

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	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
AUTHORS	Tran, Todd; Donnelly, Catherine; Nalder, Emily Joan; Trothen, Tracy; Finlayson, Marcia

VERSION 1 – REVIEW

REVIEWER	Martin PJ van Boxtel Maastricht University, the Netherlands
REVIEW RETURNED	23-Nov-2019

GENERAL COMMENTS	<p>This protocol describes a randomized controlled trial using mindfulness-based stress reduction (MBSR) in people with documented evidence of subjective cognitive complaints (SCD) or mild cognitive impairment (MCI). The background, aims and methodology of the study are well described by the authors and should (almost) suffice for replication of the study in the form of a larger RCT. I only have a few minor concerns, that may be addressed by the authors in a revised version of the manuscript.</p> <ol style="list-style-type: none">1. The intervention is described as a typical MBCT, but going over the actual program it appears that the engagement in formal exercises is substantially lower in the program when compared to the original MBSR. Also, duration of the suggested daily home exercises seems shorter. It has been shown that efficacy of the training is directly related to actual participation in the exercises, both during the training and at home. If adjustments were made to reduce this engagement (e.g. to improve compliance?) this may also reduce a potential effect of the training.2. It is mentioned that 4 occupational therapists received a training to administer the MBSR. How experienced are these trainers? If the study aims at maximizing the effect on its participants, it is essential that experienced trainers in the MBSR program are used. The level of experience is not mentioned in the protocol. Also, why are 4 trainers necessary, when only one group is expected to participate? Working with more than 2 trainers during an 8-week program would be rather atypical for MBSR.3. It is mentioned that the involved trainers are tested regarding their aptitude to deliver the training using the MBI-TAC. This instrument is quite difficult to administer, and it is not clearly mentioned how the assessment of trainers will take place and what consequences it may have when performance of a trainer is substandard.
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	4. The use of iPads seems innovative, as it enables careful assessment of the level of home practice. It is unclear how the use of technology during the training itself is implemented. There seems to be a large amount of time per session devoted to information exchange, e.g. on use of the device. In MBSR the exchange is about personal experiences during the formal exercises (as part of the 'inquiry'). Communication about other topics could interfere with the experiential learning that is essential in MBSR sessions.
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REVIEWER	Elena Salmoirago-Blotcher, Associate Professor of Medicine and Epidemiology The Miriam Hospital, Brown University School of Medicine
REVIEW RETURNED	25-Nov-2019

GENERAL COMMENTS	<p>This is the protocol for a pilot study examining the feasibility of conducting an RCT of an occupational therapist-led MBSR program for patients with cognitive impairment. Although the article is generally well written, it reads a bit like a dissertation proposal rather than a study protocol. Critical information is missing or unclear (e.g., inconsistencies in description of outcomes; blinding; PI's involvement in data management and analysis) and the study appears to have important methodological flaws. Specific comments are provided below hoping they might be helpful in addressing the concerns noted above, if possible.</p> <p>INTRODUCTION AND ABSTRACT The statement that MBSR is beneficial for 'psychosocial' issues does not seem justified. Unclear how MBSR (or medications, for that matter) would ameliorate 'social' issues. Pls clarify which are the primary and secondary outcomes for the trial. Feasibility should be the primary outcome; what listed in the introduction text is inconsistent with the abstract; and the abstract itself lists two different primary outcomes.</p> <p>STRENGTHS/LIMITATIONS -This study is evaluating the feasibility of MBSR in this population, not the 'impact'. -The very small sample size should be listed among the limitations. -The lack of an attention control comparison group should also be listed here, considering that the secondary outcomes are "soft" measures and possible improvements in the proposed measures could be explained by the attention received by the MBSR trainer.</p> <p>METHODS Unclear if both the MOCA and GDS scores are eligibility criteria for the study</p> <p>Interventionist – unclear how the occupational therapist will be trained in MBSR; credentials of MBSR instructors are unclear. Being an OT per se is not a qualification for teaching MBSR. Later in the text it is mentioned that the trainer is a qualified MBSR teacher.</p> <p>Fidelity: metrics of intervention fidelity need to be clarified (i.e., how fidelity is assessed and operationalized).</p> <p>Outcomes; again, there are inconsistencies about what constitutes the primary outcome of the trial. Feasibility metrics should be provided (i.e., what are the criteria by which the study will be</p>
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	<p>considered feasible). There seems to be some confusion between acceptability and feasibility.</p> <p>Sample size: a convenience sample is apparently proposed, but then the authors state that the proposed n is accounting for a 20% dropout rate? When describing 'acceptability', the authors say they are looking at 66% of participants completing an assessment at T3 (33% attrition?)</p> <p>Randomization – the PI apparently is involved in screening and consenting visits, as well as randomization procedures. Even with the constraints of a small study, this is problematic. PIs also clarify who will design the randomization sequence.</p> <p>Blinding - Likewise, it seems inappropriate that the PI is responsible for data management and analysis. Research allegiance bias could be an issue.</p> <p>ANALYSIS Running test statistics for baseline characteristics seems redundant given the random assignment. Unclear why the authors are looking for significant differences in outcomes between the intervention and the control group in a feasibility pilot study. Even if statistically significant, estimates from small pilot studies are typically unstable.</p> <p>CONCLUSIONS Given the pilot nature of the study and its limited scope, it is unlikely that results 'will provide insights into the management' of the population under study. The last sentence ("findings from this trial will offer feasibility challenges") is unclear.</p>
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REVIEWER	Neil Thomas Swinburne University of Technology, Australia
REVIEW RETURNED	09-Dec-2019

