Author’s response to reviews

Title: Assessing the feasibility and acceptability of Changing Health for the management of prediabetes: Protocol for a pilot study of a digital behavioural intervention

Authors:

Sophie Cassidy (sophie.cassidy@newcastle.ac.uk)
Nduka Okwose (nduka.okwose@newcastle.ac.uk)
Jadine Scragg (j.h.scragg@newcastle.ac.uk)
David Houghton (david.houghton@newcastle.ac.uk)
Kirsten Ashley (coachkirsten@changinghealth.com)
Michael Trenell (michael.trenell@newcastle.ac.uk)
Djordje Jakovljevic (djordje.jakovljevic@newcastle.ac.uk)
Kate Hallsworth (kate.hallsworth@newcastle.ac.uk)
Leah Avery (leah.avery@tees.ac.uk)

Version: 1 Date: 07 Aug 2019

Author’s response to reviews:

RE: PAFS-D-19-00104

Assessing the acceptability and feasibility of a mobile phone enhanced service pathway (Changing Health) for the management of pre-diabetes: Study protocol for a pilot study

Dear Prof Lancaster and Prof Thabane,

We would like to thank you and your reviewers for your constructive comments on our manuscript.

We have addressed all comments (see our response to each comment in red and underlined), and are pleased to enclose a revised manuscript with amendments highlighted.
If you have any questions or require any additional information please do not hesitate in letting me know.

Yours sincerely,

Dr Sophie Cassidy

P=page
L=line

Reviewer #1: The study protocol describes a pilot trial to assess the acceptability and feasibility of a digital intervention (Changing Health) that provides structured education and lifestyle behaviour change support to adults with pre-diabetes. Overall I thought that the paper was well laid out and the intervention of sound concept. I do however think that there is a lack of detail surrounding some of the material included (e.g. the mobile phone app and lifestyle behaviour coach support), and more details should also be given as to how the intervention was developed. Nevertheless, I feel that these changes are minor and would recommend publication of the manuscript once the comments presented below have been addressed.

Title: It could be made clearer in the title that this is a study protocol paper, suggest adding "study protocol for a" in-front of pilot study.

Thank you for this helpful suggestion. We have now added ‘protocol for a’ in to the title to improve clarity (P1).

Background:

1. The authors talk about healthcare professionals delivering the NHS diabetes prevention programme and the Movement as Medicine intervention - some indication of the types of HCP (GPs, diabetes nurses etc.) delivering these would be useful.

We have provided additional information about the types of HCPs delivering these programmes (P4, L12 and P5, L3).

2. The authors introduce the Movement as Medicine intervention, but little detail is given on what the intervention components actual where and what "key behavioural techniques" where
delivered during the face-to-face consultations. The authors could briefly add some more detail here.

We published a Movement as Medicine intervention development paper that reports this information in detail. However we appreciate that a summary would be helpful. We have therefore provided this and referenced our published manuscript should readers require additional information (P5, L5-11).

3. In addition, the authors state that the Movement as Medicine intervention was used to inform the development of the Changing Health intervention. Again, there are no details given on how this intervention was developed, what steps were taken in terms of developing a mobile phone application etc. The authors could provide more details on this.

We have included a summary of how the outcome of Movement as Medicine was used to inform the development of Changing Health (P5-6).

Objectives:

Objective 4: This objective is about intervention fidelity. I would suggest rewording this to: To assess if the intervention was delivered and received as intended (intervention fidelity).

Thank you for this helpful suggestion. We have revised our manuscript accordingly (P6, L10).

Methods + Design:

1. Recruitment: The authors outline how patient participants will be recruited. Some details should also be given on the process of recruiting the local primary care practices.

Local primary care practices will be recruited through the North East and North Cumbria Clinical Research Network who help identify and approach participant identification centres (PICs). Those interested will be recruited on a first come first serve basis. This has been added on P7, L3-5.

2. Intervention: Who is delivering the coaching appointments and what training was given to these individuals?

Coaching appointments will be delivered by Lifestyle Behaviour Coaches. Each coach has completed a training programme designed to equip them with the knowledge and skills to support lifestyle behaviour change in people at risk of type 2 diabetes. We have provided additional information to clarify (P9, L19-26 and P10, L1-2).

3. Acceptability: The authors state that they will use theory-based topic guides- what theory is being used here? The theoretical framework of acceptability may be a useful resource. [Sekhon

Thank you for bringing this to our attention. It appears that there is an error in our manuscript. Rather than the topic guides being ‘theory-based’, the data generated from our qualitative interviews will be analysed in accordance with theory using the Theoretical Domains Framework (TDF). We have amended our manuscript throughout where appropriate.

