

PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	MOBILE TECHNOLOGY INTERVENTION FOR WEIGHT LOSS IN RURAL MEN: PROTOCOL FOR A PILOT PRAGMATIC RANDOMIZED CONTROLLED TRIAL
AUTHORS	Eisenhauer, Christine; Brito, Fabiana; Yoder, Aaron; Kupzyk, Kevin; Pullen, Carol; Salinas, Katherine; Miller, Jessica; Hageman, Patricia

VERSION 1 – REVIEW

REVIEWER	Richard Rosenkranz Kansas State University United States
REVIEW RETURNED	28-Nov-2019

GENERAL COMMENTS	<p>I applaud the authors for undertaking research on an important topic for a large population of rural men. The manuscript is mostly in good order and reflects rigorous scientific inquiry. Despite those positive attributes, several concerns need to be addressed.</p> <p>Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.</p> <p>According to Whitehead et al (2014): A pilot study is not a hypothesis testing study. Safety, efficacy and effectiveness are not evaluated in a pilot. Contrary to tradition, a pilot study does not provide a meaningful effect size estimate for planning subsequent studies due to the imprecision inherent in data from small samples. Thus, effect sizes provided by pilot studies should not be used to power a subsequent full trial. Instead clinical experience should be used to define a clinically meaningful effect. A pilot study is a requisite initial step in exploring a novel intervention or an innovative application of an intervention. Pilot results can inform feasibility and identify modifications needed in the design of a larger, ensuing hypothesis testing study. See http://dx.doi.org/10.1016/j.cct.2014.04.001</p> <p>Page 2, Line 18: the age range contradicts ages elsewhere. Include year as unit.</p> <p>Page 3, Line 30 Source cited indicates obesity is 34.1% in Nebraska. Ogden et al data indicate OW + OB around 70%. Citation #3 is related to fruit and vegetable consumption.</p> <p>Page 3, Line 35: citation needed here and above.</p> <p>Page 4, Lines 18-20: Not appropriate justification, and not a recommended approach. See Lancaster 2015; Whitehead et al 2014.</p> <p>Page 4, Lines 37-38: unclear what this means.</p>
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	<p>Page 4, Line 43: change format to aged 40--69y, currently contradicts abstract</p> <p>Page 4, Line 46: further explanation needed on BMI value around 50 and clinician clearance in relation to 396 pounds. Be clear.</p> <p>Page 5: sync is informal version of synchronize. Recommend formality. App should not have period/full stop if being used to indicate computer application.</p> <p>Page 5, Line 37: healthy living?</p> <p>Page 5, Line 39: CDC = Centers for Disease Control and Prevention (prevention is redundant).</p> <p>Page 5, Line 52: Need to define adherence and indicate how it will be assessed.</p> <p>Page 5, Line 53: Who is he? Clarify.</p> <p>Page 6: caps needed for basic and premium?</p> <p>Page 6, Line 8: Clarify "weigh as often as they can."</p> <p>Page 6, Line 24: Rephrase "Two groups permits" for clarity regarding study design.</p> <p>Page 6: The primary outcomes do not align well with pilot study design and stated aims of the study. Provide citation for BEVQ-15 here.</p> <p>Page 7: Define GA (and PI later); Is this a cut and paste error? "This publication's contents are the sole responsibility of the authors and do not necessarily represent the official views of the VCR and NIH." Seems like this should be cut or appear elsewhere.</p> <p>Page 7: Blinding is not expected for the types of interventions being tested within the type of study being conducted. The current justification is not appropriate and could simply be cut.</p> <p>Page 7, Lines 34-35: Aims are not consistent throughout manuscript.</p> <p>Page 8: Use apostrophe on participant's height; who is their (line 32)? Short sleeve short?</p> <p>Page 8: Blood pressure device has been validated for research purposes? If so, citation needed. If not, justification needed.</p> <p>Page 9: PROMIS-29 needs citation. Check format (italics, hyphen) of a priori.</p> <p>Page 10: Citation for RM-ANOVA?</p> <p>Appendix 1: Why are weeks out of numerical order?</p>
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REVIEWER	Emma George Western Sydney University, Australia
REVIEW RETURNED	30-Nov-2019

