PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	The Peer Assisted Lifestyle (PAL) Intervention; A Protocol of a Cluster-Randomised Controlled Trial Of A Health-Coaching Intervention Delivered By Veteran Peers To Improve Obesity Treatment in Primary Care
AUTHORS	Wittleder, Sandra; Smith, Shea; Wang, Binhuan; Beasley, Jeannette; Orstad, Stephanie; Sweat, Victoria; Squires, Allison; Wong, Laura; Fang, Yixin; Doebrich, Paula; Gutnick, Damara; Tenner, Craig; Sherman, Scott; Jay, Melanie

VERSION 1 – REVIEW

REVIEWER	Michael Kingsley University of Auckland, New Zealand La Trobe University, Australia
REVIEW RETURNED	18-Aug-2020

GENERAL COMMENTS	General Comments: In general, the manuscript is relatively clear in its intention and procedures. The background, though heavily referenced, would benefit from further evidence as to why peer coaching has the potential to improve weight management in Veterans. Peer coaching might have demonstrated success in other populations, but the evidence provided to support other factors unique to the Veteran population is tenuous. There are a number of aims within this manuscript, and it would be of benefit to the reader for these to be separated with a description of how these link to the primary outcome measures. For example, the study aims might be articulated as follows: 1. determine the impact of PAL on body mass, clinical and behavioral outcomes in patients, 2. identify predictors of body mass loss related to PAL intervention components and goal-setting processes, and 3. determine the impact of PAL on PCP obesity-related counseling attitudes and practices, Clarification of the aims should follow on to the methods section with improved alignment of outcome measures to enable the reader to see how these aims are being assessed and evaluated. One thing of note is how this intervention can assist a change in practice of PCPs, when the use of brief behavioural intervention is optional by the clinician. The PCPs receive 1 session during year 1, and at least one more follow-up. The authors state that they evaluate the percentage of clinical reminders completed in the EHR to document counseling or reasons for not counseling, but there is no indication that any ongoing discussions are made with

	the PCPs to assist improve practice. As the study has started, it is understandable that major changes cannot be made to the methods, but it is difficult to see how brief educational training and prompts permit overcoming the well-documented barriers to preventive health practice by PCPs. Further to this, assessing the quality of the PCP consultations would be far better with recorded sessions, as in the peer-coaches, rather than using patient surveys. The authors must provide additional information in the discussion for the reader to understand the potential application of this work. Specific Comments: Abstract 1. The abstract contains abbreviations that have not been identified (e.g., PCP and HIPA). 2. Page 4 of 34, Abstract , line 15: “Primary care providers (PCPs) oftentimes lack the time to counsel patients and intensive programs are highly underutilized.” This sentence does not make sense as it is currently stated. 3. More clarity on intensive programs is needed. 4. Page 4, Abstract , lines 19-26: This would be better separated into primary aims and secondary aims. Background 5. Page 6, Line 4: 78% is greater than three quarters. 6. Abbreviation (PCP) and (PCPs) are used interchangeably; please ensure that the abbreviations are consistently applied throughout the document. 7. Page 6, Lines 26- 34: the authors state that peer coaching has the potential to improve weight management in Veterans. While peer coaching has been shown to improve health outcomes in studies 22-29, not all studies are specific to weight loss and obesity. Further evidence is needed to back up the potential use of veteran peers for weight management, as reference 21 is specific to female veterans only. 8. Page 6, Lines 51- 57: As per abstract, it would be beneficial to separate these into primary and secondary aims. Methods 9. Page 7, Lines 13-16: Reword 10. Page 7, Lines 28-29: Please provide further information on what obesity-related conditions are. 11. Page 7, Line 40: Please provide the range of dates for recruitment. 12. Page 8, Line 38: Please provide the 16-item questionnaire as supplementary material. 13. Page 9: Point 2 – in person peer coach visit: If possible it would be advantageous to other health services considering implementing a similar program if the authors were able to quantify how much time this process takes the peer-coach. 14. Page 9, Line 32: Patients receive a reminder call to self-monitor their weight, food intake, and physical activity for at least 3

