Author's response to reviews

Title: Development and feasibility study of very brief interventions for physical activity in primary care

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Version: 2 Date: 23 January 2015

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Title: A pragmatic approach to selecting and developing behaviour change interventions for trial evaluation: the example of very brief interventions for physical activity in primary care

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RESPONSE TO REVIEWERS’ COMMENTS
A pragmatic approach to selecting and developing behaviour change interventions for trial evaluation: the example of very brief interventions for physical activity in primary care

Dear Editors

Many thanks for inviting us to revise our manuscript. We appreciate the time and effort employed by the editors and reviewers in providing helpful comments on our manuscript.

In this cover letter we give a point-by-point response to each comment by the reviewers.

In response to Reviewer 1’s comments (particularly comment 4), we have reframed the manuscript around the research aim to “identify and develop VBIs for physical activity, and test their feasibility and acceptability in the context of preventive health checks in primary care.” This reframing has resulted in quite extensive changes to the Background and Discussion sections. In order to make the reviewing process easier, we have included these amended sections in full in our reply to the reviewers’ comments below. Please note that we have also amended the title of our manuscript as a result of the comments by reviewer1. The amended title is: “Development and feasibility study of very brief interventions for physical activity in primary care.”

We have highlighted all changes made in the revised manuscript in red. Red text denotes text that has been added to the manuscript and red strikethrough text denotes text that has been removed.

We hope we have sufficiently addressed the issues raised by the reviewers and look forward to hearing from you in due course. Thank you once again for considering our manuscript for publication in BioMed Central (BMC) Public Health.

With kind regards,

Dr Wendy Hardeman
Reviewer 1

Major Compulsory Revisions

Comment 1: There is not a well-defined research question. The paper simply “describes a pragmatic method to select, develop and optimize promising candidate interventions for further evaluation and reports the findings”. I suspect, based on the data presented, that the research question is something along the lines of “which BIs/VBIs for physical activity are most feasible to deliver in clinical settings?”

Response: Thank you for this valuable comment. We have amended the research question:

Abstract, Lines 14-16:
• “The aim of this research was to identify and develop VBIs for physical activity, and test their feasibility and acceptability in the context of preventive health checks in primary care.”

Background, Lines 135-137:
• “We aimed to identify and develop promising VBIs for physical activity that could be delivered as part of routine NHS health checks in primary care and test their feasibility and acceptability.”

Comment 2: The authors identify a significant problem to be addressed (i.e., the time it takes to identify, develop, and optimize interventions). However, the study does not address the problem laid out in the introduction. The problem laid out in the introduction is that existing methods for selecting, developing, and optimizing interventions are ‘often time consuming and require significant resources’. The reader expects a study to follow that shows the current method is shorter and more feasible than existing methods. However, there is never any mention of how long and how many resources the 2-step method took to identify the VBIs, which seems like a critical piece of data. It is not obvious that the current method is less time/resource intensive, especially considering that the primary outcomes of the study (feasibility) are not the same as those one would expect from using the MOST method (efficacy/effectiveness).

Response: Again, thank you for this comment. We agree that MOST is an intervention development approach that is more about efficacy/effectiveness testing whereas our approach focused on feasibility and acceptability of the interventions (with potential efficacy of the VBIs being tested in the next phase of our research). We have removed text that compares our approach with that of MOST from the background and discussion sections. In response to this comment and other comments, we have also refocused the manuscript and made substantial changes to the background and discussion section (see our response to Comment 4 below).

Background, Lines 107-119:
• “A number of methods have been proposed and used to guide intervention selection, and these approaches have proved to be helpful tools for selecting, developing and optimising interventions [12,13,14]. However, they are also often time-consuming and require significant resources. For example, the Multiphase
Optimisation Strategy (MOST) [12] is an approach to intervention development that requires randomised experimentation to first identify and select intervention components that merit further investigation, and then to investigate interactions among those components and determine optimal dosage levels and combinations. Because the MOST approach involves extensive systematic experimentation of all potential intervention components, applying this approach to the development of BIs or VBIs where the evidence supports a wide range of components would require a significant amount of time and resources. Consequently, there is a need for a pragmatic approach to intervention development and selection that is less time and resource intensive.