GENERAL COMMENTS	<p>Thank you for the opportunity to review this protocol. This study is targeting an important population group for the promotion of weight loss and healthy lifestyle behaviours, and the protocol is detailed and mostly clear. The following comments should be considered to enhance the manuscript.</p> <p>Abstract: In the first sentence, the authors refer to the "rural Midwest". I would suggest clarifying that this is in the United States.</p> <p>What is meant by "a rural culture"? In other contexts, those living in rural areas tend to have highly active lifestyles, comprising a lot of manual labor. As there is not a lot of space to elaborate in the abstract, it may be worth removing the term here and referring to the poor lifestyle behaviours.</p>
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	<p>I see the measurement tools will be used to assess dietary intake and physical activity are included later in the paper, but could the authors also include these in the abstract?</p> <p>P3, line 44: The authors note that access to weight loss resources is one reason for poor engagement in weight loss programs/practices, however, the paper cited is related to pediatric weight management in rural areas. Is there other evidence to suggest this in an adult population?</p> <p>P4, line 30: The design overview is clear and detailed, and the use of a community advisory board ensures the program will meet the needs of the target population. I wonder if it is possible to include a couple of examples of the types of health professions students on the board are studying?</p> <p>P5, line 23-24: There is a portion of text in the Social Support section that should be revised for clarity: "The discussion board will also provide opportunity for social comparison of others' self-monitoring experiences providing a mechanism to influence judgement and behaviour change towards one's own self-monitoring".</p> <p>P5, line 45: Has the timing for the text messages been reviewed by the CAB members, or is this informed by existing programs? Those who work 9-5 may be commuting when the 8am text is received, so I wonder if this should be considered?</p> <p>P6, line 15: Is the hands-on orientation held during a face-to-face appointment?</p> <p>P6, line 54: It may be worth explaining what "Facebook blasting" is. Also, which websites will be used for recruitment?</p> <p>P7, line 3: It is mentioned that minority men will be recruited through community health workers – can the authors elaborate on the specific minority groups they hope to reach?</p> <p>P8, Randomisation and Blinding: Will outcome assessors be blind to program allocation at the in-person health appointments?</p>
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REVIEWER	Myles Young University of Newcastle, Australia
REVIEW RETURNED	02-Dec-2019