	days before the coaching call – is this by the peer coach or an RA? 15. Page 10, Line 7: Please provide further information on who provided this training? 16. Page 10, Line 53: The surveys to assess the quality of the PCP counselling – Please provide further regarding how are these taken, and at what points? 17. Page 11, Line 2: Regarding retention, are participants given reminder calls to attend outcome measurements? They receive a reminder call regarding peer-coaching calls 18. Page 11, Line 23: Please provide further information regarding where the 'in-person study visits' occur? 19. Page 12, Line 26: Please provide further information regarding the Actigraph activity data, including ActiLife cut points used; minimum wear time; position worn. 20. Page 12, Line 40: Please provide further information in regards to the Self-monitoring and Weight-loss Behaviors- are the answers to these questions binary or ordinal? How long prior to the question are they reporting their Self-monitoring and Weight-loss Behaviors? 21. Page 15, Line 40: 'weight', which is a force, is used incorrectly here and in many cases in the manuscript. Please use 'body mass' where appropriate, which is correctly reported in kg. 22. Methods: 'height' should be replaced with 'stature' in text and Table 1. Discussion 23. The discussion would be strengthened with relevant information as to why this brief counselling intervention (3-5 minutes) is likely to have good uptake by the Primary care Practitioners when the evidence continually highlights that preventive practice rates in primary care are low. Other considerations 24. SPIRIT Item 29 : Access to data. Please provide further information regarding who will have access to the final dataset, and disclose contractual agreements that limit such access?

REVIEWER	Dr Kerstin Frie University of Oxford, United Kingdom
REVIEW RETURNED	15-Sep-2020

GENERAL COMMENTS	General Comments: This paper reports the protocol of a cluster randomised controlled trial assessing the effectiveness of a peer assisted lifestyle intervention in a veteran population. The trial is interesting and the study design seems rigorous. Most of my concerns relate to the data analysis section (see below). Introduction • You write: "Peer coaching has the potential to improve weight management in Veterans, based on the success of the model in

	other populations and other factors unique to the Veteran population." You then go on to first describe the unique Veteran factors and then the success in other populations. Please switch this around to keep the order in line with the first sentence so that this paragraph flows better (or switch the order in the first sentence). • It remains unclear here whether PAL is an adaptation of GEM or exactly the same as GEM, as you do not call the intervention PAL for the pilot trial in the Veteran population. Study Design and Overview • Who are the 12 phone coaching calls with? Also with peers? (I am aware you elaborate on this later, but it would be helpful to mention here too.) Randomisation and Blinding • You mention that 5 PCPs left the VA. Are participants who were recruited from these PCPs still included in the study? Or were they excluded? Were they assigned to another PCP? Peer Coach Intervention and Enhanced Usual Care (EUC) Description • Can you please move up the section on Peer Coach training? Whilst reading the procedure of PAL I was confused who these peer coaches were. If you do not want to move the whole section, please mention somewhere earlier who these peer coaches are (to make clear that participants do not peer coach each other). Weight Loss Predictors • How do you measure stage of change and outcome expectations? Competency and Attitudes • Can you please clarify which measures you will use to assess these outcomes? Data Analysis • Please make clear: What is your primary analysis here? What are your secondary analyses? • As your participants were randomised to control and treatment group, the assumption is that any differences between the groups on baseline characteristics will be due to random error. Consort guidelines therefore state that tests should not be conducted to compare the two treatment arms: http://www.consort-statement.org/checklists/view/32--consort-2010/510-baseline-data • Why do you plan to use non-parametric tests? And why do you even want to compare the weight loss outcomes between the groups with non-parametric tests if you run a more powerful mixed effects model afterwards? • You state: "Visualization tools (e.g., scatterplots) and descriptive analyses (e.g., Spearman correlation coefficients) will display associations between weight change and weight-loss potential predictors. Multivariate linear regression models for continuous variables and multiple logistic regression models for binary variables will further examine these predictors' associations with weight loss.". Can you please clarify which predictor variables you are speaking of? Is it the motivational factors, etc.? • How will you analyse the PCP counselling data? And the weight loss behaviours data? What about the waist circumference and blood pressure data?