GENERAL COMMENTS	<p>This paper describes the protocol for a trial of mindfulness based stress reduction targeting a novel population: older adults with cognitive decline. The trial methodology appears appropriate, but there are a number of points to clarify or reword in the protocol. Comments as follows:</p> <ol style="list-style-type: none"> 1. There are a repeated grammatical errors in the manuscript which affects its readability. Please ensure it is thoroughly proof-read before resubmission. 2. Abstract first two sentences: using the term "psychosocial issues" to refer to anxiety, low mood etc is an unusual use of this term – social issues are not referred to – suggest psychological symptoms or psychiatric symptoms. 3. Side-effects and polypharmacy as probably better described as "complications" or "disadvantages" rather than "limited benefits". 4. Abstract methods: I'd clarify that feasibility and satisfaction are the primary aims, and refer to examination of clinical outcomes as a secondary aim with functional performance outcomes as the primary clinical outcome. 5. Trial registration mentioned twice in abstract. 6. Introduction: The benefits of MBSR to mental health and in adaptation to chronic illness are well enough known to cover briefly, as done in the manuscript. However, that "MBSR may be neuroprotective against cognitive decline" is less well known.
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Please could you elaborate briefly with more detail of the studies by Wells et al 2013 and Smart et al 2016 – it will also be helpful to the reader to understand how this pilot study will build on those two pilot studies.

7. “delivering technology-based tablets for intervention and data collection” seems odd wording – do you mean “using tablet-based technology to support intervention delivery and data collection”
8. Design: As part of the initial description of the design, please highlight the assessment timepoints.
9. Exclusion criteria: it reads as if persons will be excluded with a past history of cancer, bereavement etc – please clarify as I’d suspect this would only be an exclusion if current
10. “MoCA of 21 (+/-4) or under” is unclear – what do the numbers in brackets mean?
11. Tablet computers: note that iPad is a trade name: I’d suggest using the term “tablet computer” when referring generically, and clarify the model (e.g. “Apple iPad Mini”) at an appropriate point.
12. Insight timer – please provide a reference for this.
13. I have doubts how reliable a measure of duration of mindfulness practice the Insight Timer will provide, as exercises can keep running once the person has stopped actively engaged in them. Could the researchers justify this, or provide detail on how this is validated?
14. Please detail training of MBSR therapists.
15. The MBSR Fidelity section was hard to follow. Please reword. The sentence beginning “To examine program efficacy...” did not make sense. Also clarify will the OTs/teachers be following the MBITAC as a guide to delivery or will this be used to rate their adherence/intervention fidelity? If the latter, who will rate this?
16. In the COPM section, “Strong test-retest...” sentence did not make sense. Please reword.
17. In the AAQ-II description, it sounds like test-retest reliability and internal consistency are being confused in the second sentence.
18. Feasibility – as the primary aim is to assess feasibility, I’d suggest putting this before the clinical outcomes.
19. Who are the “clinicians” who are collecting data during the period of the intervention? My guess is that these are the persons delivering the intervention – if so please use consistent terminology (OTs vs clinicians vs teachers).
20. Focus groups: it is not clear exactly when and how these will be run. Please provide detail.
21. Treatment allocation first sentence (“A randomization block size of four design...”) does not read clearly: please reword.
22. It sounds as if the PI will have knowledge of the randomisation schedule, yet will be responsible for assigning participant IDs – this does not make sense as it would allow the PI to influence which intervention participants are allocated to. Please check wording or clarify.
23. Blinding: what procedures are in place to minimise risk of unblinding, and what procedures will be used when unblinding arises?
24. Analysis. Who will conduct the analysis (the PI vs someone blind to treatment allocation)?
25. “Mean change scores and SDs will be conducted using paired t-test or ANOVA” conflates calculation of summary statistics with null hypothesis significance testing. Please reword.
26. This currently reads as if the main analysis will be pre-to-post scores, rather than there being a between groups analysis. Please clarify.