Discussion, Lines 525-526:
- “2) it required minimal time and financial resources in comparison with other approaches, e.g. MOST [12];”

Comment 3: The comparison to the MOST method is not appropriate. The MOST method is one that systematically tests the effectiveness of potential BCTs. In the current study, there is no effectiveness testing. Rather, the primary outcome is feasibility (whether the VBIs could be delivered within 5 minutes). First, it’s perfectly reasonable to expect that the MOST method and other methods for identifying evidence-based interventions are equally as effective and time-consuming in identifying interventions that are feasible in clinical settings as the current method. Second, perhaps the most time consuming part of the MOST method, to which the current method is compared, is the efficacy/effectiveness testing, where the signature feature is running experiments. The current study does not include efficacy testing and, if it did, might show that none of the BCTs are efficacious and, thus, the researchers would have to spend more time going back and selecting new BCTs.

Response: As mentioned above, we agree that the comparison to MOST is not appropriate and have removed the comparison from the background and discussion sections.

Comment 4: There is no data presented to support the claim that the 2-stage method for identifying feasible VBIs is less time consuming than other methods of identifying feasible VBIs. In Stage 1, along, the researchers conduct two systematic reviews, a scoping review, stakeholder consultations, qualitative research including observations and interviews with 51 patients, and a cost analysis study for VBIs. How long did all of that take? I think the main result of this study is not a less-time consuming method for identifying VB interventions, but the feasibility of those interventions. The manuscript either needs data to support the claim that the methods take less time than existing methods for identifying, developing, and optimizing interventions, OR the manuscript needs to be reframed around the research question above (i.e., a feasibility study) and that the methods used successfully identified feasible VBIs.
Response: Thank you for this helpful comment. In response to this comment, and the other comments above, we have decided to reframe our manuscript around the second alternative. A number of changes have been made to the Title, Abstract, Background, Discussion and Conclusions sections in order to change the focus of the manuscript. All changes are shown below. Red text denotes text that has been added to the manuscript and red strikethrough text denotes text that has been removed. These changes have not increased the overall length of the manuscript.

TITLE :

“"A pragmatic approach to selecting and developing behaviour change interventions for trial evaluation: the example of very brief interventions for physical activity in primary care. Development and feasibility study of very brief interventions for physical activity in primary care.”

Abstract (Background), Lines 3-16

“There is increasing interest in brief and very brief behaviour change interventions for physical activity as they are potentially scalable to the population level. Such interventions can contain only a limited number of ‘active ingredients’ (behaviour change techniques (BCTs)). However, evidence may support a range of BCTs and candidate interventions. Available methods for selection of the best-bet intervention are not feasible when time and resources are limited. This paper describes a pragmatic method to select, develop and optimise promising candidate very brief interventions (VBIs) for physical activity as part of preventative health checks in primary care, and reports the findings. However, few very brief interventions (VBIs) have been published, and evidence is lacking about their feasibility, acceptability and which ‘active ingredients’ (behaviour change techniques) would maximise their effectiveness. The aim of this research was to identify and develop promising VBIs for physical activity and test their feasibility and acceptability in the context of preventive health checks in primary care.”

Abstract (Conclusions), Lines 34-45

“It is feasible to use a two-stage method with multiple selection criteria and sources of evidence to select, develop and optimise several candidate interventions when limited time and resources are available. This method emphasized the importance of considering the practicability of VBIs alongside cost and effectiveness throughout the process, and enabled the development of four well-characterised, practicable and potentially effective VBIs for promoting physical activity in routine and preventative consultations. Using a two-stage approach, in which we considered the practicability of VBIs (acceptability, feasibility and cost) alongside potential efficacy from the outset, we developed a short-list of four promising VBIs for physical activity and demonstrated that they were acceptable and feasible as part of a preventive health check in primary care.”

