Author’s response to reviews

Title: Intervention planning and modification of the BUMP intervention: a digital intervention for the early detection of raised blood pressure in pregnancy

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Response to reviewers

R1 asks for a careful restructure and more detail to explain the work carried out specifically for this study in the context of the previous pilot study, any previous intervention development work and the overarching programme of work (i.e. Where does this study sit on the intervention and development testing pathway)?
RESPONSE: reference has been made to trial protocol which is currently under review with BMJ Open, and details of how the pilot and intervention development work fitted in have been added.

1. Introduction

~Difficult to understand the sequence of events, how many interventions (i.e. BUMP 1 and BUMP 2) A number of BUMP interventions are being tested? Do we need to mention BUMP2?

RESPONSE: We apologise that the details were not clear. We have added details of both trials for clarity, and have a protocol paper under review currently with BMJ Open that we will be able to reference shortly.

~ clarify findings from pilot (poor compliance to SM)

RESPONSE: This is correct, and we hope that the reordering of the introduction, as suggested, now makes this clearer.

~aim of intervention development/modification is to develop additional materials inc. an app and pilot test them on a sample of women.

~ “It would be better to first introduce the programme of work, then the pilot trial results and conclusions leading to this study, then at the end of the introduction state the aims and objectives of this study. Text on page 5 lines 17-37 introducing the PBA, and page 5 lines 59-page 6 line 10 and page 8 lines 1-17 about the pilot study results and conclusions are more suited to be placed in the introduction.”

RESPONSE: As suggested we have moved text from page 5-6, but the text on page 8 refers to the development of the logic model which we have left in that section.

2. Aims & Objectives

~ “The aims and objectives of this study need to be explicitly stated upfront. The objectives seem to be something along the lines of i) to develop accompanying educational materials to better inform women about the importance of adhering to the self-monitoring intervention, ii) to create and test a means of recording results through an app, iii) to consider possible mediating processes which may affect compliance, iv) to obtain feedback on the development process from a sample of pregnant women, PPI and professionals.

RESPONSE: Thank you for this suggestion. We have added in an Aims & Objectives section which outlines the following:

i) Identify key behavioural issues, needs and challenges of self-monitoring during pregnancy (which includes developing guiding principles and selecting psychological theory to inform intervention planning and development
ii) To develop and refine participant materials to be used in the BUMP studies which address the key behavioural issues needs and challenges identified in part (i) using guiding principles and psychological theory.

i) To develop a logic model outlining the proposed mechanisms of change of the BUMP studies.

Table 2 lists only 2 objectives and they need more detail e.g. 'to motivate .....by developing accompanying materials….'; to develop and ensure participant materials are simple….' The table needs realigning in the light of the full list of objectives.”

RESPONSE: The objectives in Table 2 are for the intervention, not the study, and are following the format for Guiding Principles, an important part of the PBA process. These provide a clear focus to guide the intervention development by summarising the key needs to be fulfilled especially during decision making processes (by reminding the development team of the specific qualities of the intervention). The purpose is not to replace all the other, more detailed sections outlined but simply outline how the intervention will address the identified challenges. We have added extra detail into the labelling of Table 2 to clarify.

3. Methods

~List only those used in this study and address how each of the objectives is to be achieved.
RESPONSE: re-written in line with aims and objectives.

~e.g. logic model developed for this study or pilot? How was it developed? Figure 2 is the result.

RESPONSE: moved Fig 2 to results. The logic model was built on the logic model developed for the HOME BP intervention - https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0553-4 - which itself was based on the same in-depth planning and development process undertaken in the context of self-monitoring of BP and using the guidance set out by the MRC. https://mrc.ukri.org/documents/pdf/mrc-phsrn-process-evaluation-guidance-final/ . However, the logic model for BUMP was developed using the planning process outlined, combined with psychological theory to visually represent the proposed mechanisms of behaviour change and identify the possible mediating processes. The process of change is similar to the pilot, as the prime substantial difference was the behavioural materials and the app.

~What methods used to gain feedback from the women + more details in section ‘qualitative data analysis’ Rationale for choosing 19 women to give feedback, how were they selected?

RESPONSE: Further details have been added about how the women were recruited and the sort of feedback that was obtained.
~ the three sections on page 8 need removing
RESPONSE: These have been moved as suggested.

~ a subsection (v) iterative qualitative user feedback adding (as per flowchart).
RESPONSE: Added into results with further details.

~ “There is also mention (page 8) of mediating processes but not how these are to be studied, and outcome data to be collected but these assessments are not presented in the Results. These sections on page 8 need realigning as to their purpose and stated as specific objectives with appropriate detail of the methods used if to be included.”
RESPONSE: these sections have been restructured so that the methods and results follow the aims and objectives.

~In Figure 1 was the pilot study data not reviewed before the qualitative literature review? Does this need adding to the diagram?
RESPONSE: We apologise if this was not clear. The pilot study data was reviewed alongside the qualitative literature, and we have added this into Figure 1 diagram.

4. Results

~need to be clearly presented in this section, with relevant quotes, feedback from the women. At present there are no results presented of the feedback gathered from each method – (focus group, PPI, participant interview)
RESPONSE: Think aloud interviews do not normally provide quotes in the same way that traditional qualitative interview studies do so it is not expected that we would provide quotes. The purpose of the think alouds is to ensure that women/participants understand the content rather than generate data for analysis that will be reported with supporting quotes. What we have done is include examples of where feedback during these interviews led to changes in the results section.

~ Figure 2 - what is BCT - it can be written in full in the heading. In the second column why does it say a) BP monitoring - there are no other interventions listed as b) etc.?
RESPONSE: we thank Reviewer 1 for highlighting this, and have made the appropriate change in Figure 2. BP monitoring is the key target behaviour being addressed by the intervention, hence why no others are listed.
5. **Discussion**

~This needs to bring together the findings for each objective in the context of the creation and feasibility/piloting of use of the materials with the women, and the implications for use in the BUMP1 trial. It would be best written as if in preparation for the BUMP1 trial.

RESPONSE: we believe this is now clearer.

~If the BUMP1 trial incorporating the modifications is already underway then this can be mentioned at the end under a heading 'Current stage of BUMP1 trial' including the stage that it is at.

RESPONSE We have added some detail on the current stage of the trial, correct at time of resubmission.

**R2.**

1) Currently it is not clear how the methods led to the results, how the methodologies employed are linked to the new version of the intervention as describe in the Results section. Some additional signposting within the paper may make this more obvious and perhaps moving a few sections around. For example the methods to develop a logic model should be in the methods and the description of the model with respect to its components should be in the Results. RESPONSE, this will be covered in the above.

2) Taking this point further, the methods used to do the development should be in the Methods and the outcomes/outputs described in the Results which then finish with a description of the resulting intervention. RESPONSE, this will be covered in the above.

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