GENERAL COMMENTS	<p>This paper presents the protocol for a pragmatic RCT testing the impact of two e-health approaches on the health of rural men with overweight or obesity. The focus of this paper is very relevant, given these men are often at high risk for chronic disease, but have limited options to access services. Adherence to traditional masculine norms also reduces the number of men who seek help in these areas. Overall, I found this to be a generally well-written manuscript concerning a novel approach to reaching these men. However, I do have some suggestions for the authors to consider as outlined below.</p> <p>Abstract - I found the incomplete sentences a bit jarring (e.g., P2 L14, L25-28)</p>
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	<p>- P2 L14-18 – The intervention description here is confusing. At first I was unsure if the three terms in brackets represented three different intervention arms. I was also unsure what MT and MT+ stood for.</p> <p>- P2, L22 – provide detail on which statistical analyses will be used (at least for primary outcomes if space is short).</p> <p>Article summary</p> <p>- The author guidelines suggest this summary section should only include the five dot points currently listed under strengths and limitations.</p> <p>Introduction</p> <p>- P3, L39-41 – Although few studies have targeted rural men with mobile health interventions, research into e-health interventions targeting men has been growing consistently in recent years. I think a brief summary of this literature would help establish the rationale of the current trial.</p> <p>- P3, L32: PA is abbreviated here, but the abbreviation isn't used consistently through the paper.</p> <p>Methods</p> <p>- P4, L14-17 – I was unclear what this sentence means, could it be reworded for clarity? (A pRCT is selected to maximize assessment of men's variations in treatment availability option (free comparator app))</p> <p>- P4, L37-38 – what do you mean by 'participants were not involved in any of the recruitment of this study'?</p> <p>- P4, L43 – what was the rationale for not including younger men in the study?</p> <p>- P5 L3-16 – is Lose-It a freely available app or was it developed by the research team? Also, is the app designed for men?</p> <p>- P5, L37 – typo – health vs healthy</p> <p>- P5, L44-46 – was there a rationale to guide the frequency/number of texts sent during the intervention?</p> <p>- P6, L45-47 – this sentence needs a reword.</p> <p>- P6, L54 - What is Facebook blasting?</p> <p>- P7, L11-16 – I am not used to seeing a declaration like this in the middle of a methods section. Perhaps this could be moved to a footnote?</p> <p>- P7, L19 – how will the participant provide a wet signature online?</p> <p>- P7, L25 – are the people assessing the outcomes also unblinded, or just the participants?</p> <p>- P7, L45 – I am unfamiliar with the new acronyms introduced here (health ITUES, PROMIS-29)</p> <p>- P7, L52 – to calculate BMI, does the Tanita scale measure height as well as weight?</p> <p>- P8, L14 – many of the text messages relate to dietary behaviours that are not being measured in this study. Was there a rationale for focusing specifically on SSB intake and fruit and vegetables in the outcomes measures?</p> <p>- P9, L40 – can you be more specific about how you will determine feasibility? When it comes to participation rates, retention rates, useability, and satisfaction, how will you know if the trial has been feasible?</p> <p>- P10, L22, at what threshold will you switch to mixed models analyses? Will you consider if missing data are missing at random or not?</p> <p>Appendices</p>
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	<p>- I like the humorous approach to some of the text messages, but I did notice that many of the messages and most of the private discussion board topics were fairly generic and did not appear to be particularly gender-tailored for men. Can you provide more detail in the methods section about how this standard health information was adapted to be particularly relevant or meaningful for men? I think this is a key point, since the app also does not appear to be gender-tailored.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer #1

Reviewer #1 Comments:

I applaud the authors for undertaking research on an important topic for a large population of rural men. The manuscript is mostly in good order and reflects rigorous scientific inquiry. Despite those positive attributes, several concerns need to be addressed.

Authors Reply. Thank you.

Reviewer #1 Recommendation 1

Protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript.

According to Whitehead et al (2014): A pilot study is not a hypothesis testing study. Safety, efficacy and effectiveness are not evaluated in a pilot. Contrary to tradition, a pilot study does not provide a meaningful effect size estimate for planning subsequent studies due to the imprecision inherent in data from small samples. Thus, effect sizes provided by pilot studies should not be used to power a subsequent full trial. Instead clinical experience should be used to define a clinically meaningful effect. A pilot study is a requisite initial step in exploring a novel intervention or an innovative application of an intervention. Pilot results can inform feasibility and identify modifications needed in the design of a larger, ensuing hypothesis testing study.

Authors Reply: We added the dates of recruitment under the “recruitment and consent” section. In addition, we clarified the language to be more consistent with our three study aims throughout the manuscript (as noted by reviewer 3), and to highlight the focus is primarily descriptive to inform the planned larger study.

Reviewer #1 Recommendation 2

Page 2, Line 18: the age range contradicts ages elsewhere. Include year as unit.

Authors Reply: We corrected the age range in the abstract as identified above to age 40-69 and included the units “years.”

Reviewer #1 Recommendation 3

Page 3, Line 30 Source cited indicates obesity is 34.1% in Nebraska. Ogden et al data indicate OW + OB around 70%. Citation #3 is related to fruit and vegetable consumption.

Authors Reply: We enhanced this to reflect the data from Ogden 2014 which indicates that 77.3% of all adults age 40-59 in the United States are overweight or obese. The citation has been added.

Citation 3 was removed as it was a mis-citation.

Reviewer #1 Recommendation 4

Page 3, Line 35: citation needed here and above.