Background, Lines 55-153 (N.B: This is the amended background section in its entirety, including sentences that have not been changed and new sentences in response to comments by Reviewer 2)
Efforts to address major public health problems such as sedentary lifestyle and obesity often involve the development and evaluation of complex interventions with multiple interacting components. Regular physical activity of moderate intensity (such as brisk walking, cycling and gardening) has significant benefits for both mental and physical health and can delay or prevent common chronic diseases such as heart disease, stroke and diabetes [1-2]. The UK government recommendations are 30 minutes of moderate-intensity activity on at least five days per week. However, the majority of adults in the UK do not meet these recommendations [3]. Globally, physical inactivity is on the rise, adding to the burden of non-communicable diseases and affecting health worldwide [2]. There is a need for scalable, cost-effective interventions to enhance the adoption and maintenance of regular, everyday physical activity. Recently, there has been a focus on developing brief and very brief behaviour change interventions targeting physical activity [4-6]. These have the potential to reach a large proportion of the adult population and could be delivered in routine or preventive primary care consultations, such as the National Health Service (NHS) health checks which target adults aged 40-74 adults [7]. Evidence in the physical activity domain recent evidence suggests shows that brief interventions (BIs) in primary care may increase physical activity in the short term [4-6,8]. There is increasing interest in brief and very brief behaviour change interventions [1-4] as they are potentially scalable to the population level. However, there is no consensus as to what constitutes a ‘brief’ intervention, with definitions ranging from durations of 2-2 minutes [5] to up to 30 minutes [1], and the content of brief interventions is often poorly described. However, definitions of BIs often include interventions that are too long for routine primary care consultations, with definitions ranging up to 30 [5] and 40 minutes [6]. Very brief interventions (VBIs), lasting no more than 5 minutes [5], could be delivered in most routine consultations. However, very few VBIs have been published and evidence for their effectiveness is weak and inconclusive [5]. Consequently, Given the paucity of VBIs, little is known about which ‘active ingredients’ (behaviour change techniques (BCTs) [9]) should be included to would maximise their effectiveness. of brief interventions (BIs), and there is even less evidence to guide the selection of effective very brief interventions (VBIs).

The UK Medical Research Council (MRC) provides guidance for the development and evaluation of complex interventions [10]. It states that ‘best practice is to develop interventions systematically, using the best available evidence and appropriate theory, then to test them using a carefully phased approach’. In the case of BIs and Given the time constraints of VBIs, the number of active ingredients that can be included is limited, only a limited number of active ingredients can be included, whereas evidence may support a range of BCTs and hence a range of candidate interventions. For example, rRecent meta-analyses of physical activity interventions have shown that intention formation [11,12], self-monitoring [12-14], goal setting and review of behavioural goals [12] are effective BCTs, either alone or in combination [12]. However, the MRC framework does not provide guidance on criteria and methods to be used in the case of when there are several candidate interventions. When there are several candidate interventions, a simple approach would be to select the most effective intervention. However, candidate interventions are likely to differ in other ways that may need to be considered in
the selection process consideration, e.g., the ease with which they can be delivered in routine practice, the extent of training required for health practitioners, intervention uptake and retention, etc. In such instances, criteria other than effectiveness alone are multiple criteria may be needed to short-list candidate interventions and decide on which intervention(s) merits further evaluation. A number of methods have been proposed and used to guide intervention selection, and these approaches have proved to be helpful tools for selecting, developing and optimising interventions [12,13,14]. However, they are also often time-consuming and require significant resources. For example, the Multiphase Optimisation Strategy (MOST) [12] is an approach to intervention development that requires randomised experimentation to first identify and select intervention components that merit further investigation, and then to investigate interactions among those components and determine optimal dosage levels and combinations. Because the MOST approach involves extensive systematic experimentation of all potential intervention components, applying this approach to the development of BIs or VBIs where the evidence supports a wide range of components would require a significant amount of time and resources. Consequently, there is a need for a pragmatic approach to intervention development and selection that is less time and resource intensive. This paper describes a pragmatic, two-stage method to select, develop and optimise promising candidate interventions for further evaluation and reports the findings. The method was developed and applied in the context of a research programme aimed at developing and evaluating very brief interventions (VBIs) to promote physical activity in primary care. The VBIs had to be deliverable within 5 minutes as part of the National Health Service health checks. These health checks target adults between 40 and 74 years for an assessment of their risk of vascular disease (e.g., diabetes, heart disease, kidney disease and stroke) and offer of appropriate management of risk. The health checks, delivered by a range of practitioners including nurses and health care assistants, offer an ideal opportunity to promote physical activity among a large proportion of the adult population. The method of selecting, developing and optimising candidate VBIs included two stages: 1) a development stage in which we generated a short-list of promising VBIs and developed them, and 2) a feasibility study in which we optimised these VBIs and decided which VBIs should be carried forward to a pilot trial. We aimed to identify and develop promising VBIs for physical activity that could be delivered as part of routine NHS health checks in primary care and test their feasibility and acceptability. These health checks are delivered by a range of practitioners including nurses and health care assistants. They target adults between 40 and 74 years and include an assessment of vascular disease risk (e.g., type 2 diabetes, heart disease, kidney disease and stroke) [7] and therefore offer an ideal opportunity to promote physical activity among a large proportion of the adult population. Financial and time pressures are high in routine care, so interventions need to be cost-effective, feasible (e.g. can be delivered faithfully), and acceptable. We used a two-stage approach to identify promising VBIs for physical activity, considering from the outset the practicability of the VBIs as well as their potential efficacy. Stage 1 was a development stage in which we combined evidence and expertise from multiple sources to develop a short-list of promising VBIs. In this stage the selection of BCTs was guided by evidence for their potential effectiveness,
feasibility, acceptability and cost within the constraints of the target population, intervention providers, setting and target behaviour. Stage 2 was a feasibility study in which we assessed the feasibility and acceptability of the short-listed VBIs and decided which VBIs (or combinations of VBIs) should be carried forward for efficacy testing in a pilot trial.”

