 Canada
38

39 And

40 VHA Home HealthCare
41 30 Soudan Avenue, Suite 600
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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

1
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3 backup provided by the research team. If participants have difficulty with using tablets,
4 additional support will be provided during or after class. If any participant does not have access
5 to Wi-Fi, we will provide them with CDs for ease of adherence for their guided homework
6 practices, and homework will be tracked exclusively using pencil and paper sheets. Similarly, if
7 participants have difficulty with using tablet computers, switching to CDs will be offered as an
8 alternative low technology option.
9

10
11 Monitoring of adherence will include (i) attendance records (ii) home practice logs (iii)
12 tablet computer use (login, frequency, duration) and (iii) field notes from Qualified-MBSR
13 teachers in regards to the level of participation, engagement and group process.
14

15
16 Any participants who experience emotional issues (e.g. increased anxiety, low mood)
17 during the group will be referred to other health-care professionals on the interprofessional
18 primary care team (e.g. social worker, consultant psychiatrists) for psychological support.
19

20
21 The control group (usual care) will be identical to the intervention group and will be
22 offered the MBSR program three months after the intervention group.
23

24 25 **Assessment of Intervention (MBSR) Treatment Fidelity**

26
27 This study will use Gearing et al. (29) four major (intervention) fidelity components:
28 *Design, Training, Delivery* and *Receipt*. The *design fidelity* of this feasibility RCT is to follow an
29 existing eight-week protocol of MBSR following the authorized curriculum guide from the
30 University of Massachusetts, Medical School, Center for Mindfulness in Medicine, Health Care
31 and Society. Design fidelity will be met by ensuring: a fixed number and length of sessions,
32 following the scripted manual for the course, including external monitoring by the research team
33 recording any protocol deviations based on the population, monitoring of the home practice logs.
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37 The *training fidelity* is significant as the teacher's embodiment of mindfulness is central
38 to the participant's learning within the 8-week curriculum. To maintain training fidelity, three
39 facilitators are Qualified-MBSR teachers who have undergone training at the University of
40 Massachusetts, Medical School; one facilitator has equivalent MBSR-qualifications from a
41 different institution in Toronto, Canada using the same standardized MBSR treatment manuals.
42 All qualified-MBSR Teachers have over three years of facilitating MBSR groups. Training
43 fidelity will be met by: teachers meeting regularly to debrief, using the same teachers for the
44 duration of the 8-weeks, and lastly, participant focus group inquiring about the curriculum will
45 be used.
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48 *Delivery fidelity* is the implementation of the MBSR curriculum by following both the
49 MBSR curriculum protocol from the University of Massachusetts, Medical School and the
50 Mindfulness-Based Interventions Teaching Assessment Criteria (MBI:TAC); a tool that assesses
51 mindfulness-based teaching integrity that will be used as a guide to support the delivery of the
52 MBSR curriculum. Delivery fidelity will also be measured by: participant focus group reflection
53 of the teachers' embodiment of mindfulness practice, attendance, and intervention handouts
54 provided for all participants along with tablet computers or CDs with home practice recordings.
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3 Lastly, *receipt fidelity* will be achieved by attendance during the 8-week program, in conjunction
4 with logins and doing the home practices on participant's computer tablets. Additionally, receipt
5 fidelity will be met by: the collection of participant's weekly handwritten home practice log
6 sheets and inquiry discussions during the weekly sessions. This demonstrates that participants
7 are practicing the skills during the study period and are engaged and adherent to the program.
8 However, any missing attendance or drop-outs will be followed-up with a telephone call.
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11 ***Primary AIM: Feasibility Outcome Measures***

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13 As a feasibility study, the overarching purpose is to determine whether MBSR is
14 worthwhile for a definitive larger clinical trial for community-dwelling older adults living with
15 SCD or MCI in an interprofessional primary care setting.
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18 *Objective 1a: Feasibility Measures*

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- 20 i. Recruitment rate: will be defined as feasible for a future study if 30-40 participants
21 are recruited within three to four months (May to August 2019), similar to other
22 feasibility studies (30).
23
- 24 ii. Retention rate: will be deemed feasible if at least 75-80% of participants complete six
25 or more of the nine sessions as well as a follow-up assessment at T3 based on other
26 feasibility studies.
27
- 28 iii. Adherence rate: will be deemed to have adequate adherence for a future study if
29 participants complete three logins per week and practice homework for at least 1.5
30 hours per week (duration), which would be deemed moderate adherence rate at 51-79
31 (29, 31). The treatment adherence rate is determined by the number of sessions
32 completed in full (180 minutes).
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36 *Objective 1b: Acceptability of technology*

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- 38 iv. Acceptability of using a tablet computer as a tool for home practice delivery will be
39 determined through. (i) field notes by Qualified-MBSR teachers documenting group
40 participation, (ii) number of participants that switch from computer tablets to low
41 technology for the homework practices during the duration of the 8-weeks, and (iii)
42 focus groups at follow-up at the end of 8-weeks (T2) examining perceived value and
43 benefits of using technology.
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47 *Objective 1c: Satisfaction with the MBSR program*

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- 49 v. The overall experience of the 8-week intervention will be evaluated by field notes,
50 mid-way participants surveys, interviews with Qualified-MBSR teachers (T3-week-
51 12) and participant focus groups (T2-week-8). The dimensions of satisfaction with
52 the program will include length (number of weeks), difficulty (e.g. pacing, workload
53 or other challenges), and session duration (e.g. too short, too long).
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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) 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 Item	(Time 1)			(Time 2)				(Time 3)		
	0-week	1-week	2-week	3-week	4-week	5-week	6-week	7-week (Post-MBSR)	8-week (Follow-Up)	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	X	
Weekly Field Notes	X	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):

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3 The number of login (frequency) and length of home practice (duration) are extracted by the
4 following: days, weeks, months and total hours overall for the duration of the MBSR program.
5 Descriptive statistics, including paired-sample *t*-tests or Wilcoxon, signed rank tests, is
6 conducted to compare pre-post change scores on outcomes.
7

8 9 **Benefits of Participants**

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11 This protocol has been designed to explore the feasibility of conducting an RCT to
12 determine whether an 8-week MBSR program is feasible for a future larger clinical trial. There is
13 growing recognition that interprofessional primary care teams are able to better support
14 individuals with complex health conditions as compared to physician care alone. This study will
15 be the first to explore the feasibility of an occupational therapist-led MBSR program and provide
16 valuable insights as to how MBSR can be best delivered with this population. In addition, this
17 study will provide details to better implement this intervention with the use of technology, such
18 as computer tablets to deliver the MBSR program. Last, findings from this trial, if successful,
19 will lay the foundation for a larger clinical trial. This study will highlight the possible benefits of
20 MBSR and evaluation as a way to support psychological symptoms for those living with early
21 memory issues within interprofessional primary care context.
22
23