Authors Reply: Thank you for pointing that out. We added three citations supporting agricultural mechanization and BMI trends in rural individuals.

Reviewer #1 Recommendation 5

Page 4, Lines 18-20: Not appropriate justification, and not a recommended approach. See Lancaster 2015; Whitehead et al 2014.

Authors Reply: We clarified our intent and added Browne 1995 and Lancaster 2004 here for justification of sample size.

Reviewer #1 Recommendation 6

Page 4, Lines 37-38: unclear what this means.

Authors Reply: We deleted this sentence and further defined the types of students who will be involved in the study based upon the R15 mechanism goals.

Reviewer #1 Recommendation 7

Page 4, Line 43: change format to aged 40--69y, currently contradicts abstract

Authors Reply: We corrected the age in the abstract to reflect the corrected age range cited as the inclusion criteria for this study which are 40-69 years.

Reviewer #1 Recommendation 8

Page 4, Line 46: further explanation needed on BMI value around 50 and clinician clearance in relation to 396 pounds. Be clear.

Authors Reply: We agree that clarity is needed. We added language to note that 396lbs was an upper limit because this was the upper limit of the smart scale used in the study. We also clarified that per our universities IRB policy, BMIs greater than 50 required clinician clearance. This language was added under the section "inclusion criteria."

Reviewer #1 Recommendation 9

Page 5: sync is informal version of synchronize. Recommend formality. App should not have period/full stop if being used to indicate computer application.

Authors Reply: We updated the language throughout the document and used the terms "application" and "synchronize."

Reviewer #1 Recommendation 10

Page 5, Line 37: healthy living?

Authors Reply: Thank you for noticing, we adjusted this in the document.

Reviewer #1 Recommendation 11

Page 5, Line 39: CDC = Centers for Disease Control and Prevention (prevention is redundant).

Authors Reply: We omitted the word prevention and used the full name instead of the acronym.

Reviewer #1 Recommendation 12

Page 5, Line 52: Need to define adherence and indicate how it will be assessed.

Authors Reply: We changed the language to "frequency of logging" instead of "adherence".

Reviewer #1 Recommendation 13

Page 5, Line 53: Who is he? Clarify.

Authors Reply: We changed the pronoun "he" to "the participant".

Reviewer #1 Recommendation 14

Page 6: caps needed for basic and premium?

Authors Reply: We removed the caps for “basic” and “premium” throughout the document.

Reviewer #1 Recommendation 15

Page 6, Line 8: Clarify "weigh as often as they can."

Authors Reply: We changed this language to “weigh daily”.

Reviewer #1 Recommendation 16

Page 6, Line 24: Rephrase "Two groups permits" for clarity regarding study design.

Authors Reply: Thank you, we clarified this language and included a citation.

Reviewer #1 Recommendation 17

Page 6: The primary outcomes do not align well with pilot study design and stated aims of the study. Provide citation for BEVQ-15 here.

Authors Reply: We agree, our outcomes were not consistent throughout the manuscript. We adjusted our outcomes so they are consistent with our three aims of the study. We deleted the use of “primary and secondary outcomes” and used the three outcomes: Feasibility and acceptability, clinical outcomes, and community capacity. The sub-header titled “outcomes” in the original document was deleted and merged with the header “outcomes, measurements, data management, and analysis” for clarity. We added the citation for BEVQ-15.

Reviewer #1 Recommendation 18

Page 7: Define GA (and PI later); Is this a cut and paste error? "This publication's contents are the sole responsibility of the authors and do not necessarily represent the official views of the VCR and NIH." Seems like this should be cut or appear elsewhere.

Authors Reply: We replaced the term “GA” with “graduate level student nurse on the investigative team” for descriptive clarity. See paragraph under “public and patient involvement” where we deleted the sentence: “This publication's contents are the sole responsibility of the authors and do not necessarily represent the official views of the VCR and NIH” from this paragraph and added it to the section “ethics and dissemination”.

Reviewer #1 Recommendation 19

Page 7: Blinding is not expected for the types of interventions being tested within the type of study being conducted. The current justification is not appropriate and could simply be cut.