**Discussion, Lines 514-619 (N.B: This is the amended discussion section in its entirety, including sentences that have not been changed and new sentences in response to comments by Reviewer 2)**

- “In this paper we described the methods used in selecting, developing and optimising promising candidate VBIs for further evaluation and reported the findings of the early phases and the feasibility study. We developed a two-stage method which used multiple criteria (effectiveness, feasibility, acceptability and cost) and sources of evidence to inform the selection of a short list of candidate interventions and to decide which ones merited evaluation in our feasibility study. This study showed that all four short-listed VBIs were feasible and acceptable and could be delivered in five minutes.

  The main strengths of our method were that: 1) feasibility, acceptability and cost were identified as important selection criteria in the early phases in addition to effectiveness, thereby increasing the likelihood that selected interventions would be practicable as well as effective; 2) it required minimal time and financial resources in comparison with other approaches, e.g. MOST [12]; and 3) it enabled us to identify and select the most promising VBIs from a wide range of potential VBIs, despite a dearth of knowledge of their potential effectiveness and mechanism of effect.

  We identified and developed very brief interventions (VBIs) for physical activity that could be delivered in preventive consultations (NHS health checks). Using a two-stage approach we identified and developed four promising and well-characterised VBIs for physical activity. The feasibility study showed that all four VBIs could be delivered in approximately five minutes as part of the health check, could be delivered with moderate to good fidelity, and were acceptable to participants and practitioners. We found that combining techniques from the four VBIs might increase their potential effectiveness, feasibility and acceptability, and therefore selected a combined Motivational/Pedometer VBI alongside a Motivational and Pedometer VBI alone, respectively, for further evaluation in a pilot trial. The pilot trial will examine their potential efficacy for increasing objective and self-reported physical activity, feasibility (including delivery time and fidelity), and acceptability to participants and practitioners.

  Although participants and practitioners found all four VBIs acceptable, the fidelity assessment showed that on average participants were ambivalent to somewhat enthusiastic about the VBIs. However, by definition opportunities for active engagement were limited to five minutes, participants had positive views about the VBIs immediately after their delivery, and the interviews or audio-recordings of consultations did not suggest how participant engagement could be increased.