	<p>27. Although it continues to be widely used, LOCF has been criticised as biased compared with other imputation methods. The authors may wish to reconsider this approach to missing data.</p> <p>28. Conclusion: please reword final sentence “offer feasibility challenges” should perhaps be “highlight feasibility challenges”.</p> <p>29. SPIRIT Checklist – I don’t think the numbers correspond to the article. This looks like a version that was submitted for another purpose.</p> <p>30. DMC – the study does not appear to have an independent DMC (a PhD student committee would not usually have the functions of a DMC and have competing priorities): please explain why a DMC is not needed as per SPIRIT guidelines in this scenario (e.g. if not routinely required in Canada for psychosocial intervention trials).</p> <p>31. Harms – please provide more detail on how adverse effects (serious adverse events and adverse effects of the intervention) will be monitored and reported in publication. This is particularly important as there is not a dedicated DMC. For instance, what procedures are in place to review serious adverse events (e.g., hospital admissions) and withdrawals to consider whether these are related to the intervention.</p> <p>32. Unless required by the journal, the participant information and consent forms are not required as part of the manuscript supplementary materials, but the program outline is useful to include.</p>
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VERSION 1 – AUTHOR RESPONSE

<p>Reviewer #1 (Dr. van Boxtel)</p> <p>Question 1:</p> <p>“The level of engagement of the MBSR program appears to be substantially lower in the program.”</p>	<p>249, Page 6</p>	<p>The level of engagement is the same as a typical MBSR program (3 hours per class) see line 251. The home practice recording is a bit shorter at 38 mins versus traditional 45 mins (just short 7 minutes). This is based on other literature other studies by (1) that older adults with cognitive impairment, their ability to focus and concentrate is decreased and thus, would need a bit of accommodation. A slight reduction in the home practice minutes should not be significant enough to impact the study. It was also noted that there is other homework on top of the mindful practices e.g. readings, 9-dot exercise, pleasant or unpleasant calendar, along with informal practices e.g. washing the dishes, taking out the garbage etc. so we are aware of the reality of the time commitment.</p> <p>The outline of the curriculum is also reflective of this on the consent form. My apologies for the miscommunication. Thank you.</p>
<p>Question 2a:</p>	<p>244, Page 6</p>	<p>All four MBSR facilitators are experienced mindfulness teachers for a minimum of 3-</p>