24 25 **Patient and public involvement**

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

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3 Data Statement:

4 Technical appendix, statistical code, and dataset available from the Dryad repository, DOI:
5
6
7

8 **Author Contribution Statement:**
9

10 **Todd Tran** (Principal Investigator, Occupational Therapist and Ph.D. Candidate)

11 I came up with the conception of the design of the study, along with conducting and will be
12 responsible for the reporting of the study. I am also responsible for achieving the overall
13 timelines and wrote this manuscript.
14
15

16 **Catherine Donnelly** Ph.D. (Associate Professor)

17 Catherine is heavily involved in this study by providing supervision, planning, conducting and
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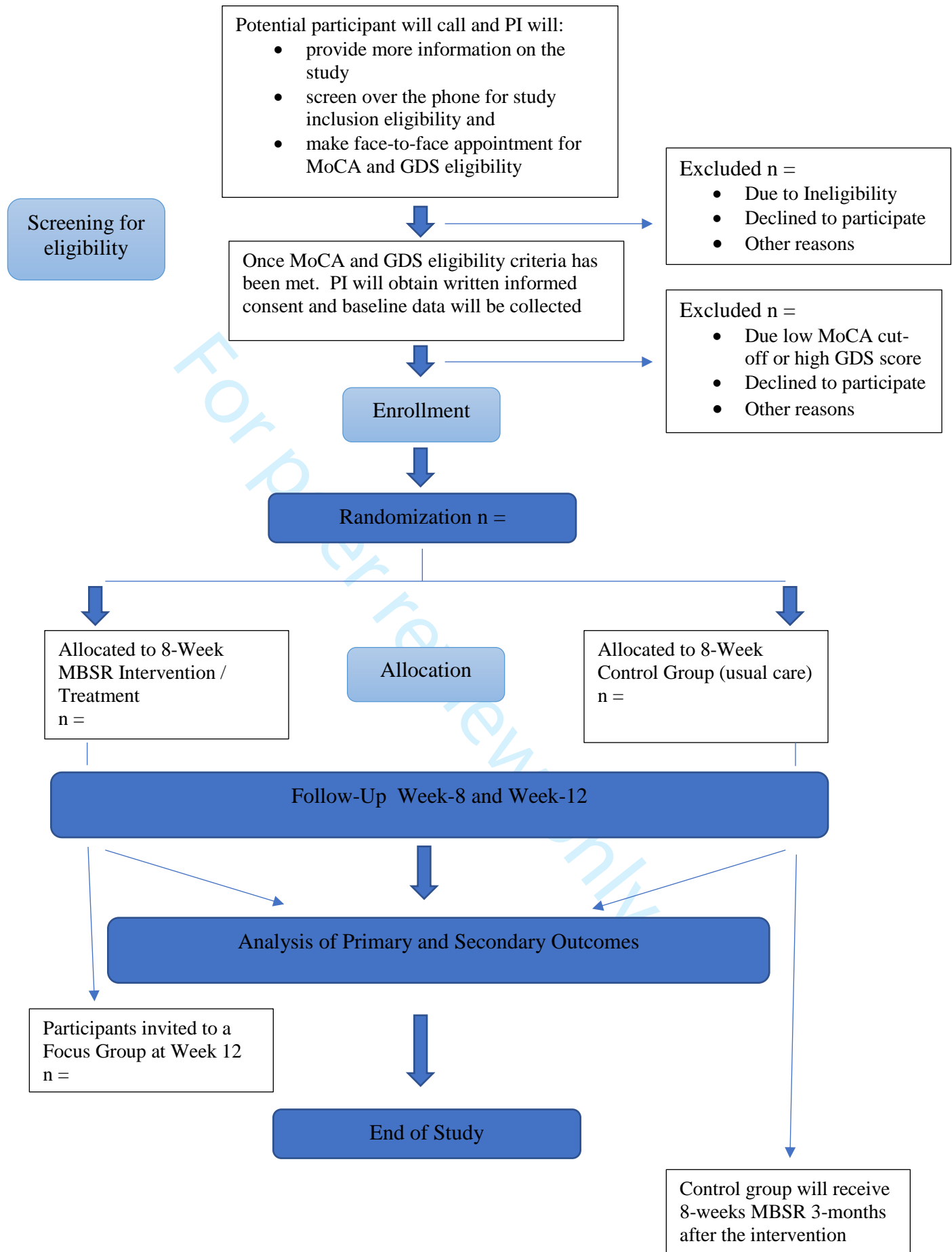
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3 **Figure legend/caption (in the following order):**
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- 5
6 1. **Table 1.** “Timeframe of Measurement for participants in MBSR Intervention” (*to be*
7 *placed around page 11 before sample size section or to your discretion*)
8 Abbreviations: MBSR, Mindfulness-Based Stress Reduction; MoCA, Montreal Cognitive
9 Assessment; GDS, Geriatric Depression Scale; COPM, Canadian Occupational
10 Performance Measure; PHQ-9, Patient Health Questionnaire; GAI, Geriatric Anxiety
11 Inventory; CAMS-R, The Cognitive and Affective Mindfulness Scale-Revised; PSS,
12 Perceived Stress Scale; QoL-AD, Quality-of-Life in Alzheimer’s Disease; AAQ-II,
13 Acceptance and Action Questionnaire
14
15
16 2. **Figure 1.** “SPIRIT-flow diagram of participants through the study” (*anywhere after*
17 *Blinding section*)
18
19 3. **Figure 2.** “Protocol Flowchart” (*to be at the end of the paper before the Benefits of*
20 *Participants section?*)
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Step 1

Quantitative
 1a. Assess participant recruitment, intervention adherence and retention
 2a. Explore effect sizes of clinical outcomes

Qualitative
 1b. Explore acceptability of technology (computer tablets)
 1c. Explore the perspectives of participants and healthcare providers concerning satisfaction

and

Step 2

Quantitative Data
 1a. Feasibility Outcomes
 2a. Clinical outcomes

Qualitative Data
 1b. Focus group and feedback with participants
 1c. Focus group with participants and interviews with healthcare providers

and

Analysis
 SPSS

Analysis
 NVivo

Step 3

Merging of Results

Step 4

Interpret Merged Results

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

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Primary Subject Heading:	Rehabilitation medicine
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Keywords:	PRIMARY CARE, MENTAL HEALTH, Anxiety disorders < PSYCHIATRY, Delirium & cognitive disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Old age psychiatry < PSYCHIATRY