	• Is your analysis based on intention-to-treat? Patient and Public Involvement • You mention exit interviews for the first time here. Can you please clarify the methods for these interviews earlier on in the methods section? Sample Size and Power Analysis • What are your assumptions regarding the inter-class correlation coefficient and the coefficient of variation based on?

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
We very much appreciate the reviewer's detailed and helpful comments related to our manuscript. We have made the following changes to address the reviewer's comments.

Comment 1.1: The abstract contains abbreviations that have not been identified (e.g., PCP and HIPAA).

Response: We thank the reviewer for pointing this out. We have corrected the abbreviations.
Changes:

a. On page 2, we now write: "Primary care providers (PCP) often lack time to counsel and refer patients to intensive programs (≥six sessions over three months)."
b. On page 15, we now write: "All participants are provided oral and written information on the study and asked to sign an informed consent form and a Health Insurance Portability and Accountability Act (HIPAA) authorization."

Comment 1.2: "Primary care providers (PCPs) oftentimes lack the time to counsel patients and intensive programs are highly underutilized." This sentence does not make sense as it is currently stated.
Comment 1.3: More clarity on intensive programs is needed.

Response: We have reworded the sentence and clarified the characteristics of intensive programs.
Change:

a. On page 2, we now write: "Primary care providers (PCP) often lack time to counsel and refer patients to intensive programs (≥six sessions over three months)."

Comment 1.4: This would be better separated into primary aims and secondary aims.

Response: We now specify the separate study aims.
Change:

a. On page 2, we now write: "We describe the rationale and design of a cluster-randomised controlled trial to test the efficacy of the Peer Assisted Lifestyle (PAL) intervention compared to enhanced usual care (EUC) to improve BM loss, clinical and behavioral outcomes (Aim 1), identify BM-loss predictors (Aim 2), increase PCP counselling (Aim 3)."
b.

Comment 1.5: 78% is greater than three quarters.

Response: We thank the reviewer for pointing this out. We have corrected the sentence.
Change:

a. On page 4, we now write: “In 2014, more than 78% of U.S. Veterans had a body mass index (BMI) in the overweight (≥25 kg/m2) or obese range (≥30 kg/m2) [1–5] despite their access to care through the Veterans Health Administration (VHA), America’s largest integrated health care system.“

Comment 1.6: Abbreviations (PCP) and (PCPs) are used interchangeably; please ensure that the abbreviations are consistently applied throughout the document.

Response: We thank the reviewer for pointing this out. We have corrected the abbreviations. Changes are marked in bold throughout the manuscript.

Comment 1.7: The authors state that peer coaching has the potential to improve weight management in Veterans. While peer coaching has been shown to improve health outcomes in studies 22-29, not all studies are specific to weight loss and obesity. Further evidence is needed to back up the potential use of veteran peers for weight management, as reference 21 is specific to female veterans only.

Response: We have revised the introduction to include background to justify the potential use of Veteran peers for lifestyle change interventions.
Change:

a. On page 4, we now write: “Peer coaching has the potential to improve obesity treatment for Veterans. In other populations and settings, including primary care, peer coaches effectively delivered obesity interventions to support health behavior change.[20–27] The peer coaching approach may be appropriate for Veterans given the strong communal identity and the camaraderie felt by those with shared military experience.[28–30]. Because peer coaches share a similar background, they can understand and help address barriers specific to Veterans such as the change from leaving the highly structured military environment.[31] Among Women Veterans support from military friends after separation from service has been associated with better health outcomes.[28] Further, peer-led interventions among Veterans with diabetes improved glucose control.[32,33]”

Comment 1.8: As per abstract, it would be beneficial to separate these into primary and secondary aims.