**What have we learned about VBIs to promote physical activity?**
Overall, although current literature on brief interventions BIs provides general support for their use of brief interventions [4-6,8] and favours the use of supplements (e.g. written materials) to brief advice [16], but highlights uncertainty remains about the effectiveness, feasibility and acceptability of very brief interventions VBIs [4-6,16]. Furthermore, definitions of BIs often include interventions that are too long for routine primary care consultations [5,6,16]. Here we focused on selecting and developing very brief interventions (VBIs) that could be delivered in a preventive health check, and defined a VBI as any intervention consisting of a single session lasting no more than 5 minutes. Use of our two-stage method our findings have advanced the evidence base about VBIs for physical activity, where very few VBIs existed with poorly described active ingredients [16]. It enabled a systematic identification of four promising, well-characterised VBIs: a Motivational VBI, an Action Planning VBI, a Pedometer VBI and a Physical Activity Diary VBI. The feasibility study showed that all four VBIs are feasible and acceptable when delivered by health care practitioners as part of a preventive consultation were deliverable in around five minutes as part of the health check, were feasible in other aspects of delivery, and were acceptable to participants and practitioners. It also showed that combining techniques from the four VBIs might increase their potential effectiveness, feasibility and acceptability. Therefore we selected a combined motivational/pedometer VBI alongside a motivational and pedometer VBI alone, respectively, for evaluation in a large pilot trial. The feasibility study was designed to assess the feasibility and acceptability of the short-listed VBIs, but did not examine their effectiveness. Therefore, the pilot trial will use all four selection criteria, including effects on objectively measured physical activity compared with the health check alone, to select the best-bet VBI for evaluation in a full-scale randomised controlled trial. The main advantage of conducting the feasibility study before the pilot trial was that it enabled us to explore a wide range of VBIs with minimal time and resources (evaluating effectiveness in addition to feasibility and acceptability would have substantially increased both sample size and recruitment time) and ensured that only VBIs that were practicable were considered for more intensive evaluation.

Our study had a number of strengths. First, selecting BCTs based on evidence for their potential effectiveness, feasibility, acceptability and cost enabled us to develop a number of promising VBIs, given the lack of evidence about how to select BCTs to target theoretical constructs [15]. Second, this approach enabled the development of VBIs that were practicable as well as potentially effective. Finally, we developed and tested multiple VBIs simultaneously, rather than a best-bet VBI only. Key challenges of using our method approach were deciding which criteria should be used to select interventions, what evidence should be collected to inform those criteria, and whether and how criteria should be weighted when short-listing interventions. We identified four key selection criteria (effectiveness, feasibility, acceptability and cost) at the outset, and used an iterative approach to combine evidence and expertise from multiple sources. We decided that, given the primary care context, feasibility and acceptability should be considered to be of equal importance as effectiveness and cost. Future research may identify other criteria depending on context, behaviour and target group, e.g. the potential to reduce health inequalities, and might also develop a more refined approach to weighting
criteria. In terms of weighting the criteria, we decided that given the primary care context, participant and practitioner views on feasibility and acceptability should be considered to be of equal importance as effectiveness and cost. Future research might develop a more systematic approach to weighting criteria. Testing multiple VBIs simultaneously allowed us to collect data quickly and minimised the effect of potential confounders such as seasonal effects, but was finally, this approach was also challenging in terms of the practicalities of evaluating several interventions in the context of routine primary care. For example, it increased the burden on practitioners, who were trained in four VBIs within limited time, and had to randomise delivery of each VBI. We addressed the latter by randomising VBI delivery by week rather than by participant, and produced a brief script for each VBI to guide delivery. Future research may identify other ways to deal with these challenges, such as clustering by practice or practitioner, though it is likely that this would increase the sample size significantly.

We recommend this pragmatic approach when selecting and developing brief and very brief interventions, for physical activity and other behaviours, when evidence supports a wide range of potential intervention components, and when time and resources are limited that anyone using this approach to intervention development defines a priori: key selection criteria (tailored to context, target population and target behaviour), the evidence needed to inform those criteria, and the method for weighting/combining the criteria should be established a priori. Similarly, we also recommend that the practical challenges posed by combining multiple sources of evidence and testing multiple interventions simultaneously need to be considered at the outset when deciding how many interventions to shortlist and evaluate further.

Conclusions, Lines 621-632: (N.B: This is the amended conclusions section in its entirety)

• “A two-stage method using multiple selection criteria and sources of evidence was found to be a pragmatic approach to selecting and developing very brief behaviour change interventions for trial evaluation. This method emphasized the importance of considering the practicability of VBIs alongside cost and effectiveness in the early stages, and enabled the development of four well-characterised, practicable and potentially effective VBIs for promoting physical activity in routine and preventative consultations.