4. Fidelity: It would also be interesting to look at the number of times the mobile phone platform is accessed by the participants.

We agree and this is something we plan to do but appreciate this isn’t explicitly reported in our manuscript. We have now provided this information. Thank you for highlighting this omission (P11, L7-13).

General Comments:

1. Standardise the use of pre-diabetes versus prediabetes throughout the paper.

Thank you, we have standardised the use of prediabetes throughout our revised manuscript.

Reviewer #2: This manuscript reports on a protocol for a pilot study of a digital behaviour change intervention targeting prediabetes. The proposed research will help inform the design of a larger evaluation of the intervention. The comments below primarily relate to clarification and order of the manuscript content.

General comments

There is some inconsistency throughout in terms of the terminology used to describe the intervention; e.g. title refers to a "mobile phone enhanced service pathway", abstract refers to a "digital intervention" etc.

Thank you for highlighting these inconsistencies, we have removed references to a service pathway, and used ‘digital intervention’ instead as this more closely reflects the intervention.

Inconsistent capitalisation of the word "diabetes"; inconsistent hyphenation of term "prediabetes"/"pre-diabetes"

Thank you, we have addressed these inconsistencies throughout our revised manuscript.
I think the term feasibility should come before acceptability throughout the manuscript as you are focused on the study feasibility to begin with and following this up with a qualitative study to explore acceptability.

We agree, thank you. We have revised our manuscript accordingly.

References: Please check to make sure that references comply with journal requirements.

We have checked our reference list and can confirm it now complies with journal requirements.

Title

I think the term protocol should be incorporated into the title to make it clear to the reader that this is a study protocol.

Thank you. We have added ‘study protocol’ in to the title to improve clarity (P1).

Abstract

Methods:

-Suggest moving section on embedded qualitative design down to the end of this section.

-It is not quite clear why there are two visits at baseline and if both visits constitute baseline data.

Thanks for your suggestion, we have moved the section on embedded qualitative design down to the end of this section (P2, L21-22). The baseline visit was separated into two visits because it would have been too time consuming for patients to attend a single visit, this has been explained in the methods section of the main text (P12, L2-3).

Discussion

-Again, suggest moving sentence relating to qualitative data to end.

We have moved the qualitative data towards the end of this paragraph (P2, L26-27).

Background

It would be nice to follow up the opening sentence with a sentence giving some statistical information on predicted increases in prevalence.
We could not identify a suitable reference for predicted increases in prevalence in the UK, therefore we have provided some figures for the number of individuals living with increased risk of Type 2 diabetes (P4, L2-3).

Line 2: need to clarify/specify what weight gain is the leading cause of

Thank you, we have amended the wording to refer to weight gain being the leading cause of prediabetes (P4, L3-4).

Line 7: the last sentence in this opening paragraph is particularly long; suggest breaking up.

We have removed ‘to initiate weight loss and its maintenance’ to improve concision.

The term NHS needs to be defined for an international audience

Thank you, we have now defined NHS throughout our revised manuscript.

Line 22: suggest replacing "the majority" with "most"

We have now replaced ‘the majority’ with ‘most’ (P4, L11).

Reference 8 does not appear to be directly linked to the programme that has been referred to; it also predates the programme by 10 years

Thank you for highlighting this error. We have amended the reference (now reference 9, P4, L16).

Line 31: I am not quite convinced that digital interventions offer a solution to the time commitment required by patients to achieve weight loss

Apologies if our manuscript is not clear. A common barrier reported to completion of structured education sessions is having to attend face-to-face sessions that are often scheduled at inconvenient times and clash with work and family commitments. The Changing Health for prediabetes intervention aims to address this barrier by providing structured education in digital format that can be completed at any time. Furthermore, coaching delivered by telephone is provided at a time that is convenient to each individual patient. We acknowledge that reducing the time commitment required by patients to achieve weight loss is difficult because this is dependent on the individual challenges patients face. We have amended our manuscript to provide clarity (P5, L18-20).
Line 43: the authors have specifically mentioned "theory-informed" intervention; is there evidence that this type of intervention is more effective than an intervention that is not theory based?

Findings are mixed in terms of whether these type of intentions are more effective when theory-based. We have provided additional information that we hope helps to support our decision-making (P4, L22-23).

Line 55: it would be helpful to elaborate on the professionals involved

We have provided additional information about the types of HCPs delivering these programmes (P4, L12 and P5, L3).