Response: We now separate our three study aims.
Change:

a. On pages 4-5, we now write: “The PAL study’s aims are to (1) determine the impact of PAL on BM, clinical and behavioral outcomes, (2) identify predictors of BM loss related to PAL intervention components and goal-setting processes, and (3) evaluate PAL’s impact on PCP obesity-related counselling attitudes and practices.”

Comment 1.9: Reword

Response: We thank the reviewer for pointing this out. We have corrected the sentence.
Change:

a. On page 5, we now write: “At the Brooklyn campus of the Veterans Affairs New York Harbor Healthcare System (Brooklyn VA) primary care teams have one to five PCP among other medical staff (e.g., registered nurses).“

Comment 1.10: Please provide further information on what obesity-related conditions are.

Response: We have added information on obesity-related conditions.
Change:

a. On page 5, we now write: “Eligible patients are between the ages of 18-69 years (MOVE! eligibility criteria),[18] under the care of a PCP with at least one prior visit in the past two years, have a BMI of ≥30kg/m^2 or a BMI of ≥25kg/m^2 with an obesity-associated condition (i.e., hypertension, high cholesterol, sleep apnea, osteoarthritis, metabolic syndrome, or pre-diabetes),[14,16] have access to a telephone, and ability to travel to the Brooklyn VA.“

Comment 1.11: Please provide the range of dates for recruitment.

Response: We now specify the dates of recruitment.
Change:

a. On page 5, we now write: “Enrollment began in January 2018 and has been suspended since March 2020 due to the COVID-19 pandemic.”

Comment 1.12: Please provide the 16-item questionnaire as supplementary material.

Response: We have added the questionnaire as a supplementary file. Please see supplementary file A.

Comment 1.13: Point 2 – in-person peer coach visit: If possible it would be advantageous to other health services considering implementing a similar program if the authors were able to quantify how much time this process takes the peer-coach.

Response: We have added estimates to quantify how much time the process takes the health coach.
Change: On pages 7-8, we now write: “2. In-person peer coach visit (40 minutes, baseline visit). After the patients complete the online tool, they meet with a non-clinician, peer coach. The peer coach works with patients to achieve health-related goals using MI[38] and SMART (Specific, Measurable, Attainable, Relevant, Timely) goal setting.[42] The peer coach performs the following tasks:

- Use worksheets to turn goals into SMART goals[42] and encourage participation in MOVE!, MOVE!TLC, or other programs by providing brief MI with SMART Action Planning[43] to address barriers (20 minutes).
- Teach self-monitoring of BM, diet, and physical activity behaviors via pedometer, food log, and/or apps (e.g., MOVE! Coach,[44] My Fitness Pal)[45] (10 minutes).
- Enter a report for the PCP into CPRS summarizing the encounter to communicate patients’ progress to the PCP (10 minutes).”

Comment 1.14: Patients receive a reminder call to self-monitor their weight, food intake, and physical activity for at least 3 days before the coaching call – is this by the peer coach or an RA?

Response: We now specify that participants receive reminder calls from their peer coach.
Change:

a. On page 8, we now write: “Patients receive a reminder call from the peer coach to self-monitor their BM, food intake, and physical activity for at least 3 days before the coaching call.”

Comment 1.15: Please provide further information on who provided this training?

Response: We added details on who delivers the peer coach training.
Change:

a. On page 6, we now write: “They receive a minimum of 20 hours of training delivered by the principal investigator (PI) and/or senior coaches based on a prior intervention.[37]”

Comment 1.16: The surveys to assess the quality of the PCP counselling – Please provide further regarding how are these taken, and at what points?