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4 1
5 2 An occupational therapist-led Mindfulness-Based Stress Reduction for older adults living
6 3 with subjective cognitive decline or mild cognitive impairment in primary care: A
7 4 feasibility randomized control trial protocol
8 5

9 6
10 7 Keywords: mindfulness, occupational therapy, subjective cognitive decline, mild
11 8 cognitive impairment, primary care, interprofessional primary care
12 9

13 10
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15 12

16 13
17 14 **Authorship (my research team – are the only people to have access to research data)**
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82 Abstract

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

88
89 Exploring non-pharmacological interventions such as mindfulness within primary care is
90 vital in enabling individuals to develop strategies to manage cognitive impairment or
91 psychological symptoms. Mindfulness-Based Stress Reduction (MBSR) is an 8-week program
92 that is beneficial in alleviating psychological symptoms; however, its impact on perceived
93 satisfaction on overall functional performance with this population has not been evaluated. The
94 primary objective of this study is to explore the feasibility of conducting an RCT of an
95 occupational therapist-led MBSR program within primary care.

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

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

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

111 Strengths and limitations of this study

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

- 125 • The study is innovative in exploring the acceptability of a tablet computer as a method of
126 intervention delivery and data collection with this population
- 127
- 128 • The lack of an attention control comparison group and the small sample size is a study
129 limitation

130

131 Introduction

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

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

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

155 Evidence from the past 20 years suggests that mindfulness meditation, such as
156 Mindfulness-Based Stress Reduction (MBSR), could benefit those living with SCD and MCI
157 (16, 17). MBSR may be neuroprotective against cognitive decline as it has been found to
158 produce brain changes along with decreased cognitive complaints and increased memory self-
159 efficacy (17). Furthermore, a small proof-of-concept study identified that MBSR is feasible with
160 older adults living with MCI and that it may positively affect QoL and well-being (16). This
161 study will build on these proof-of-concept and pilot studies as MBSR has demonstrated mental
162 health benefits, including the reduction of emotional distress and worry (18, 19).

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

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3 166 when older adults and their families are concerned about cognitive problems (24). There is an
4 167 increasing emphasis on interprofessional primary care teams or patient medical homes to address
5 168 the challenges of an ageing population. Currently, no studies to date have examined the
6 169 feasibility of MBSR for those living with SCD or MCI receiving care from interprofessional
7 170 primary care teams. A growing number of occupational therapists working in primary care teams
8 171 are ideally positioned to support individuals with SCD and MCI through their expertise in
9 172 understanding the impact of cognitive impairment on daily function. Examining effective
10 173 interventions such as an occupational therapist-led, MBSR for individuals at the early stages of
11 174 cognitive changes is critical to support ageing-in-place (25).

14
15 175 The overarching purpose is to determine whether occupational therapist-led MBSR in
16 176 primary care is appropriate for a larger clinical trial in the future. The study has two aims:

17 177 18 178 **Primary Aim:**

19 179
20 180 To explore the feasibility of conducting an RCT of an occupational therapist-led, 8-week
21 181 MBSR program in an interprofessional primary care setting. The following objectives will assess
22 182 feasibility outcomes:

- 23 183
24 184
25 184 1a. Assess participant recruitment, intervention adherence, and study retention (Quantitative)
26 185 1b. Explore the acceptability of using tablet computer technology to support intervention,
27 186 delivery and data collection in the MBSR program (Qualitative)
28 187 1c. Explore the perspectives of participants and healthcare providers concerning satisfaction
29 188 (e.g., the intervention and its' delivery), perceived value, and barriers and facilitators of
30 189 implementation of the MBSR program in a primary care setting (Qualitative)

31 190 32 191 **Secondary Aim:**

33 192
34 193 To evaluate the effect sizes of satisfaction on functional performance as a primary
35 194 clinical outcome and psychological symptoms as secondary clinical outcomes in individuals with
36 195 SCD or MCI completing an 8-week MBSR program in an interprofessional primary care setting.
37 196 (Quantitative)

38 197 39 198 **Methods**

40 199
41 200 This study will use a convergent mixed-methods, single-blind RCT with two parallel
42 201 groups and will follow SPIRIT reporting (26) guidelines for randomized feasibility trials. See
43 202 Trial Design (**See Figures 1 and 2**). There will be three assessment time points: Baseline (Time-
44 203 1) at week-0, on completion of the intervention (Time-2) at week-8, and one-month post-
45 204 intervention follow-up (Time-3) at week-12.

46 205 47 206 **Study Setting**

48 207 The study will take place at an interprofessional primary care clinic in the province of
49 208 Ontario, Canada. Interprofessional team members include occupational therapy, physiotherapy,
50 209 nursing, pharmacy, social work, and dietetics. There are approximately 18,000 rostered patients
51 210 with the clinic.

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4 212 **Eligibility Criteria**

5
6 213 To qualify for the study, participants will be screened using the Montreal Cognitive Assessment
7 214 (MoCA), with a score of 22 or greater and a Geriatric Depression Scale (GDS) score of 6 or lower to be
8 215 eligible to participate in the study. Scores of greater than 7 on the GDS and lower than 22 on the MoCA
9 216 will warrant further assessment with their family physician and will be excluded from the study. The
10 217 inclusion and exclusion criteria are:

11 218
12 219 Inclusion Criteria:

- 13 220
14 221 (1) Age \geq 60 years
15 222 (2) English fluency
16 223 (3) Living independently (non-assisted living, e.g. retirement or any long-term care facility; self-
17 224 report)
18 225 (4) Have a self-reported SCD or an MCI diagnosis in their chart
19 226 (5) Must be a patient with the interprofessional primary care clinic
20 227

21 228 Exclusion Criteria:

- 22 229
23 230 (1) History of prior participation in any MBSR or other mindfulness-based interventions in the
24 231 past or having 2-3 times per week or more of either mindfulness or yoga practice
25 232 (2) Current history of significant medical (e.g. cancer), neurological (e.g. brain injury) or
26 233 psychiatric condition (e.g. depression with 6 or greater on the GDS), active psychosis,
27 234 bereavement that significantly impacts on mood, i.e. depression
28 235 (3) Alcoholism or other substance abuse
29 236 (4) Participating in other cognitive or memory training programs in the community or is involved
30 237 in another research study
31 238