Line 58: it would be good to include some examples of relevant BCTs

We have now included examples of relevant BCTs incorporated. (P9, L10-11).

Line 1, p5: the authors make claims about the feasibility/acceptability of the previous intervention, however, no reference source is provided.

We have now provided a reference source (P5, L13).

Line 14, P5: "Data generated from the Movement as Medicine for Type 2 Diabetes study was therefore used to inform the development of the Changing Health intervention to address the needs identified": this would be worth elaborating on

Thank you. We have provided additional information to add further detail (P5, L5-11).

Line 21: the clinical parameters for diagnosing prediabetes should be outlined earlier or else in the methods and not in the aim

Thank you, we have removed this from the aim and kept it in the methods (Table 1).

Study objectives: is assessing feasibility of data collection methods also part of the study?

Yes, and apologies if this isn’t clear. We have provided additional information (P10, L15 and P11 paragraph 2).

Objective 4: suggest incorporating the term fidelity

We have incorporated the term ‘fidelity of delivery’ throughout. The methods section of our manuscript has a sub-section ‘fidelity of delivery assessment’ (P11, paragraph 2).
Secondary objectives: Despite weight loss being a goal of the intervention, there is no explicit mention of it or BMI as an outcome.

Thank you for highlighting this error, we have now added this into the secondary aims (P6, L13) and methods (P12, L5-9).

Methods section: I would remove "+ Design" from section heading

Thank you. We have removed + Design from the section heading.

I think some of the subsections need to be reordered to aid flow

We have moved the ethics and recruitment sections to aid flow. The methods section is structured as follows:

- Study design, setting and ethics
- Recruitment and inclusion criteria
- Intervention
- Primary + secondary outcomes
- Analysis

Also if referring to the study as mixed methods, this should be outlined early in the methods and details of how data will be triangulated need to be incorporated in the data analysis section

We have referred to our study as mixed methods directly beneath the ‘Outcome measures’ heading (P10, L5). Our new section on criteria to proceed to a larger evaluation (P11, L14-20) provides insight into how data will be used to reach an overall decision on feasibility and acceptability.

Recruitment and sampling should be presented as a separate section

Thank you, we have moved incorporated a separate ‘recruitment’ section that includes eligibility criteria (P7, L1).

If would be good to include more information about the setting - it's not quite clear if this environment is completely artificial to a normal clinical setting

Participants will attend a clinical research facility for each of the four visits of the study, however the actual intervention is carried out in their own time and setting. Participants will receive a mobile phone application that provides structured education and behaviour change tools to complete in their own time and lifestyle behaviour coach support delivered by telephone.
This means that there is no need to attend additional clinics for the purpose of intervention delivery/receipt. This has been made clearer in our revised manuscript (P6, L21-23).

Further information needs to be provided on what the screening visit entails.

We have added more information on P7, L9-11 and a list of measurements undertaken in each visit can be seen in Figure 1.

Table 1: remove ≥ before 18; add unit to BMI; I am not quite clear of necessity of weight stability in the previous 6 months and if that rules out potential participants who mightn't engage with health services until it is too late.

Thank you for highlighting these points, we have now added units to BMI. We require weight stability within the previous 6 months to separate the impact of this intervention on weight loss, from any other weight loss strategies.

Inclusion criteria

Cross reference to table 1 should be here as part of a separate section on sampling and recruitment; this should also outline how many participants you intend to sample/recruit.

We have included a separate section on recruitment and eligibility criteria that also provides details of the sample size (P7, L2-3).

I don't quite follow when/how blood tests are being performed; you mention "recruiting from GPs" but that isn't quite accurate as you are only disseminating information about the study from clinical practices and asking potential participants to contact you if they wish to participate; you refer to "a number of blood tests" but I am not sure what they are; can historical results on file be used as part of the screening process?

Apologies for not making this clear in the text. We plan to recruit patients based on their HbA1c and/or FPG measured in primary care. Separate to this, we will be taking blood samples and measuring HbA1c and FPG as part of the clinical testing (four visits to the lab), and due to different testing methods and inherent biological variability we expect discrepancies. This is why we outline how we would deal with these discrepancies between results. We have made this clearer in the text (P7, L14-15 and P8, L1-6).
Ethical approval

This doesn't sit quite right where it currently is; suggest adding to end of study design section above

Thank you for this helpful suggestion. We have ethics to the study design and setting section (P6, L23-25).

I would also just state that "Ethical approval was granted by…"

We have amended our manuscript accordingly (P6, L23).