Authors Reply: We omitted the section about blinding from this paragraph.

Reviewer #1 Recommendation 20

Page 7, Lines 34-35: Aims are not consistent throughout manuscript.

Authors Reply: We agree with this. Therefore, we included all three aims in the abstract that now match our aims outlined in the body of the manuscript. We also expanded our outcomes section to reflect these three aims.

Reviewer #1 Recommendation 21

Page 8: Use apostrophe on participant's height; who is their (line 32)? Short sleeve short?

Authors Reply: We corrected this error, should read as “short sleeve shirt.”

Reviewer #1 Recommendation 22

Page 8: Blood pressure device has been validated for research purposes? If so, citation needed. If not, justification needed.

Authors Reply: The sphygmomanometer used for this study has been used by other clinical trials measuring blood pressure. In addition, we also did a test-retest before using this unit and the

determined the auto feature was appropriate for field trials such as ours. We added a citation to this section under the sub-header “blood pressure and pulse rate”.

Reviewer #1 Recommendation 23

Page 9: PROMIS-29 needs citation. Check format (italics, hyphen) of a priori.

Authors Reply: We omitted the use of the PROMIS-29 survey, so this was removed from the manuscript.

Reviewer #1 Recommendation 24

Page 10: Citation for RM-ANOVA?

Authors Reply: Based upon evidence pointed out in Whitehead (2014) and Lancaster (2004), we have revised this section to emphasize our planned descriptive analysis. An independent group t-test will be used to assess overall weight loss at follow-up solely to estimate an effect size (Cohen’s d for weight loss between groups) for sample size estimation for a future large trial. Thank you for pointing out these resources to us.

Reviewer #1 Recommendation 25

Appendix 1: Why are weeks out of numerical order?

Authors Reply: Thank you for noticing this, we corrected this error and weeks should be in the correct order now.

Reviewer #2

Reviewer #2 Comments

Thank you for the opportunity to review this protocol. This study is targeting an important population group for the promotion of weight loss and healthy lifestyle behavior, and the protocol is detailed and mostly clear. The following comments should be considered to enhance the manuscript.

Authors Reply Thank you.

Reviewer #2 Recommendation 1

In the first sentence, the authors refer to the “rural Midwest”. I would suggest clarifying that this is in the United States.

Authors Reply: We corrected this, and it now reads “rural Midwestern United States”.

Reviewer #2 Recommendation 2

What is meant by “a rural culture”? In other contexts, those living in rural areas tend to have highly active lifestyles, comprising a lot of manual labor. As there is not a lot of space to elaborate in the abstract, it may be worth removing the term here and referring to the poor lifestyle behaviour.

Authors Reply: Thank you for pointing that out. We eliminated the phrase “rural culture” consistently throughout the document and used the term “poor lifestyle behaviors”.

Reviewer #2 Recommendation 3

I see the measurement tools will be used to assess dietary intake and physical activity are included later in the paper, but could the authors also include these in the abstract?

Authors Reply: We added these measurements of BRFSS for physical activity and fruits and vegetable consumption into the abstract.

Reviewer #2 Recommendation 3

P3, line 44: The authors note that access to weight loss resources is one reason for poor engagement in weight loss programs/practices, however, the paper cited is related to pediatric weight management in rural areas. Is there other evidence to suggest this in an adult population?

Authors Reply: Thank you for pointing this out. We adjusted the citation (Ogden 2014) reflect prevalence of overweight/ obesity in the U.S. adult population.

Reviewer #2 Recommendation 4

P4, line 30: The design overview is clear and detailed, and the use of a community advisory board ensures the program will meet the needs of the target population. I wonder if it is possible to include a couple of examples of the types of health professions students on the board are studying?

Authors Reply: We included examples of health profession students used including nursing, physical therapy, and public health.

Reviewer #2 Recommendation 5

P5, line 23-24: There is a portion of text in the Social Support section that should be revised for clarity: "The discussion board will also provide opportunity for social comparison of others' self-monitoring experiences providing a mechanism to influence judgement and behavior change towards one's own self-monitoring".