32 239 **Intervention/Treatment (MBSR) Group**

33 240 Participants randomized to the intervention arm will participate in an 8-week MBSR
34 241 program established in 1979 by Kabat-Zinn (27). Four occupational therapists, also Qualified-
35 242 MBSR teachers, will be involved in the delivery of the intervention group. The traditional
36 243 MBSR curriculum usually has two teachers, but due to the unique population with cognitive
37 244 impairment and the use of tablet computers, having two additional MBSR teachers will be
38 245 beneficial to assist with any issues that may arise, including technological issues or memory
39 246 challenges. The group will be 3-hours in duration (with a 15-minute break) for 8-weeks, along
40 247 with an orientation and one all-day retreat. Sessions will consist of: lying down (body scan),
41 248 sitting (focusing on the breath), and mindful movement (yoga and walking). Daily home
42 249 practice will be given to be performed for 30 to 45 minutes outside of class.
43 250

44 251 We will distribute a tablet computer (mini-iPad 3 model) to each participant to access the
45 252 Application (App), Insight Timer (28), for the duration of the study. Insight Timer contains
46 253 guided meditation homework practices, with homework accessed by logging directly into Insight
47 254 Timer. All homework data will be downloaded at the end of the 8-week program. In addition to
48 255 the App, all participants will be asked to record their home practice using pen and paper weekly
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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.

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3 298 Lastly, *receipt fidelity* will be achieved by attendance during the 8-week program, in
4 299 conjunction with log-ins and doing the home practices on participant's computer tablets.
5 300 Additionally, receipt fidelity will be met by: the collection of participant's weekly handwritten
6 301 home practice log sheets and inquiry discussions during the weekly sessions. This demonstrates
7 302 that participants are practicing the skills during the study period and are engaged and adherent to
8 303 the program. However, any missing attendance or drop-outs will be followed-up with a
9 304 telephone call.
10 305

11 306 ***Primary AIM: Feasibility Outcome Measures***

12 307
13 308 As a feasibility study, the overarching purpose is to determine whether MBSR is
14 309 worthwhile for a definitive larger clinical trial for community-dwelling older adults living with
15 310 SCD or MCI in an interprofessional primary care setting.
16 311

17 312 *Objective 1a: Feasibility Measures*

- 18 313
19 314 i. Recruitment rate: will be defined as feasible for a future study if 30-40 participants
20 315 are recruited within three to four months (May to August 2019), similar to other
21 316 feasibility studies (30).
22 317
23 318 ii. Retention rate: will be deemed feasible if at least 75-80% of participants complete six
24 319 or more of the nine sessions as well as a follow-up assessment at T3 based on other
25 320 feasibility studies.
26 321
27 322 iii. Adherence rate: will be deemed to have adequate adherence for a future study if
28 323 participants complete three logins per week and practice homework for at least 1.5
29 324 hours per week (duration), which would be deemed moderate adherence rate at 51-79
30 325 (29, 31). The treatment adherence rate is determined by the number of sessions
31 326 completed in full (180 minutes).
32 327

33 328 *Objective 1b: Acceptability of technology*

- 34 329
35 330 iv. Acceptability of using a tablet computer as a tool for home practice delivery will be
36 331 determined through. (i) field notes by Qualified-MBSR teachers documenting group
37 332 participation, (ii) number of participants that switch from computer tablets to low
38 333 technology for the homework practices during the duration of the 8-weeks, and (iii)
39 334 focus groups at follow-up at the end of 8-weeks (T2) examining perceived value and
40 335 benefits of using technology.
41 336

42 337 *Objective 1c: Satisfaction with the MBSR program*

- 43 338
44 339 v. The overall experience of the 8-week intervention will be evaluated by field notes,
45 340 mid-way participants surveys, interviews with Qualified-MBSR teachers (T3-week-
46 341 12) and participant focus groups (T2-week-8). The dimensions of satisfaction with
47 342 the program will include length (number of weeks), difficulty (e.g. pacing, workload
48 343 or other challenges), and session duration (e.g. too short, too long).
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4 345 **Secondary AIM: Clinical Outcome Measures**

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7 347 Demographic data will be collected at baseline (e.g. age, education, income, physical
8 348 activity, etc.) along with primary and secondary clinical outcome measures.

9 349
10 350 **Quantitative Data**

11 351
12 352 The *primary clinical outcome* will be the average change scores on the perceived
13 353 satisfaction with functional performance as measured by the *Canadian Occupational*
14 354 *Performance Measure (COPM)*; (32).

15
16
17 *Secondary clinical outcomes* will include mood, anxiety, perceived stress, mindfulness
18 traits, QoL and acceptance, as shown:

- 19 357
20 358 1. Patient Health Questionnaire-9 (PHQ-9); (33, 34)
21 359 2. Geriatric Anxiety Inventory (GAI); (35)
22 360 3. Perceived Stress Scale (PSS); (36)
23 361 4. Cognitive and Affective Mindfulness Scale-Revised (CAMS-R); (37)
24 362 5. Quality of Life-Alzheimer's Disease (QoL-AD); (38)
25 363 6. Acceptance and Action Questionnaire (AAQ-II); (39)
26 364

27 364
28 365 **Time of Outcome Measures**

29
30 366 Outcome measures will be assessed at baseline (Time-1: week-1) on completion of the
31 367 intervention at (Time-2: week-8) and one-month post-intervention follow-up (Time-3: week-12).
32 368 **See Table 1**

33 369
34 370 **Clinical Outcome Measures:**

35 371
36 372 **Primary Outcome**

37 373
38 374 *Canadian Occupational Performance Measure*

39 375
40 376 The COPM is an individualized, client-centred outcome measure. Through a semi-
41 377 structured interview, individuals identify areas of difficulty in the performance of everyday
42 378 activities and satisfaction with their performance. Maximum of five activities can be identified,
43 379 and each is rated on a 10-point scale for self-perceived performance and satisfaction for their
44 380 functional performance. COPM demonstrates strong test-retest reliability for both the
45 381 performance and satisfaction scores when tested a week apart (40) and has demonstrated good
46 382 responsiveness (41). A change of at least 3 points or more is recommended to distinguish
47 383 between older adults who report a clinically significant change compared to those who do not
48 384 (42).
49 385

50 386 **Secondary Outcome**

51 387
52 388 *Patient Health Questionnaire (PHQ-9)*
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3 389 The PHQ-9 is a self-administered tool that scores each of the 9 DSM-IV criteria as '0'
4 390 (not at all) to '3' (nearly every day), giving a total score of 27 (33). PHQ-9 represents a
5 391 reasonable alternative to the Geriatric Depression Scale with older adults in primary care settings
6 392 (33, 34). The internal reliability of the PHQ-9 is excellent, with a Cronbach's of 0.89 in a PHQ-9
7 393 Primary Care Study, with excellent test-retest reliability. PHQ-9 has a sensitivity of 88% and a
8 394 specificity of 88% for use in a population with major depression (33).