<p>Reviewer 1 and 3</p> <p>Level of experience of the MBSR facilitators not mentioned in the protocol</p>		<p>years. Three of the four facilitators are Qualified-MBSR Teachers who have undergone training at the University of Massachusetts Medical School, Centre for Mindfulness in Medicine, Health Care and Society. And one facilitator has the MBSR-qualifications from elsewhere. Thank you for this important question.</p>
<p>Question 2b:</p> <p>Rationale for working with two or more MBSR teachers</p>	<p>246, Page 6</p>	<p>Yes, a typical MBSR group usually has two facilitators; however, due to the unique population with cognitive impairment and the use of technology, e.g. iPads, having additional staff is beneficial to assist with any technological and cognitive issues that may arise. Having additional facilitators is beneficial to follow-up with participants with missed classes, coming in late etc. Lastly, having the 4 facilitators allowed for life situations such as sickness or vacation time when one of the facilitators cannot make it for a session. In one case, one of the facilitators got married and was away for 2 weeks. This is a reflection on life and personal obligations. But the least number of facilitators available is 3 per session. Thank you for clarifying.</p>
<p>Question 3:</p> <p>“Trainers are tested regarding their aptitude to deliver the training using the MBI-TAC”.</p>	<p>296, Page 8</p>	<p>Thank you for your clarification. MBI-TAC is only used as a tool for supporting “proficiency” of fidelity and integrity of the practice of mindfulness-based teaching within this study. This is done through discussions and feedback to one another and modelling what the embodiment of mindfulness practice (professionally and personally) is. This tool was not used to test each other, as this is not the focus of the study. The MBI-TAC is used as a guide for facilitators and each other to model for each other. All four Qualified-MBSR Teachers are rated as proficient to advanced, based on the 5+ years of teaching MBSR. Facilitator(s) who do not have the minimum (e.g. Qualified-MBSR Teacher status) requirement is not invited to participate in the study. Thank you.</p>
<p>Question 4:</p> <p>It is unclear how the use of technology during the MBSR program is implemented? There seems to be a large amount of time</p>	<p>Consent Form revised</p>	<p>The iPads will be introduced during Orientation (Week 0), and the facilitators will be available to deal with any technological issues before and after class. Another opportunity would be at break time as not to interrupt the flow of the MBSR curriculum (practice and inquiry). As well, technical issues can be dealt with over the phone if appropriate. Lastly, we made a lot of</p>

per session devoted to information exchange on tablets, which may interfere with the experiential learning essential to the MBSR sessions.		accommodations on the iPad for ease of facilitation of use, e.g. removing passwords, all unnecessary Apps, newsfeed or anything that is distracting and keeping only the App that is required for home practice. As this is a feasibility study, this point is valuable and will be part of the discussion in a future paper. Thank you.
Reviewer #3: Dr. Neil Thomas #1 – The manuscript has been thoroughly proof-read for grammatical errors.		Apologies, many attempts were made to proof-read this manuscript and thank you.
Reviewer #2 and #3: #2 – Changed wording from psychosocial to “psychological issues.”	Throughout manuscript	I have changed this in the abstract. <u>Reviewer’s Comment #2:</u> We have changed “psychosocial” to “psychological symptoms,” which will differentiate from “social issues.” Correct, MBSR and medication cannot help with social issues but can with psychological symptoms. Thank you.
#3 - Using “complications” to better describe side-effects and polypharmacy	91, Page 3	Made these changes. Thank you for your suggestion.
Reviewer #2 and #3: #4 - Clarified Primary and Secondary Aims along with primary and secondary clinical outcomes	101 Page 3 and 181 Page 5	Changed in Abstract Methods. I much appreciated your comment. Thank you. <u>Reviewer’s Comment #2:</u> Primary and secondary aims clarified along with the primary and secondary clinical outcomes. Thank you.
#5 – Removed the second duplication of Trial Registration	Removed	I removed the duplication. Thank you.
#6 – Building on Wells et al 2013 and Smart et al 2016	162 Page 4	Due to word count, elaborated based on suggestion. Thank you.

#7 – Changed the wording from “delivering technology...” to recommended wording of “using tablet-based technology to support...”	188, Page 5	I made the recommended revision. Thank you.
#8 – Please highlight the assessment time points	205, Page 5	Added the three different assessment time points. Thank you.
#9 – Clarify exclusion criteria with “History of cancer...” to “Current...”	235, Page 6	I made the change. Thank you for the suggestion.
#10 – Please explain the MoCA with (+/-4)	217, Page 6	The MCI cut-off is ≤ 22 on the MoCA (2). This article used the (+/-4) but it adds confusion, so we will <u>remove</u> this and will leave it at ≤ 22 . MoCA is only used as a screening tool. Thank you.
#11 – Use the term “tablet computer” and will clarify the model (e.g. Apple iPad Mini) at an appropriate point.	Throughout the manuscript	The term “tablet computer” has been made throughout the manuscript. Thank you.
#12 – Providing reference for Insight Timer	255 Page 7	Apologies, reference provided. Thank you!
#13 – Validation of how reliable a measure of the duration of mindfulness practice with the Insight Timer App	262 Page 7	Exactly, and this can be a manuscript on itself. However, as this is a feasibility study, we will track the App metrics for duration, frequency and log-ins but also will ask participants to write down their weekly home practice by using pen and paper, and we will compare this to the App for accuracy. We suspect that participants may over-inflate their written home practice times. However, we are interested in clinical change, and by collecting home practice hours, we can analyze if duration (by using both App and traditional handwritten logs) impact clinical outcomes. Thus, improvements in clinical outcomes will be examined in terms of duration of home practice both by the App and handwritten logs. Thank you for clarification.