Authors Reply: Language changed to "the discussion board will also provide an opportunity for participants to share self- monitoring experiences providing a mechanism to influence awareness towards one's own self- monitoring".

Reviewer #2 Recommendation 6

P5, line 45: Has the timing for the text messages been reviewed by the CAB members, or is this informed by existing programs? Those who work 9-5 may be commuting when the 8am text is received, so I wonder if this should be considered?

Authors Reply: The timing of message receipt was based on feedback received from midlife, rural male participants from a peer county in the preliminary study (Eisenhauer, 2016).

Reviewer #2 Recommendation 7

P6, line 15: Is the hands-on orientation held during a face-to-face appointment?

Authors Reply: Hands on orientation was done during the face- to- face baseline visit. We corrected this and stated this in the manuscript.

Reviewer #2 Recommendation 8

P6, line 54: It may be worth explaining what "Facebook blasting" is. Also, which websites will be used for recruitment?

Authors Reply: Thank you. We attempted to clarify "Facebook blasting" by changing the language to "Facebook advertising". Websites used for recruitment were ClinicalTrials.gov and a University webpage.

Reviewer #2 Recommendation 9

P7, line 3: It is mentioned that minority men will be recruited through community health workers – can the authors elaborate on the specific minority groups they hope to reach?

Authors Reply: Yes, the group of men targeted were men who identify as non-white-Hispanic.

Reviewer #2 Recommendation 10

P8, Randomization and Blinding: Will outcome assessors be blind to program allocation at the in-person health appointments?

Best of luck with the study.

Authors Reply: We omitted the section about blinding based upon recommendation and evidence shared from reviewer 1 comment #19 and referenced by Lancaster, 2004.

Reviewer #3

Reviewer #3 Comments

This paper presents the protocol for a pragmatic RCT testing the impact of two e-health approaches on the health of rural men with overweight or obesity. The focus of this paper is very relevant, given these men are often at high risk for chronic disease, but have limited options to access services. Adherence to traditional masculine norms also reduces the number of men who seek help in these areas. Overall, I found this to be a generally well-written manuscript concerning a novel approach to reaching these men. However, I do have some suggestions for the authors to consider as outlined below.

Authors Reply: Thank you.

Reviewer #3 Recommendations 1

Abstract: I found the incomplete sentences a bit jarring (e.g., P2 L14, L25-28)

Authors Reply: We appreciate your comment. We adjusted the abstract to reflect complete sentences.

Reviewer #3 Recommendations 2

P2 L14-18 – The intervention description here is confusing. At first, I was unsure if the three terms in brackets represented three different intervention arms. I was also unsure what MT and MT+ stood for.

Authors Reply: We have adjusted the abstract and further defined the terms “MT” and “MT+” for clarification.

Reviewer #3 Recommendations 3

P2, L22 – provide detail on which statistical analyses will be used (at least for primary outcomes if space is short).

Authors Reply: We revised our language (removed primary/secondary) and statistical analysis description in this section (outcomes- Aim 1, Aim 2) based upon evidence shared (Whitehead, 2014; Lancaster, 2004) by reviewer 1 (comment 1) regarding recommended outcomes reporting in pilot studies.

Reviewer #3 Recommendations 4

Article summary: The author guidelines suggest this summary section should only include the five dot points currently listed under strengths and limitations.

Authors Reply: In response to your point, we deleted this section.

Reviewer #3 Recommendations 5

P3, L39-41 – Although few studies have targeted rural men with mobile health interventions, research into e-health interventions targeting men has been growing consistently in recent years. I think a brief summary of this literature would help establish the rationale of the current trial.

Authors Reply: Thank you for this comment. Current systematic review by Robertson et al (2017) examined weight loss RCTs for men only. The review found 14 eligible studies and noted in their limitations there was little research on weight loss for men specifically. We added a citation for this systematic review.