Response: We now provide further information regarding the collection of surveys to assess the quality of PCP counselling.
Change:

a. On page 7, we now write: “We assess the quality of PCP counselling with patient surveys during in-person study visits (see Aim 3: PCP Counselling measures section and Table 1 for timing).“

Comment 1.17: Regarding retention, are participants given reminder calls to attend outcome measurements? They receive a reminder call regarding peer-coaching calls

Response: We have added more detailed information on our retention strategy.
Change:

a. On page 8, we now write: “Retention. Follow-up visits are scheduled at the baseline visit. One month prior to study visits, patients receive a reminder flyer in the mail. Additionally, one week and one day before their visits patients receive reminder phone calls from the RA.“

Comment 18: Please provide further information regarding where the ‘in-person study visits’ occur?

Response: We now specify the location for the in-person study visits.
Change:

a. On page 9, we now write: “In-person study visits to collect data occur in a private research office or clinic room at the Brooklyn VA at baseline, 6 months, and 12 months (Table 1).“

Comment 19: Please provide further information regarding the Actigraph activity data, including ActiLife cut-points used; minimum wear time; position worn.

Response: As suggested, we have added further information regarding the Actigraph activity data, including minimum wear time and position worn.
Change:

a. On page 10, we now write: “Participants also wear Actigraph Link accelerometers (model GT9X-BT) on the non-dominant wrist for seven days after all in-person visits (Figure 1). The data from the ActiGraph monitor will be processed using ActiLife software. Physical activity behavior characterized will include total physical activity expressed as average daily vector magnitude units, time spent sedentary, and in light and moderate to vigorous intensity.“

Comment 20: Please provide further information in regards to the Self-monitoring and Weight-loss Behaviors- are the answers to these questions binary or ordinal? How long prior to the question are they reporting their Self-monitoring and Weight-loss Behaviors?

Response: We have added information in regards to the self-monitoring questions including the scale and time frame.
Change:

a. On page 10, we now write: “Patients report on how many days (Scale: 0-7) during a typical week in the previous six months they have performed the following behaviors: weighing themselves, tracking their diet and physical activity, cooking a healthy meal at home, and working out.[53]”

Comment 21: ‘weight’, which is a force, is used incorrectly here and in many cases in the manuscript. Please use ‘body mass’ where appropriate, which is correctly reported in kg.

Response: We thank the reviewer for pointing this out. We now refer to body mass instead of weight. Changes are marked in bold throughout the manuscript.

Comment 22: Methods: ‘height’ should be replaced with ‘stature’ in text and Table 1.

Response: We now refer to stature instead of height in the measures section and Table 1.
Change:

a. On page 9, we now write: “Stature is measured once, rounded up to the nearest 0.5 cm, using a SECA 213 Portable Stadiometer.”

Comment 23: The discussion would be strengthened with relevant information as to why this brief counselling intervention (3-5 minutes) is likely to have good uptake by the Primary care Practitioners when the evidence continually highlights that preventive practice rates in primary care are low.

Response: We thank the reviewer for pointing this out. We have revised the discussion with relevant information as to why this brief counselling intervention is likely to have good uptake by the Primary Care Practitioners.
Change:

a. On page 13, we now write: “To promote PCP counselling, PAL includes brief PCP training, peer coaching notes, and clinical reminders. PAL is designed to fit into the workflow without overburdening the healthcare team, addressing important PCP barriers to counselling: lack of time and training. [11,12] It requires 3-5 minutes of PCP time for brief counselling and documentation, which is a workload that was acceptable to most healthcare staff.[41,68]”

Comment 24: SPIRIT Item 29: Access to data. Please provide further information regarding who will have access to the final dataset, and disclose contractual agreements that limit such access?

Response: We have included information regarding who will have access to the dataset in the ‘Ethics and Dissemination’ section. There are no contractual agreements to limit such access. We have updated the SPIRIT Checklist accordingly.
Change:

a. On page 15, we now write: “Ethics and dissemination: All study procedures have been reviewed and approved by the Institutional Review Board and the Research and Development Committee at the VA NY Harbor Health Systems (#01607). All participants are provided oral and written information on the study and asked to sign an informed consent form form (see supplementary file D) and a Health Insurance Portability and Accountability Act (HIPAA) authorization (see supplementary file E). Only authorised study staff will have access to the study data.”