<p>Reviewer #1, #2 and #3:</p> <p>#14 – Training of MBSR therapists</p>	<p>285, Page 7</p>	<p>Clarified and explained. Thank you.</p>
<p>Reviewer #2 and #3:</p> <p>#15 – Rewording of the section on “Fidelity”</p> <p>How fidelity is assessed and operationalized</p>	<p>277 Page 7</p>	<p>Reworded and modified. Thank you.</p>
<p>#16 – Rewording of the COPM section as “strong test-retest..” sentence does not make sense. Please reword.</p>	<p>381 Page 8</p>	<p>Reworded and modified. Thank you.</p>
<p>#17 – In the AAQ-II description, test-retest reliability and internal consistency being confused in the second question</p>	<p>430 Page 10</p>	<p>Correct. I made the changes. Thank you.</p>
<p>#18 – Add feasibility as a primary outcome</p>	<p>308 Page 8</p>	<p>Moved the feasibility outcomes before the clinical outcomes as recommended. Thank you.</p>
<p>#19 – Clarification of who are the clinicians (OTs vs clinicians vs teachers) collects the data during the period of the intervention.</p>	<p>Changes made throughout the manuscript</p>	<p>To use consistent terminology, clinicians have been changed to Qualified-MBSR Teachers, who happen to be occupational therapists. Yes, the MBSR Teachers will be collecting feasibility outcomes throughout the intervention and, in the end, will be interviewed individually. The Research Assistant (RA) will be collecting only clinical outcome measures at three different time points, and the RA is not involved in the study. Made terminology more consistent.</p> <p>Thank you.</p>
<p>#20 – Explaining “when” and “how” of the focus group and MBSR Teacher interviews will be run</p>	<p>When: 341 Page 9</p>	<p>This is modified in the manuscript to answer the focus group question of the “when” and “how.” Thank you.</p>

	How: 521 Page 12	
#21 – Treatment allocation 1 st sentence does not read clearly. Please rewording of the first sentence in the treatment allocation section	482 Page 12	Reworded the first two sentences as per request to read clearly. Thank you.
<u>Reviewer #2 and #3:</u> Reviewer #2: Who will design the randomization sequence? #22 – PI knowing the randomization schedule, yet will be responsible for assigning participant IDs – this does not make sense as it would allow the PI to influence which intervention participants are allocated to. Please check or clarify.	488 Page 12 488 Page 12	Apologies for the incorrect wording. The PI will be blinded to the randomization schedule as this has been designed and prepared by a research staff member not involved in the study. Thus, it would not allow the PI to influence which intervention participants are allocated to. Thank you. See previous comments.
#23 – Blinding: What procedures are in place to minimize the risk of unblinding, and what procedures will be used when unblinding arises?	498 Page 12	I've added the procedures to minimize the risk of unblinding and discussed what procedures will be used when unblinding arises. Thank you.
#24 – Analysis: Who will conduct the analysis, the PI versus someone blind to the treatment allocation?	548, Page 13	Both, the PI will analyze in conjunction with an independent biostatistician who is not involved in the study and is blinded to the treatment allocation. Thank you.
#25 – “Mean change scores and SDs will be conducted using paired t-test or ANOVA” conflates calculation of summary with null hypothesis significance testing. Please reword.	562 Page 13	This paragraph has been reworded. Thank you.