11 395 *Geriatric Anxiety Inventory (GAI)*

12 396
13 397 The GAI consists of 20 'Agree/Disagree' items designed to assess typical common
14 398 anxiety symptoms for the last week (35). GAI was developed specifically for community-
15 399 dwelling older adults. The GAI has high internal consistency ($\alpha = .76$), as well as high inter-rater
16 400 ($r = .89$) and test-retest ($r = .86$) reliability (35).

18 401 19 402 *Perceived Stress Scale (PSS)*

20 403
21 404 PSS is an assessment of the global appraisal of stress (36). The 10-item questionnaire
22 405 examines stress of respondents using a 4-point scale (0-Never to 4-Very Often). The PSS has
23 406 acceptable psychometric properties, with satisfactory test-retest reliability criterion assessed at
24 407 >0.70 (43).

26 408 27 409 *The Cognitive and Affective Mindfulness Scale-Revised (CAMS-R)*

28 410
29 411 CAMS-R is a brief comprehensive measure designed to capture mindfulness based on
30 412 Jon Kabat-Zinn's definition of mindfulness (37). The CAMS-R is a 10-item questionnaire with a
31 413 4-point scale (1 -Rarely to 4 -Almost Always) s and has demonstrated internal consistency
32 414 reliability with Cronbach's alpha ranges from 0.61 to 0.81. The CAMS-R has also demonstrated
33 415 concurrent validity with moderate to large correlation with other measures of mindfulness ($r =$
34 416 0.51 to 0.67) (37).

36 417 37 418 *Quality-of-Life in Alzheimer's Disease (QoL-AD)*

38 419
39 420 The QoL-AD is a 13-item questionnaire covering multiple domains including health,
40 421 mood, living situation, memory, and money (44). The measure has demonstrated good test-retest
41 422 reliability and strong inter-rater reliability with Cohen's kappa values >0.70 . Internal consistency
42 423 is also high with a Cronbach's alpha coefficient of 0.82 (38).

44 424 45 425 *Acceptance and Action Questionnaire-II (AAQ-II)*

46 426
47 427 The AAQ-II is a 7-item questionnaire that measures psychological flexibility-
48 428 inflexibility and experiential avoidance (45). The measure has shown that psychological
49 429 flexibility is a prominent factor in understanding psychological health (46). The AAQ-II has an
50 430 alpha coefficient of 0.84 and demonstrates good test-retest reliability at 3-months at 0.81 and 12-
51 431 months at 0.79 (45).

53 432 54 433 **loginTable 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 (Post-MBSR)	8-week (Follow-Up)	12-week (Follow-Up)
Screening											
(MoCA and GDS)	X										
Feasibility Measures											
		X	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	X	
Weekly Field Notes		X	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.

496 **Blinding**

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

511 **Data Management**

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

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

1
2
3 530 delivery), acceptability, perceived value, barriers and facilitators of the 8-week occupational
4 531 therapist-led MBSR program in primary care.

5 532

6 533 **Qualitative Analysis**

7 534

8 535 Participant focus group and individual MBSR teacher interviews will be audio-recorded
9 536 and transcribed verbatim. All transcripts will be de-identified and pseudonyms will be given to
10 537 each of the participants. Transcripts will be read and re-read by both the PI and the research team.
11 538 An inductive process of sorting, initial coding and grouping the data into broad topic-oriented
12 539 categories, which is refined into fewer analytical themes, will be used (49). Critical discussion
13 540 with the research staff of emerging themes will occur throughout the analysis process. The
14 541 qualitative software package NVivo 11 (QSR International) will be used to support the analysis.

15 542

16 543 To enhance trustworthiness, member checking will be used as a strategy (50). Peer
17 544 debriefing, triangulation, and an audit trail will be used to clarify interpretations of the data that
18 545 may identify possible sources of bias. Each of these strategies will enhance trustworthiness to
19 546 ensure dependability, credibility and transferability in the qualitative analysis (51).

20 547

21 548 **Quantitative Analysis**

22 549

23 550 The primary and secondary outcome measures will be analyzed by the PI using IBM
24 551 Statistical Package for Social Sciences software (SPSS). A biostatistician will be consulted to
25 552 provide an arms-length review of the analysis. Every attempt to minimize missing data will be
26 553 implemented; however, the research team will use intent-to-treat (ITT), an approach that includes
27 554 every participant. The ITT analysis will preserve the same sample size and reduce type I error.
28 555 As a feasibility study with a small sample size, missing data is dealt with by using the last
29 556 observation carried forward (LOCF) method, where the last available measurement for each
30 557 participant at the point before withdrawal from the study, is retained and used in the analysis. In
31 558 a future larger study, researchers will undertake a more sophisticated approach to allow
32 559 additional factors to account for attrition (52).

33 560

34 561 Baseline differences between the two groups will be tested using two-sample t-tests for
35 562 normal distribution variables using the Shapiro-Wilk test and chi-squared tests for categorical
36 563 variables. Determining differences in clinical outcomes is not the object of this study. However,
37 564 comparisons will be undertaken to investigate the estimates of the treatment effects for these
38 565 potential clinical outcomes. Baseline at T1-week-1 to T2-week-8 and T1-week-1 to T3-week-12
39 566 will be analyzed relative to change from baseline using one-way repeated analysis of variance
40 567 (ANOVA) for each participant and outcome measure. However, if there are any differences
41 568 between the two groups, an analysis of covariance (ANCOVA) will be performed and
42 569 adjustments will be made for baseline scores, as appropriate e.g. age, sex and education as
43 570 possible confounders. For clinical outcome data, results will be reported as between-group mean,
44 571 SD, change scores, and treatment effects with a confidence interval (CI) at 95%. Significance
45 572 levels and Cohen's *d* effect sizes will be reported at 95% CI (53). Similarly, feasibility and
46 573 acceptability outcomes will be analyzed using descriptive statistics (e.g. adherence, attrition,
47 574 frequency and duration logins) of intervention at baseline and the post-intervention outcome will
48 575 be undertaken.