Intervention

Additional detail is needed as to how participants will get set up with the app; will it be downloaded for them; will they have any training materials on how to use it etc

Participants will receive an email with instructions on how to obtain access to the App. Once the email is sent, the time taken to access the App is monitored, therefore if no activity is logged, participants will be contacted by a lifestyle behaviour coach who will provide support to gain access. We have provided this information in our revised manuscript (P8, L15-18).

How do you define a behaviour coach? What qualifications do they need?

In relation to a previous comment received, we have now provided additional information about the qualifications and professional experience of lifestyle behaviour coaches including detailed information about the training they have received (P9, L19-26 and P10, L1-2).

Measures; suggest using the term outcomes and making more explicit reference to study endpoints as outcomes;

Thank you, we have used the term ‘outcomes’ as suggested.

I think adherence should be separated from recruitment and retention

We have separated adherence from recruitment and retention (P10, L10).

Again, there is no mention of the feasibility of collecting relevant outcome data - this would be important in terms of informing any subsequent study.

Thank you for highlighting this. We have amended our manuscript accordingly to include this information (P10, L15 and P11, L19-20).
Do the authors have any a priori stop/go criteria that will help to inform decisions as to whether or not to proceed to a larger evaluation of the intervention?

Stop/go criteria are linked to our primary outcomes feasibility and acceptability. We have incorporated additional information into our revised manuscript to provide clarity (P11, L14-20).

A separate subheading is needed in terms of the qualitative phase

Thank you. We have, as suggested included a separate subheading for the qualitative phase (P10, L23).

I am not clear where the sample size of 18 participants comes from

We have provided additional information that we hope provides clarifies the sample size (P11, L4). While doing this we also identified an error (i.e. sample size of n=18 should have been n=16).

It appears that both interviews and focus groups are being used; can individuals take part in both? This seems quite burdensome; what is each data collection method contributing to the study objectives?

The original aim was to conduct interviews to obtain participant views and experiences of using the intervention and to identify barriers and facilitators, and then to use focus group discussions to gain consensus from group members on the most salient barriers and facilitators. Upon reflection (taking in to account the concern raised about this approach being burdensome), we have revised our protocol to limit our qualitative investigation to interviews only. The manuscript has been revised accordingly to reflect this change (P13, L12-17 and P14, L1-3).

The section on fidelity assessment is vague; there is insufficient information for this to be replicated

Thank you for highlighting this. We have added further detail to the section on ‘fidelity of delivery assessment’ to provide clarity and facilitate replicability (P11, L7-13).

The section on clinical outcomes should come earlier and should be merged under one single heading on outcomes

We have now labelled the ‘clinical outcomes’ as ‘secondary outcomes’. As the clinical outcomes are secondary we feel that they should come below the primary outcomes.
What do the two visits at baseline entail?

The details of measurements and testing performed during the two baseline visits to the clinical research facility can be seen in Figure 1.

Analysis section

The quantitative analysis should come before qualitative analysis to align with the methods reported; both of these subsections need to be reconsidered in light of previous comments; the level of detail regarding the qualitative analysis is insufficient, particularly as the authors state that a theory based topic guide will be used.

We have placed the quantitative analysis section before the qualitative analysis section as suggested. Thank you. We have also added details regarding the qualitative analysis. We agree with the reviewer and have reorganised the analysis section accordingly. In response to previous comments relating to the use of interviews and focus group discussions being burdensome, and theory-informed topic guides, we have revised the qualitative analysis section of the manuscript. We hope that this adequately addresses the comments raised.

I am not quite convinced that reference 19 is the best source to use to guide calculations; it dates back to 1996.


Discussion

What does "at scale " mean?

‘At scale’ refers to the ability to reach a large number of recipients across a number of geographical areas.

Has it been established that digital intervention can be delivered at a "lower unit cost"?

Little et al 2017, showed that a behavioural internet intervention, with very restricted face-to-face and remote follow-up is well below the cost per kilogram loss of commercial weight-loss programmes. We have added this information to our revised manuscript (P4, L17).
Lines 25-30, Page 13; the sentences regarding impact need to be revised to clarify that you are referring to potential impacts of the intervention

We have made it clearer that we are aiming to measure potential impacts of the intervention (P15, L11).

Table 2

Should instruction on how to perform the behaviour be included as a BCT under "changing your diet"?

Participants will receive information on how to change their diet. In accordance with the BCT taxonomy v1, the information and support provided to achieve this meets the definition of the BCT ‘instruction on how to perform the behaviour’.