#26 – This reads as if the main analysis will be pre-to-post scores, rather than there being a between-groups analysis. Please clarify	563 Page 13	This has been reworded to have better clarification in line 616. Thank you.
#27 – LOCF has been criticized as biased compared with other imputation methods. The authors may wish to reconsider this approach to missing data.	553, Page 13	<p>We as a team, decided to use LOCF based on the fact that:</p> <ul style="list-style-type: none"> i. The aim of the study is the feasibility ii. Small sample size iii. Future studies will be larger, and we will use a more sophisticated approach to allow additional factors to account for the missing data. As well as using thorough data analysis for missing data through multiple ways under different sets of assumptions (3). <p>A very valid point, thank you.</p>
<p><u>Reviewer #2 and #3:</u></p> <p>#28 – Reword final sentence to perhaps be “highlight feasibility challenges” instead of “offer feasibility challenges.”</p> <p><u>Conclusions:</u></p> <p>The last sentence is unclear, reword.</p>	592 Page 14	The final sentence reworded to “highlight” feasibility challenges, based on the Reviewer’s recommendation. Thank you.
#29 – SPIRIT Checklist does not correspond to the article	204 Page 5	The SPIRIT checklist is attached. Thank you. I also added a reference to the SPIRIT guideline in the Methods section. Thank you
#30 – The study does not have an independent Data Monitoring Committee (DMC)	510 Page 12	We added the Data Management section. The committee from Queen’s University and the University of Toronto will service the role

		of DMC as part of PI's research/Ph.D. program. Thank you for this comment.
#31 – What procedures are in place to review serious adverse events (e.g. hospital admissions) and withdrawals to consider whether these are related to the intervention	270 Page 7	<p>Based on my experience as a clinician running previous MBSR groups since 2012, there is minimal, if any, adverse events. The only adverse events that may come in mind would be a trigger of PTSD symptoms (trauma) or an exacerbation of prolonged anxiety and depression, which is rare. If this happens, as per protocol in line 270, we can refer to a Social Worker on the team to address any exacerbation of symptoms. Additionally, there is also a psychiatrist on the team that can also provide consults if required. Other adverse events could be, e.g. falls, weather conditions, physical pain related to gentle mindful movements (but this can be individually modified based on their physical limitations).</p> <p>The best thing about working on an academic Family Health Team (FHT) is that we collaborate with their family physicians regularly. For those who drop out, we will be contacting them for reason of dropping out, and follow-up to make sure that there are no adverse events. Based on my experience, most dropouts are related to a lack of time for home practices. But for any adverse events, it will be documented and noted in the analysis and will be discussed in the results section. And with consent from the participant(s), we will collaborate with their family physician on the FHT. Based on the literature review on other mindfulness studies, adverse events are extremely rare, if any.</p>
#32 – The participant information and consent forms are not required as part of the manuscript supplementary materials		Noted. Thank you for the information.
Reviewer #2 (Dr. Salmoirago-Blotcher)	101 Page 3; onwards	Modified based on the comments. Thank you.

<p><u>Strengths/Limitations Section:</u></p> <p>i.) Replace “feasibility” instead of “impact.”</p> <p>ii.) The very small sample size is a limitation</p> <p>iii.) Lack of an attention control comparison group</p>	<p>131 Page 4</p>	<p>I added this. Thank you.</p>
<p><u>Methods:</u></p> <p>Unclear if both the MoCA and the GDS scores are eligibility criteria for the study</p>	<p>216 Page 6</p>	<p>Correct, the MoCA and the GDS scores are eligibility criteria. This has been modified for better clarity. Thank you.</p>
<p><u>Outcomes:</u></p> <p>Inconsistencies with the primary outcome of the trial. <i>Feasibility</i> metrics should be provided. Confusion between acceptability and feasibility.</p>	<p>308 Page 8</p>	<p>This has been reworded for better clarity. And also, the subheadings are changed to objective (e.g. feasibility, acceptability and satisfaction) to have a better flow. Thank you.</p>
<p><u>Sample Size:</u></p> <p>The convenience sample size is proposed but then states the proposed sample size is accounting for 20% drop-out rate? When describing feasibility, the researchers are looking at 66% of participants to complete at T3 (33%) attrition rate.</p>	<p>461 Page 11 and 322 Page 8</p>	<p>Modified this in the feasibility section line 322 and this is more consistent with the sample size section in line 461. We are hoping our attrition rate is like other feasibility studies at 20%. Thank you.</p>
<p><u>Blinding:</u></p> <p>It seems inappropriate that the PI is responsible for data management and analysis as research allegiance bias could be an issue.</p>	<p>498 Page 12</p>	<p>As the PI, I will have to make sure that everything is done correctly and on time as this is my dissertation work. However, my committee will make sure that everything will be conducted ethically. We added a section on the Data Management section. To avoid allegiance bias, a biostatistician who is not</p>