Using a two-stage approach, in which we considered the practicability of VBIs (acceptability, feasibility and cost) as well as potential efficacy from the outset, we developed and tested the feasibility of four promising VBIs for physical activity and demonstrated that all were acceptable and feasible as part of routine preventive health checks in primary care.”
Reviewer 2

Major Compulsory Revisions

Thank you for your valuable comments.

Comment 1:

**METHODS, Line 217**

The authors present the design as an adapted cluster randomised feasibility trial, which suggests an effectiveness study. Cluster randomisation would mean that practices would have been randomly assigned to a certain intervention, in this case one of the VBIs. However, in line 364 to 366, it appears that randomisation took place on patient level. As a consequence, I have my doubts about whether this design is actually a cluster randomized design.

Response: Thank you for this valuable comment. All practices delivered all four VBIs. The order of VBI delivery was block randomised by week and all participants in a single practice received the same VBI that week. So, participants were clustered by week, and technically this was an adapted cluster randomised design. However, the readers of the journal may not be familiar with this term and therefore we have made the following changes:

**Study Design, Line 269-270:**

- This sentence has been changed to “The study was a feasibility study with a randomised design to assess the fidelity, feasibility and acceptability of the short-listed VBIs identified in Stage 1.”

**Randomisation, Lines 273-274:**

- This sentence has been changed to “The order of the four arms was block randomised for each practice on a week-by-week basis, and participants were allocated to receive the intervention that was scheduled for delivery during the week of their health check appointment.”

Comment 2:

**METHODS, Lines 234 to 240 Participants paragraph**

Is it true that the current level of physical activity was not an inclusion criterion? This may have serious consequences for the opinion of participants about the VBIs. Could the authors explain why they decided to ignore that criterion (if they did).

Response: We did not ignore this criterion but discussed this extensively prior to the feasibility study. We decided not to use current physical activity as an inclusion criterion for the following three reasons. Firstly, the VBIs were developed for delivery in a routine preventive consultation (the NHS Health Check), targeting all UK adults aged 40-74 years attending health checks, not just to individuals who are currently insufficiently active. Secondly, the Health Survey for England 2008\(^1\) found that than only 6% of men and 4% of

women currently meet the physical activity recommendations (according to objective accelerometer data), indicating that the vast majority of our target population can benefit from increasing their physical activity. Thirdly, self-report measures of physical activity are subject to bias\(^2\), such as over-reporting of physical activity levels. Therefore including a self-report assessment during the health check would be unreliable, likely to exclude sedentary participants, and be too time-intensive and costly for a scalable intervention. An objective measure of participant’s physical activity at baseline (prior to attending the health check) would only be feasible in a research context, not in routine clinical practice. In another strand of pilot work for our main trial (unpublished) we piloted objective physical activity measurement before the health check, and found that it was not feasible for a number of reasons. For example, adding an objective measure of PA at baseline reduced recruitment rates by approximately 25%.

Participants, Lines 294-298:

- We have added the following sentence to the methods section to highlight that current level of physical activity was not an inclusion criterion: “Current level of physical activity was not an inclusion criterion for the study as the VBIs were developed for delivery in a routine preventive consultation (the NHS Health Check) targeting all UK adults aged 40-74 years attending health checks, not just individuals who are currently insufficiently active.”

Comment 3:

RESULTS, Lines 361-363

It appears that in the end two practices and four practitioners remained in the feasibility study. Since all VBIs were delivered in both practices, the practitioners were probably trained to deliver at least two VBIs. Moreover, all four VBIs were delivered to patients in both practices. Both factors could have been a source of contamination because practitioners may have used principles of one VBI while delivering another one, and patients opinions about the VBI they received may have been influenced by information of other patients receiving another VBI in the same practice. Could the authors explain how they have dealt with this possible threat.

Response: Yes, it is possible that cross-intervention contamination could have occurred in both these ways, and we did not report in the previous version of our manuscript how we attempted to minimise contamination. To help reduce contamination via VBI delivery, we block-randomised the order of VBI delivery each week for each practice, so that practitioners only delivered one VBI each week. In addition, we assessed cross-intervention contamination when we coded the fidelity of intervention delivery. Only two minor incidences of contamination were observed where the same practitioner mentioned the usefulness of pedometers to one participant receiving the Motivational VBI and one participant mistakenly received the Physical Activity Diary VBI. In sum, contamination of VBI delivery is unlikely.