Reviewer 2
We thank the reviewer for their constructive comments. We have made the following changes to address the reviewer’s concerns.

Comment 2.1: You write: “Peer coaching has the potential to improve weight management in Veterans, based on the success of the model in other populations and other factors unique to the Veteran population.” You then go on to first describe the unique Veteran factors and then the success

in other populations. Please switch this around to keep the order in line with the first sentence so that this paragraph flows better (or switch the order in the first sentence).

Response: We thank the reviewer for pointing to this aspect. We have revised the paragraph to improve the flow. In response to Reviewer 1, we have also revised the introduction to include background to justify the potential use of Veteran peers for lifestyle change interventions (see Comment 1.7 above).
Change:

a. On page 4, we now write: “Peer coaching has the potential to improve obesity treatment for Veterans. In other populations and settings, including primary care, peer coaches effectively delivered obesity interventions to support health behavior change.[20–27] The peer coaching approach may be appropriate for Veterans given the strong communal identity and the camaraderie felt by those with shared military experience.[28–30]. Because peer coaches share a similar background, they can understand and help address barriers specific to Veterans such as the change from leaving the highly structured military environment.[31] Among Women Veterans support from military friends after separation from service has been associated with better health outcomes.[28] Further, peer-led interventions among Veterans with diabetes improved glucose control.[32,33]”

Comment 2.2: It remains unclear here whether PAL is an adaptation of GEM or exactly the same as GEM, as you do not call the intervention PAL for the pilot trial in the Veteran population.

Response: We have revised our description of the PAL intervention to specify that it is an adaption of the GEM intervention.
Change:

a. On page 4, we now write: ” We developed a novel technology-assisted peer coaching intervention, called the Peer Assisted Lifestyle (PAL) intervention that uses the 5As (Assess, Advise, Agree, Assist, Arrange) counselling framework[34] and was adapted from our Goals for Eating and Moving (GEM) study.[35] A pilot study of the GEM intervention (n=22) showed modest BM loss when compared to control (n=23) 6 months (−1.5 ± 3.1kg vs. 0.2 ± 3.6 kg, p = 0.08).[36] The PAL intervention builds upon our experience with GEM[35] with the added focus on peer coaches to address the specific needs of Veterans.“

Comment 2.3: Who are the 12 phone coaching calls with? Also with peers? (I am aware you elaborate on this later, but it would be helpful to mention here too.)

Response: We now specify that the phone coaching calls are delivered by the peer coach.
Change:

a. On page 5, we now write: “This cluster-randomised controlled study compares the PAL intervention to enhanced usual care (EUC). PAL includes an in-person peer coaching session, 12 peer coaching phone calls over 1 year, and brief PCP obesity counselling during routine medical visits.“

Comment 2.4: You mention that 5 PCPs left the VA. Are participants who were recruited from these PCPs still included in the study? Or were they excluded? Were they assigned to another PCP?

Response: We have added information to describe the strategy for treating enrolled patients of PCP that left the VA.
Change:

a. On page 6, we now write: “In 2017, PCP (n=17), along with their eligible patients, were initially randomised to either PAL (n=8) or EUC (n=9) using a random number generator. In 2018, five PCP left the VA, and in 2019, two new PCP joined the VA and were randomised so

that 14 PCP are currently active in the study (PAL=6; EUC=8). Patients of PCP that left were assigned new PCP by the VHA. Those patients remained in the same study arm assigned at the time of enrollment due to the intention-to-treat methodology."

Comment 2.5: Can you please move up the section on Peer Coach training? Whilst reading the procedure of PAL I was confused who these peer coaches were. If you do not want to move the whole section, please mention somewhere earlier who these peer coaches are (to make clear that participants do not peer coach each other).

Response: We appreciate the reviewer's suggestion. We have moved up the section on peer coach training to improve understandability.