Reviewer #3 Recommendations 6

P3, L32: PA is abbreviated here, but the abbreviation isn't used consistently through the paper.

Authors Reply: We appreciate this observation. We have removed PA throughout the document to now consistently state “physical activity”.

Reviewer #3 Recommendations 7

P4, L14-17 – I was unclear what this sentence means, could it be reworded for clarity? (A pRCT is selected to maximize assessment of men's variations in treatment availability option (free comparator app))

Authors Reply: We have clarified the wording in this section to now say "This pRCT will observe men in real-life rural conditions using varied versions of a mobile phone based self-monitoring application: one that is free and available in the community setting and an enhanced, premium version".

Reviewer #3 Recommendations 8

P4, L37-38 – what do you mean by 'participants were not involved in any of the recruitment of this study'?

Authors Reply: We deleted this sentence as it was not relevant.

Reviewer #3 Recommendations 9

P4, L43 – what was the rationale for not including younger men in the study?

Authors Reply: We prioritized midlife men in our age selection (over younger men) based upon current national overweight/obesity trends and the breadth of current evidence supporting decreasing midlife risk factors (weight loss, physical activity) and increased healthy survival. We added citations to the narrative in support of this.

Reviewer #3 Recommendations 10

P5 L3-16 – is Lose-It a freely available app or was it developed by the research team? Also, is the app designed for men?

Authors Reply: We clarified your question at the beginning of the section titled "self-monitoring." Lose-It! is a commercially available self-monitoring application designed for the general public and includes both a basic (free) and a premium (\$39.99/annually) version.

Reviewer #3 Recommendations 11

P5, L37 – typo – health vs healthy

Authors Reply: Thank you for noticing this error. We corrected this word to reflect healthy.

Reviewer #3 Recommendations 12

P5, L44-46 – was there a rationale to guide the frequency/number of texts sent during the intervention?

Authors Reply Yes- this was based on feedback from participants from the preliminary study. The rationale and citation were added to the bottom of the paragraph "text messaging".

Reviewer #3 Recommendations 13

P6, L45-47 – this sentence needs a reword.

Authors Reply: Thank you, we corrected the wording.

Reviewer #3 Recommendations 14

P6, L54 - What is Facebook blasting?

Authors Reply: "Facebook blasting" language changed to "Facebook advertising" to enhance clarity.

Reviewer #3 Recommendations 15

P7, L11-16 – I am not used to seeing a declaration like this in the middle of a methods section.

Perhaps this could be moved to a footnote?

Authors Reply: Thank you for your suggestion. We deleted this declaration statement in the methods section. We added it to the "ethics and dissemination" section.

Reviewer #3 Recommendations 16

P7, L19 – how will the participant provide a wet signature online?

Authors Reply: The wet signature is a feature in REDCap which allows participants to sign consent forms online in real time, by signing their name with their finger or computer mouse on a document as if the participant is using a pen and paper. This process does not require an additional confirmation procedure and is customary in REDCap consenting and data collection. We provided a citation about wet signatures in the section under “Recruitment and consent” and included citations.

Reviewer #3 Recommendations 17

P7, L25 – are the people assessing the outcomes also unblinded, or just the participants?

Authors Reply. We deleted this section on blinding per reviewer #1 recommendation #19 (Lancaster, 2004).

Reviewer #3 Recommendations 18

P7, L45 – I am unfamiliar with the new acronyms introduced here (health ITUES, PROMIS-29)

Authors Reply: We wrote out the full names of the health ITUES survey. We removed the PROMIS-29 reference from the manuscript.

Reviewer #3 Recommendations 19

P7, L52 – to calculate BMI, does the Tanita scale measure height as well as weight?

Authors Reply Yes, the Tanita scale does measure height and weight, and then it prints out a paper copy that has the calculated BMI.

Reviewer #3 Recommendations 20

P8, L14 – many of the text messages relate to dietary behaviors that are not being measured in this study. Was there a rationale for focusing specifically on SSB intake and fruit and vegetables in the outcome’s measures?