To assess contamination via participants who received different VBIs communicating with one another, we interviewed participants immediately after they received the VBI. Thus, we eliminated the possibility that they discussed the VBIs they received with other participants. It is still possible that participants had communicated with previous participants before receiving their VBI. However, no participant spontaneously reported this to be the case during their interviews. Furthermore, the main aim of our study was to determine the acceptability and feasibility of the four VBIs. Therefore, we felt that having knowledge of other the VBIs would not reduce the value of the feedback we received from participants. For example, if participants had reported that they would have preferred a different VBI to the one that they received, this would have been very useful information.

The following changes have been made to the methods section:

**Randomisation, Lines 273-279:**

- This paragraph has been changed to emphasise that the block randomisation by week was done in an attempt to reduce cross-intervention contamination. “The order of the four arms was block randomised for each practice on a week-by-week basis, and participants were allocated to receive the intervention that was scheduled for delivery during the week of their health check appointment. This was done to ensure that the time and order of the VBIs were balanced on average across practices and also to reduce cross-intervention contamination by making it easier for practitioners to focus on one VBI per week, rather than switching between four VBIs.”

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**Comment 4:**

**RESULTS, Lines 389 to 391 Mean values...in VBI4 (Pedometer)**

With scores ranging from 3.0 to 3.5 out of 5, participants’ engagement doesn’t seem to be very high. This might have some consequences for the effectiveness of the VBIs. Did the authors identify further reasons for this limited engagement and did they adjust the VBIs accordingly? If not it might be a topic for the discussion.

**Response:** This is a good point, thank you. Average participant engagement with the VBIs, although not very high, was also not very low – on average participants were ambivalent to somewhat enthusiastic. We did not expect a priori that participants would be highly engaged with the VBIs: there was little opportunity to be actively engaged as all VBIs were limited to five minutes. In addition, they were delivered towards the end of a 20 minute preventive health check which included a number of assessments, including a blood test. We were aware that participants might be resistant to the VBIs, however our observed level of participant engagement did not suggest this to be the case. This was supported by the finding that participants’ comments about the VBIs during the interviews immediately after intervention delivery were predominantly very positive.

Although the effectiveness of the VBIs might be influenced by participant engagement during the consultation, the aim of our study was to determine the feasibility and acceptability of the VBIs, not efficacy. Increasing participant engagement might improve VBI acceptability, but it was not obvious from interviews or audio-recordings what could be changed to increase participant engagement. The following change has been made to the manuscript:
Discussion, Lines 542-546:

• We have added the following to the discussion: “Although participants and practitioners found all four VBIs acceptable, the fidelity assessment showed that on average participants were ambivalent to somewhat enthusiastic about the VBIs. However, by definition opportunities for active engagement were limited to five minutes, participants had positive views about the VBIs immediately after their delivery, and the interviews or audio-recordings of consultations did not suggest how participant engagement could be increased.”

Comment 5:

RESULTS

Lines 404 to 409 Practitioners reported that...increasing their PA

This paragraph exactly seems to touch on a sensitive point of the approach that is presented in this paper. The authors have chosen for a pragmatic approach in which they omitted a problem analysis. A problem analysis is a time consuming step that precedes the choice for or development of an intervention and enables the choice of BCTs most suitable to influence the determinants underlying the problem. So by omitting this step the authors really shortened their approach and made it more pragmatic, but it may have reduced the appropriateness of the VBIs (also consider the limited engagement of the participants). Could the authors elaborate in this in the discussion?

Response:

Again, thank you for this valuable comment. We did not omit a problem analysis from our approach as our VBI development stage (Stage 1) served this purpose. This stage did not include development work to identify the determinants of physical activity in our target population, as we already had done this work and identified determinants of physical activity and theory-based mediators of physical activity change in our previous trials in similar target populations.3,4 Furthermore, a number of intervention parameters were pre-determined: the context (NHS Health Checks), intervention deliverers (health care practitioners), target behaviour (physical activity), target population (all patients eligible for a health check), and intervention duration (5 minutes). Therefore, our problem analysis focused on identifying what works to increase physical activity within these constraints, and the selection of BCTs was guided by evidence for their potential effectiveness, feasibility, acceptability and cost from multiple sources. These included systematic reviews of the literature as well as qualitative interviews with patients attending health checks and practitioners delivering health checks, consultation with stakeholders about intervention content (academics with expertise in behaviour change, GPs, nurses, health service commissioners, and a patient public involvement panel), and cost estimation.