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4 577 (*Insight Timer - App metrics*):

5 578
6 579 The number of login (frequency) and length of home practice (duration) are extracted by the
7 580 following: days, weeks, months and total hours overall for the duration of the MBSR program.
8 581 Descriptive statistics, including paired-sample *t*-tests or Wilcoxon, signed rank tests, is
9 582 conducted to compare pre-post change scores on outcomes.
10 583

11 583 12 584 **Benefits of Participants**

13 585
14 586 This protocol has been designed to explore the feasibility of conducting an RCT to
15 587 determine whether an 8-week MBSR program is feasible for a future larger clinical trial. There is
16 588 growing recognition that interprofessional primary care teams are able to better support
17 589 individuals with complex health conditions as compared to physician care alone. This study will
18 590 be the first to explore the feasibility of an occupational therapist-led MBSR program and provide
19 591 valuable insights as to how MBSR can be best delivered with this population. In addition, this
20 592 study will provide details to better implement this intervention with the use of technology, such
21 593 as computer tablets to deliver the MBSR program. Last, findings from this trial, if successful,
22 594 will lay the foundation for a larger clinical trial. This study will highlight the possible benefits of
23 595 MBSR and evaluation as a way to support psychological symptoms for those living with early
24 596 memory issues within interprofessional primary care context.
25 597

26 597 27 598 **Patient and public involvement**

28 599
29 600 Patients and public members were not invited to provide feedback on the study design
30 601 and the conduct of carrying out the study. The main results of the study will be disseminated to
31 602 participants either through a letter or a face-to-face meeting if interested with respect to their
32 603 results from baseline and end-of-study assessments.
33 604

34 604 35 605 **Ethics and Dissemination**

36 606
37 607 Ethics permission has been granted by local and national registries. The findings of the
38 608 study will be published in peer-reviewed journals and disseminated to patient organizations,
39 609 national and international conferences and through social media.
40 610
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For peer review only

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3 753 Data Statement:

4 754 Technical appendix, statistical code, and dataset available from the Dryad repository, DOI:

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7 757

8 **Author Contribution Statement:**

9 758

10 759 **Todd Tran** (Principal Investigator, Occupational Therapist and Ph.D. Candidate)

11 760 I came up with the conception of the design of the study, along with conducting and will be

12 761 responsible for the reporting of the study. I am also responsible for achieving the overall

13 762 timelines and wrote this manuscript.

14 763

15 764 **Catherine Donnelly** Ph.D. (Associate Professor)

16 765 Catherine is heavily involved in this study by providing supervision, planning, conducting and

17 766 instrumental in providing feedback on this manuscript. This manuscript would not have been

18 767 written without many hours of contribution.

19 768

20 769 **Emily Nalder** Ph.D. (Assistant Professor)

21 770 Emily provided support at the inception of the design of the study design and also provided

22 771 instrumental feedback, both verbal and written, on this manuscript. This study would not have in

23 772 the state it would be without her valuable comments and clinical support.

24 773

25 774 **Tracy Trothen** Th.D. (Professor who provided written guidance)

26 775 Tracy provided valuable feedback around the ethics of running such a trial by providing valuable

27 776 comments and feedback at the conception and design of the study.

28 777

29 778 **Marcia Finlayson** Ph.D. (Professor who provided substantial feedback)

30 779 Marcia provided insightful comments and feedback on this manuscript from the inception of the

31 780 idea to the design and implementation of this study. Marcia is an experienced researcher that

32 781 provided a tremendous amount of guidance to allow for this study to be viable and for it to be

33 782 replicable.

34 783

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44 793 Susan Hum

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3 796 **Figure legend/caption (in the following order):**

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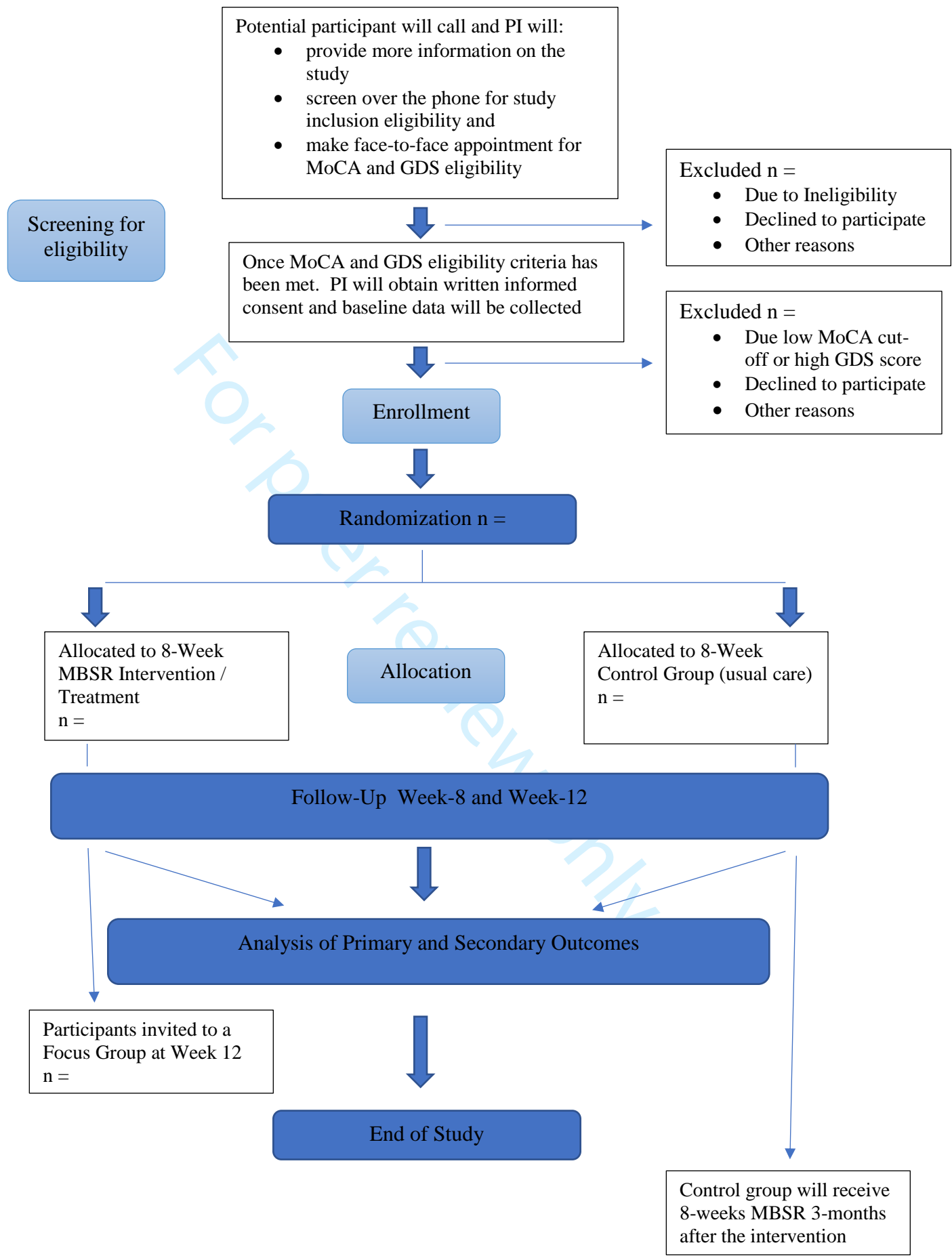
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1. **Table 1.** “Timeframe of Measurement for participants in MBSR Intervention” (*to be placed around page 11 before sample size section or to your discretion*)
Abbreviations: MBSR, Mindfulness-Based Stress Reduction; MoCA, Montreal Cognitive Assessment; 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?*)



