Reviewer’s report

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

Version: 0 Date: 12 Jun 2019

Reviewer: Cathal Cadogan

Reviewer's report:

This manuscript reports on a protocol for a pilot study of a digital behaviour change intervention targeting prediabetes. The proposed research will to 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.

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

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

References: Please check to make sure that references comply 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

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
Discussion

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

Background

It would be nice to follow up the opening sentence with a sentence giving some statistical information on predicted increases in prevalence

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

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

The term NHS needs to be defined for an international audience

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

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

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

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

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

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

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

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

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

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

Objective 4: suggest incorporating the term fidelity
Secondary objectives: Despite weight loss being a goal of the intervention, there is no explicit mention of it or BMI as an outcome.

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

I think some of the subsections needs to be reordered to aid flow.

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.

Recruitment and sampling should be presented as a separate section.

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.

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

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.

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.

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?

Ethical approval:

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

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

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

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

I think adherence should be separated from recruitment and retention

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

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?

A separate subheading is needed in terms of the qualitative phase

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

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

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

What do the two visits at baseline entail

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

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?

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

Table 2

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

Level of interest
Please indicate how interesting you found the manuscript:

An article whose findings are important to those with closely related research interests

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests
I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal

Were you mentored through this peer review?

No