Comment 2.6: Weight Loss Predictors: How do you measure stage of change and outcome expectations?
Comment 2.7: Competency and Attitudes: Can you please clarify which measures you will use to assess these outcomes?

Response: We now provide details on study measures such as the stage of change and outcome expectations as supplementary files. Please see supplementary files B and C.

Comment 2.8: Please make clear: What is your primary analysis here? What are your secondary analyses?

Response: We now clarify our primary analysis.
Change:

a. On page 12, we now write: "Aim 1: Anthropometric Measures And Behavioral Outcomes. The primary outcome is mean body-mass loss at 12 months."

Comment 2.9: As your participants were randomised to control and treatment group, the assumption is that any differences between the groups on baseline characteristics will be due to random error. Consort guidelines therefore state that tests should not be conducted to compare the two treatment arms: http://www.consort-statement.org/checklists/view/32--consort-2010/510-baseline-data

Response: We thank the reviewer for pointing this out. We agree that the CONSORT 2010 suggests to not compare baseline differences because, theoretically, the randomization
should balance study arms. There is, however, an ongoing debate because some variables may be unbalanced by chance. We chose to include baseline comparisons in our data analysis plan to understand the extent of such potential imbalance and to provide comprehensive results for readers' convenience.
Change:

a. On page 11, we now write: "Although the randomisation should balance the treatment arms, we will use Mann-Whitney tests for continuous variables and Fisher's exact tests for categorical variables to explore if both patients' and PCP baseline characteristics may differ between the two arms."

Comment 2.10: Why do you plan to use non-parametric tests? And why do you even want to compare the weight loss outcomes between the groups with non-parametric tests if you run a more powerful mixed effects model afterwards?

Response: We thank the reviewer for bringing this concern to our attention. We chose to combine the strength of both nonparametric and parametric tests to help justify our findings. Nonparametric tests require fewer distribution criteria and are more robust. Using mixed-effects models are more powerful

and can provide model-adjusted estimates for the treatment effects controlling for study design under more assumptions.
Change:

a. On page 12, we now write: “These analyses combine the strength of both nonparametric tests, which are more powerful, and parametric tests, which are more robust, to justify our findings.”

Comment 2.11: You state: “Visualization tools (e.g., scatterplots) and descriptive analyses (e.g., Spearman correlation coefficients) will display associations between weight change and weight-loss potential predictors. Multivariate linear regression models for continuous variables and multiple logistic regression models for binary variables will further examine these predictors’ associations with weight loss.”. Can you please clarify which predictor variables you are speaking of? Is it the motivational factors, etc.?

Response: We have revised the sentence to clarify our predictor variables.
Change:

a. On page 12, we now write: “Aim 2: BM-Loss Predictors. Visualization tools (e.g., scatterplots) and descriptive analyses (e.g., Spearman correlation coefficients) will display associations between BM change and potential BM-loss predictors (i.e., motivational factors and use of PAL).“

Comment 2.12: How will you analyse the PCP counselling data? And the weight loss behaviours data? What about the waist circumference and blood pressure data?

Response: We now structure the data analysis section according to the study aims to clarify how the anthropomorphic measures (e.g., blood pressure and waist circumference) for Aim 1 and PCP counselling data for Aim 3 will be analyzed.
Changes:

a. On page 12, we now write: “Aim 1: Anthropometric Measures And Behavioral Outcomes. The primary outcome is mean body-mass loss at 12 months. To compare outcomes between the two arms, we will use Mann-Whitney tests for continuous outcomes (e.g., BM loss) and Fisher’s exact tests for categorical outcomes (e.g., number of patients achieving ≥5% BM loss).“
b. On page 12, we now write: “Aim 3: PCP Counselling. Mann-Whitney tests for continuous provider-level outcomes and Fisher’s exact tests for categorical provider-level outcomes will be used to compare the study arms at each survey. Confidence intervals of the effects will be computed as well.”