Authors Reply: We agree that we addressed many weight-related dietary behaviors the text messages that would be valuable to measure. We decided to focus on fruit and vegetable SSB consumption indicators of a healthy overall diet given the resource-constrained nature of feasibility studies and to reduce participant’s burden for data collection. Fruit and vegetable intake is an indicator used nationally to monitor and establish benchmarks of a healthy overall diet. Being the Behavioral Risk Factor Surveillance System (BRFSS), in most U.S. states, is currently the only source of uniform nutritional data for adults. Sugar-sweetened beverage (SSB) consumption are a major source of calories and has received increasing attention in recent years as playing a role in the obesity epidemic. Additionally, a lack of fruit and vegetable intake is more common among men and rural residents which relates to our study population.

Reviewer #3 Recommendations 21

P9, L40 – can you be more specific about how you will determine feasibility? When it comes to participation rates, retention rates, usability, and satisfaction, how will you know if the trial has been feasible?

Authors Reply: To determine feasibility of recruitment and retention, studies with similar designs, and recruitment and retention rates were used as a threshold. The study we cited was the SHED-IT study by authors Morgan et al. They demonstrated in their RCT 159 participants recruited with 107 of these randomized between two groups, leaving the overall participation rate of 67%. Of the 107 participants randomized, 67 participants completed the trial at 6 months, with a retention rate of 62.6%. Feasibility, usability, and satisfaction ratings will be measured from modified health-iTUES survey, which has been validated to be used as a customizable technology survey.

Reviewer #3 Recommendations 22

P10, L22, at what threshold will you switch to mixed models analyses? Will you consider if missing data are missing at random or not?

Authors Reply: The attrition rate that was assumed in our sample size justification was up to 25%. This would be the threshold in question. We added this to the statistical analysis description in Aim 2. As this will be a longitudinal model, the primary determinant of missing data is time, which would be accounted for in the models.

Reviewer #3 Recommendations 23

Appendices: I like the humorous approach to some of the text messages, but I did notice that many of the messages and most of the private discussion board topics were fairly generic and did not appear to be particularly gender-tailored for men. Can you provide more detail in the methods section about how this standard health information was adapted to be particularly relevant or meaningful for men? I think this is a key point, since the app also does not appear to be gender-tailored.

Authors Reply: We tested discussion board topics with the CAB comprised of men and women from the region. In addition to this, acceptability feedback about discussion board topics was gathered from subjects in our pilot study. It is noted that the men desired both a combination of both gender-tailored and standardized private discussion board topics. We added this information and citation under the sub-header “social support”.

Reviewer #3 Formatting Recommendations:

Required amendments will be listed here; please include these changes in your revised version:

Please re-upload your supplementary files in PDF format.

Figure/s should not be embedded.

Please remove all your figures in your main document and upload each of them separately under file designation ‘Image’ (except tables and please ensure that figures are in better quality or not pixelated when zoomed in).

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Authors Reply: We adjusted Table 1 and made it a figure and titled it “Figure 2”. We removed this figure and the appedices from the main text uploaded them as a separate PDF documents. We added two captions at the end of the main manuscript for Figure 1 and Figure 2.

VERSION 2 – REVIEW

REVIEWER	Emma George Western Sydney University, Australia
REVIEW RETURNED	06-Feb-2020

GENERAL COMMENTS	The authors have adequately addressed reviewer comments.
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REVIEWER	Myles Young University of Newcastle, Australia
REVIEW RETURNED	20-Jan-2020

GENERAL COMMENTS	<p>Thank you for considering my suggestions - I am glad to see these responses/revisions. My only comment is that the retention rate in the SHED-IT trial (which I was involved in) is not correct as participants randomised to the control group have not been accounted for. Please see the primary outcomes paper for this paper to clarify:</p> <p>Morgan P.J. et al (2013). The SHED-IT Community Trial: A randomised controlled trial of internet- and paper-based weight</p>
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	loss programs tailored for overweight and obese men. <i>Annals of Behavioral Medicine</i> , 45(2), 139-152.
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