		part of the study will provide consult in the analysis phase. Thank you.
<u>Analysis:</u> Running test statistics for baseline characteristics seem redundant given the random assignment.	559 Page 13	Most literature does ask for a baseline t-test to make sure the two groups are normally distributed. For that reason, we are following the literature. Just in case the two groups were not randomly allocated. Thank you.
Unclear why the authors are looking for significant differences in outcomes between the two groups in a feasibility pilot study. Even if statistically significant, estimates from a small pilot are unstable.	317 Page 8	Correct; however, as cited by Aguirre et al (2017) they recommended guidelines for good practice for the analysis of pilot studies by focusing the results on the estimates of the treatment effects rather than on statistical significance, and as such, no hypothesis testing will be undertaken. Thus, this feasibility study will follow that recommendation (4)(5) (6) Reference 33 in manuscript.
<u>Conclusion:</u> Due to the pilot nature and scope of the study, it is unlikely that results “will provide insights into the management” of the population under study	587, Page 14	Point taken. This paragraph has been reworded and given a new heading “Benefits of Participants”. Thank you.

References

1. Smart CM, Segalowitz SJ, Mulligan BP, Koudys J, Gawryluk JR. Mindfulness Training for Older Adults with Subjective Cognitive Decline: Results from a Pilot Randomized Controlled Trial. *Journal of Alzheimer's disease* 2016;52(2):757.
2. Clarnette R, O’Caoimh R, Antony DN, Svendrovski A, Molloy DW. Comparison of the Quick Mild Cognitive Impairment (Qmci) screen to the Montreal Cognitive Assessment (MoCA) in an Australian geriatrics clinic. *International Journal of Geriatric Psychiatry*. 2017;32(6):643-9.
3. Wong WK, Boscardin WJ, Postlethwaite AE, Furst DE. Handling missing data issues in clinical trials for rheumatic diseases. *Contemporary Clinical Trials*. 2011;32(1):1-9.
4. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *Journal of evaluation in clinical practice*. 2004;10(2):307-12.
5. Simpson R, Mair FS, Mercer SW. Mindfulness-based stress reduction for people with multiple sclerosis - a feasibility randomised controlled trial. *BMC Neurology* U6 - ctx_ver=Z3988-2004&ctx_enc=info%3Aofi%2Fenc%3AUTF-8&rft_id=info%3Aasid%2Fsummonserialsolutionscom&rft_val_fmt=info%3Aofi%2Ffmt%3Akev%3Amtx%3Ajournal&rftgenre=article&rftatitle=Mindfulness-based+stress+reduction+for+people+with+multiple+sclerosis+-+a+feasibility+randomised+controlled+trial&rftjtitle=BMC+Neurology&rftau=Robert+Simpson&rftau=Frances+S+Mair&rftau=Stewart+W+Mercer&rftdate=2017-01-01&rftpub=BioMed+Central&rftissn=1471-2377&rftvolume=17&rft_id=info:doi/10.1186%2Fs12883-017-0880-8¶mdict=en-US U7 - Journal Article. 2017;17.

6. Aguirre E, Stott J, Charlesworth G, Noone D, Payne J, Patel M, et al. Mindfulness-Based Cognitive Therapy (MBCT) programme for depression in people with early stages of dementia: study protocol for a randomised controlled feasibility study. 2017;3.

VERSION 2 – REVIEW

REVIEWER	Martin. P. J. van Boxtel, MD PhD Dept. Psychiatry and Neuropsychology School for Mental Health and Neuroscience (MHeNs) Maastricht University The Netherlands
REVIEW RETURNED	11-Feb-2020
GENERAL COMMENTS	All issues that were raised based on the first version of the manuscript have been addressed adequately by the authors.