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Step 1

Quantitative
 1a. Assess participant recruitment, intervention adherence and retention
 2a. Explore effect sizes of clinical outcomes

Qualitative
 1b. Explore acceptability of technology (computer tablets)
 1c. Explore the perspectives of participants and healthcare providers concerning satisfaction

and

Step 2

Quantitative Data
 1a. Feasibility Outcomes
 2a. Clinical outcomes

Qualitative Data
 1b. Focus group and feedback with participants
 1c. Focus group with participants and interviews with healthcare providers

and

Analysis
 SPSS

Analysis
 NVivo

Step 3

Merging of Results

Step 4

Interpret Merged Results

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 SPIRIT reporting 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

1	Trial registration	#2a	Trial identifier and registry name. If not	3
2			yet registered, name of intended	
3			registry	
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9	Trial registration:	#2b	All items from the World Health	n/a
10				
11	data set		Organization Trial Registration Data Set	
12				
13				
14	Protocol version	#3	Date and version identifier	1
15				
16				
17	Funding	#4	Sources and types of financial, material,	2
18			and other support	
19				
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21				
22				
23	Roles and	#5a	Names, affiliations, and roles of	1,19
24				
25	responsibilities:		protocol contributors	
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27	contributorship			
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30	Roles and	#5b	Name and contact information for the	2
31				
32	responsibilities:		trial sponsor	
33				
34	sponsor contact			
35				
36	information			
37				
38				
39				
40	Roles and	#5c	Role of study sponsor and funders, if	2
41				
42	responsibilities:		any, in study design; collection,	
43				
44	sponsor and		management, analysis, and	
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46	funder		interpretation of data; writing of the	
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1	Roles and	#5d	Composition, roles, and responsibilities	2, 19
2				
3	responsibilities:		of the coordinating centre, steering	
4			committee, endpoint adjudication	
5	committees		committee, data management team,	
6			and other individuals or groups	
7			overseeing the trial, if applicable (see	
8			Item 21a for data monitoring committee)	
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18	Introduction			
19				
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21	Background and	#6a	Description of research question and	4
22			justification for undertaking the trial,	
23	rationale		including summary of relevant studies	
24			(published and unpublished) examining	
25			benefits and harms for each	
26			intervention	
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35	Background and	#6b	Explanation for choice of comparators	7
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37	rationale: choice			
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39	of comparators			
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42				
43	Objectives	#7	Specific objectives or hypotheses	5
44				
45				
46	Trial design	#8	Description of trial design including type	5
47			of trial (eg, parallel group, crossover,	
48			factorial, single group), allocation ratio,	
49			and framework (eg, superiority,	
50			equivalence, non-inferiority,	
51			exploratory)	
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1 **Methods:**

2

3 **Participants,**

4 **interventions, and**

5 **outcomes**

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8				
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11	Study setting	#9	Description of study settings (eg,	6
12			community clinic, academic hospital)	
13			and list of countries where data will be	
14			collected. Reference to where list of	
15			study sites can be obtained	
16				
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23	Eligibility criteria	#10	Inclusion and exclusion criteria for	6
24			participants. If applicable, eligibility	
25			criteria for study centres and individuals	
26			who will perform the interventions (eg,	
27			surgeons, psychotherapists)	
28				
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35	Interventions:	#11a	Interventions for each group with	6
36			sufficient detail to allow replication,	
37	description		including how and when they will be	
38			administered	
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45	Interventions:	#11b	Criteria for discontinuing or modifying	7
46			allocated interventions for a given trial	
47	modifications		participant (eg, drug dose change in	
48			response to harms, participant request,	
49			or improving / worsening disease)	
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1 2 3 4 5 6 7 8 9	Interventions: adherence	#11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	8
10 11 12 13 14 15 16 17	Interventions: concomitant care	#11d Relevant concomitant care and interventions that are permitted or prohibited during the trial	7
18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43	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
44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	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

1	Sample size	#14	Estimated number of participants	11
2				
3			needed to achieve study objectives and	
4			how it was determined, including clinical	
5			and statistical assumptions supporting	
6			any sample size calculations	
7				
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13	Recruitment	#15	Strategies for achieving adequate	11
14			participant enrolment to reach target	
15			sample size	
16				
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21	Methods:			
22				
23	Assignment of			
24				
25	interventions (for			
26				
27	controlled trials)			
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31	Allocation:	#16a	Method of generating the allocation	11, 12
32			sequence (eg, computer-generated	
33	sequence		random numbers), and list of any	
34			factors for stratification. To reduce	
35	generation		predictability of a random sequence,	
36			details of any planned restriction (eg,	
37			blocking) should be provided in a	
38			separate document that is unavailable	
39			to those who enrol participants or	
40			assign interventions	
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1	Allocation	#16b	Mechanism of implementing the	12
2				
3	concealment		allocation sequence (eg, central	
4			telephone; sequentially numbered,	
5	mechanism		opaque, sealed envelopes), describing	
6			any steps to conceal the sequence until	
7			interventions are assigned	
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15	Allocation:	#16c	Who will generate the allocation	12
16				
17	implementation		sequence, who will enrol participants,	
18			and who will assign participants to	
19			interventions	
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24				
25	Blinding (masking)	#17a	Who will be blinded after assignment to	12
26				
27			interventions (eg, trial participants, care	
28			providers, outcome assessors, data	
29			analysts), and how	
30				
31				
32				
33				
34				
35	Blinding	#17b	If blinded, circumstances under which	12
36				
37	(masking):		unblinding is permissible, and	
38				
39	emergency		procedure for revealing a participant's	
40			allocated intervention during the trial	
41	unblinding			
42				
43				
44				
45	Methods: Data			
46				
47	collection,			
48				
49	management, and			
50				
51	analysis			
52				
53				
54				
55	Data collection	#18a	Plans for assessment and collection of	12
56				
57	plan		outcome, baseline, and other trial data,	
58				
59				
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1 including any related processes to
 2 promote data quality (eg, duplicate
 3 measurements, training of assessors)
 4 and a description of study instruments
 5 (eg, questionnaires, laboratory tests)
 6 along with their reliability and validity, if
 7 known. Reference to where data
 8 collection forms can be found, if not in
 9 the protocol