Comment 2.13: Is your analysis based on intention-to-treat?

Response: Yes, we have added information to clarify that our main outcomes will be analyzed using intention-to-treat methodology.
Change:

a. On page 11, we now write: “Main outcomes will be analyzed using intention-to-treat methodology.”

Comment 2.14: You mention exit interviews for the first time here. Can you please clarify the methods for these interviews earlier on in the methods section?

Response: We have revised the method section to include information on exit interviews for patient and PCP participants.
Change:

a. On page 11, we now write: “During exit interviews after the 12-month visit, the patients answer open-ended questions about any other health and lifestyle-related changes and their experiences with PAL.“
b. On page 11, we now write: “PCP will participate in exit interviews, to answer open-ended questions about their experiences with PAL“

Comment 2.15: What are your assumptions regarding the inter-class correlation coefficient and the coefficient of variation based on?

Response: We thank the reviewer for their question. We have revised the power analysis section to include a justification for our assumptions.
Change:

a. On page 13, we now write: “We base our sample size on within-person BM change from baseline to 12 months in each arm. As similarities in BM change within clusters should only stem from PCP potentially treating their patients in their unique way, we assume a small but conservative inter-class correlation coefficient of 0.03[66] for patients of each PCP and a coefficient of variation of 0.25 for the cluster size, which was based on the data available at the Brooklyn VA.“

Editorial Comments
We have made the following changes to address the editor’s comments.

Comment 3.1: Please ensure that the main text contains an “Ethics and Dissemination” section as per our instructions for authors: https://bmjopen.bmj.com/pages/authors/#protocol

Response: We have added an Ethics and Dissemination section.
Changes:

a. On page 15, we now write: ”Ethics and dissemination: All study procedures have been reviewed and approved by the Institutional Review Board and the Research and Development Committee at the VA NY Harbor Health Systems (#01607). All participants are provided oral and written information on the study and asked to sign an informed consent form form (see supplementary file D) and a Health Insurance Portability and Accountability Act (HIPAA) authorization (see supplementary file E). Only authorised study staff will have access to the study data.

Dissemination of the research findings: Study findings will be disseminated via conference presentations and publications in scientific peer-reviewed journals. We will also meet with stakeholders to share study results.”
Comment 3.2: Along with your revised manuscript, please provide an example of the patient consent form as a supplementary file as per item #32 of the SPIRIT checklist.

Response: We have added an example of the patient consent as well as the HIPAA form as supplementary files D and E, respectively.

Comment 3.3: Please revise the ‘Strengths and limitations’ section of your manuscript (after the abstract). This section should contain five short bullet points, no longer than one sentence each, that relate specifically to the methods.

Response: We have revised the ‘Strengths and limitations’ to contain five short bullet points related to the methods.

Changes:

a. In the Strengths and limitations' section, on page 3, we now write:

1) The PAL intervention was developed through rigorous formative work to provide evidence-based 5As counselling delivered by peer coaches in combination with brief counselling by primary care providers (PCP).
2) PAL was designed to serve as an adjunct or stand-alone intervention, providing more moderate intensity systematic obesity counselling, appealing to patients who do not have the time, ability, or motivation to attend an intensive program.
3) The evidence gained from this study will inform a broader model for integrating peer-supported counselling within private and public healthcare settings.
4) Assessment accuracy could be reduced because some of the study measures rely on self-report, which can be affected by recall and social desirability biases.
5) Difficulties might arise regarding implementing a rigorous study protocol in a real-world setting due to factors such as PCP and peer coach turnover, which may affect counselling quality and frequency.

Comment 3.4: Please remove the Conclusion header as this is not required.

Response: We have removed the Conclusion header on page 14.

Comment 3.5: Please ensure that the information provided in your protocol article is consistent with that included in the trial registry. For example, inclusion criteria. Please update the manuscript and/or trial registry accordingly.

Response: We have revised the information included in the trial registry to reflect the final protocol.