3 Hardeman W, Kinmonth AL, Michie S, Sutton S for the ProActive project team. Impact of a physical activity intervention program on cognitive predictors of behaviour among adults at risk of Type 2 diabetes (ProActive randomised controlled trial). JBNPA. 2009;6(16):1-10.
In response to Reviewer 1’s comments (particularly comment 4), we have reframed the manuscript around the research aim to “identify and develop VBIs for physical activity and test their feasibility and acceptability in the context of preventive health checks in primary care.” As part of this we have clarified that our approach to intervention development focused on selecting BCTs based on their potential effectiveness, feasibility, acceptability and cost, rather than on their theoretical mechanism of effect. This approach is justified given the lack of evidence about which BCTs are effective at changing specific determinants of physical activity:

**Background, Lines 146-150:**

- “Stage 1 was a development stage in which we combined evidence and expertise from multiple sources to develop a short-list of promising VBIs. In this stage the selection of BCTs was guided by evidence for their potential effectiveness, feasibility, acceptability and cost within the constraints of the target population, intervention providers, setting and target behaviour.”

**Discussion, Lines 580-585:**

- “Our study had a number of strengths. First, selecting BCTs based on evidence for their potential effectiveness, feasibility, acceptability and cost enabled us to develop a number of promising VBIs, given the lack of evidence about how to select BCTs to target theoretical constructs [15]. Second, this approach enabled the development of VBIs that were practicable as well as potentially effective. Finally, we developed and tested multiple VBIs simultaneously, rather than a best-bet VBI only.”

**Comment 6:**

**RESULTS, Lines 419 to 438 First, the qualitative...Motivational and Pedometer VBIs.**

*In particular the Motivational VBI seems to come with an extensive pile of paperwork, since the Action planning and the PA diary were incorporated in the VBI. I wonder if, in its final format, the Motivational VBI can still defined as a VBI? Another question is, taking into consideration that participants’ engagement is already limited, what are the chances that they are actually going to make action plans and use the diary? Are there any further adjustments planned, to monitor this for instance?*

**Response:** Our definition of a very brief intervention is based on duration of delivery (5 minutes or less), and not on enactment (e.g. participants reading the booklet). The additions to the motivational VBI were primarily to the patient materials. Only limited additions were made to the face to face delivery (for example, practitioners were asked to highlight that the booklet contained a physical activity diary without explaining in detail how to complete it, as full written instructions were given in the booklet). In the pilot trial we assess duration of intervention delivery and participants’ use of the written materials (including the diary and action planner) in a questionnaire at four-week follow-up. A manuscript reporting the pilot trial is in preparation.
Comment 7:
**RESULTS, Lines 453 to 454 The amended...range of techniques**
It seems that this VBI requires quite some explanation to participants. Is it still possible to deliver this VBI in 5 minutes?

Response: As stated above, we will assess duration of VBI delivery in the pilot trial.

**Discussion, Lines 538-541:**

- We have added the following to the discussion to make this clearer: “The pilot trial will examine their potential efficacy on objective and self-reported physical activity, feasibility (including delivery time and fidelity), and acceptability to participants and practitioners.”

While revising the manuscript we added the following text to our acknowledgements:

**Acknowledgements, Lines 644-652:**

- “We thank study participants, participating GP practice teams and practitioners who delivered the interventions; Laura Lamming and Dan Mason for leading the systematic reviews; the programme management team (Simon Griffin and Ann Louise Kinmonth); the qualitative research team (Simon Cohn and Philip Miles); all individuals who took part in our stakeholder consultations for their contributions to the development of the interventions; Richard Parker and Toby Prevost for their advice on study design and statistical guidance; the East of England Primary Care Research Network (Kim Fell) for their help with practice recruitment.”