21				
22	Data collection	#18b	Plans to promote participant retention	12
23				
24	plan: retention		and complete follow-up, including list of	
25			any outcome data to be collected for	
26			participants who discontinue or deviate	
27			from intervention protocols	
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34	Data management	#19	Plans for data entry, coding, security,	12
35			and storage, including any related	
36			processes to promote data quality (eg,	
37			double data entry; range checks for	
38			data values). Reference to where	
39			details of data management procedures	
40			can be found, if not in the protocol	
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50	Statistics:	#20a	Statistical methods for analysing	13
51			primary and secondary outcomes.	
52	outcomes		Reference to where other details of the	
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1 statistical analysis plan can be found, if
 2
 3 not in the protocol
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 6 **Statistics:** [#20b](#) Methods for any additional analyses 13
 7
 8 additional (eg, subgroup and adjusted analyses)
 9
 10 analyses
 11

12
 13 **Statistics: analysis** [#20c](#) Definition of analysis population relating 13
 14 population and to protocol non-adherence (eg, as
 15
 16 missing data randomised analysis), and any
 17
 18 statistical methods to handle missing
 19
 20 data (eg, multiple imputation)
 21
 22
 23
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25 **Methods:**

26 **Monitoring**

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 31 **Data monitoring:** [#21a](#) Composition of data monitoring 1 (Queens University &
 32 formal committee committee (DMC); summary of its role University of Toronto
 33 and reporting structure; statement of committee members who are
 34 whether it is independent from the not involved directly in the
 35 sponsor and competing interests; and study but are at an arm's
 36 reference to where further details about length only to provide
 37 its charter can be found, if not in the guidance)
 38 protocol. Alternatively, an explanation of
 39 why a DMC is not needed
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52 **Data monitoring:** [#21b](#) Description of any interim analyses and 1 (Queens University &
 53 interim analysis stopping guidelines, including who will University of Toronto
 54 have access to these interim results committee members will be
 55
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1		and make the final decision to terminate	notified with the PI's final
2			
3		the trial	decision to terminate the trial
4			
5			if required)
6			
7			
8	Harms	#22 Plans for collecting, assessing,	7 (field notes)
9			
10		reporting, and managing solicited and	
11			
12		spontaneously reported adverse events	
13			
14		and other unintended effects of trial	
15			
16		interventions or trial conduct	
17			
18			
19			
20	Auditing	#23 Frequency and procedures for auditing	12
21			
22		trial conduct, if any, and whether the	
23			
24		process will be independent from	
25			
26		investigators and the sponsor	
27			
28			
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30	Ethics and		
31			
32	dissemination		
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35	Research ethics	#24 Plans for seeking research ethics	3, 14
36			
37	approval	committee / institutional review board	
38			
39		(REC / IRB) approval	
40			
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42			
43	Protocol	#25 Plans for communicating important	If such an amendment is
44			
45	amendments	protocol modifications (eg, changes to	required, it will be agreed
46			
47		eligibility criteria, outcomes, analyses)	upon by the committee and
48			
49		to relevant parties (eg, investigators,	resubmission for Ethics will
50			
51		REC / IRBs, trial participants, trial	be made
52			
53		registries, journals, regulators)	
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1	Consent or assent	#26a	Who will obtain informed consent or	12
2				
3				
4			assent from potential trial participants or	
5				
6			authorised surrogates, and how (see	
7				
8			Item 32)	
9				
10				
11	Consent or	#26b	Additional consent provisions for	n/a
12				
13	assent: ancillary		collection and use of participant data	
14				
15	studies		and biological specimens in ancillary	
16				
17			studies, if applicable	
18				
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21	Confidentiality	#27	How personal information about	13 (de-identification)
22				
23			potential and enrolled participants will	
24				
25			be collected, shared, and maintained in	
26				
27			order to protect confidentiality before,	
28				
29			during, and after the trial	
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33	Declaration of	#28	Financial and other competing interests	1
34				
35	interests		for principal investigators for the overall	
36				
37			trial and each study site	
38				
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40				
41	Data access	#29	Statement of who will have access to	1 (only my research team)
42				
43			the final trial dataset, and disclosure of	
44				
45			contractual agreements that limit such	
46				
47			access for investigators	
48				
49				
50				
51	Ancillary and post	#30	Provisions, if any, for ancillary and post-	n/a
52				
53	trial care		trial care, and for compensation to	
54				
55			those who suffer harm from trial	
56				
57			participation	
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1	Dissemination	#31a	Plans for investigators and sponsor to	3, 14
2				
3	policy: trial results		communicate trial results to	
4			participants, healthcare professionals,	
5			the public, and other relevant groups	
6			(eg, via publication, reporting in results	
7			databases, or other data sharing	
8			arrangements), including any	
9			publication restrictions	
10				
11	Dissemination	#31b	Authorship eligibility guidelines and any	19 (no intention use of
12			intended use of professional writers	professional writers)
13	policy: authorship			
14				
15	Dissemination	#31c	Plans, if any, for granting public access	3 (<i>Data sharing statement</i>
16			to the full protocol, participant-level	<i>No later than 2 year after the</i>
17	policy:		dataset, and statistical code	<i>collection of the 1-year</i>
18	reproducible			<i>feasibility and clinical</i>
19	research			<i>outcomes, we will deliver a</i>
20				<i>completely deidentified data</i>
21				<i>set to an appropriate data</i>
22				<i>archive for sharing</i>
23				<i>purposes.)</i>
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47	Appendices			
48				
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50	Informed consent	#32	Model consent form and other related	(See attached consent form)
51			documentation given to participants and	
52	materials		authorised surrogates	
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1	Biological	#33	Plans for collection, laboratory	n/a
2				
3	specimens		evaluation, and storage of biological	
4			specimens for genetic or molecular	
5			analysis in the current trial and for	
6			future use in ancillary studies, if	
7			applicable	
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Notes:

- 19 • 31c: 3 (pre-results on clinicaltrials.gov) The SPIRIT checklist is distributed under the terms of the
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21 October 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in
22 collaboration with [Penelope.ai](#)
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