Re: Development of a complex intervention to test the effectiveness of peer support in type 2 diabetes (MS: 1975486050135708)

Dear Dr Le Good,

Thank you for considering this paper for publication in BMC Health Services Research. We welcomed the reviewer’s considered and detailed comments. We have rewritten the paper based on these comments and suggestions. We have highlighted our responses to each comment or section of comments and the exact changes made in the revised manuscript. These amendments are detailed below.

We hope the amendments are to the reviewer’s satisfaction. Please contact us if you have any queries.

Many thanks,

__________________
Gillian Paul
Susan M Paul
Fergus O’Kelly
David Whitford
Tom O’Dowd
Author responses to reviewer’s comments

Title: Development of a complex intervention to test the effectiveness of peer support in type 2 diabetes

Reference: (MS: 1975486050135708)

Reviewer One report:
General
1. The question posed by the authors is new and well defined. The study addresses an important problem area. The need for the study is well defined. Although some references are old, there are excellent current ones included.
2. The methods are appropriate and well described, and sufficient details are provided to replicate the work. Using the UK Medical Research Council guide for intervention development and citing the work by Sturt, et al. (2006) indicate an acceptable approach to achieving the desired outcomes. With the emphasis on randomized clinical trials the importance of the preliminary work is often lost. Sharing the results of these phases of a study is important too. The training of the people for the peer support role is necessary for success of the project. Testing this before starting a large scale project needs to be done.
3. Data are sound and well controlled. The results of the first phases of the intervention are presented. Very brief data have been given for the qualitative part of the study, but was illustrative of how the interventions were developed. The data on which the critique given of the work by Lorig and Holman (1989) is based were not presented. Also the only citation noted is old so the difference of the proposed intervention and those studied by Lorig and colleagues over the past several years is unclear.
4. The manuscript adheres to the relevant standards for reporting and for data disposition. The manuscript is well written.
5. The discussion and conclusions are well balanced and adequately supported by the data. Although all the issues included in the Discussion had not been presented clearly in the manuscript as part as resulting from the study, the reader knows that these issues arose during the study. They are important to include. The Conclusions are very brief.
6. The title of manuscript and the names of authors were share with the reviewer; an abstract was not shared for review. Maybe the reviewer just did not locate it.
7. The writing is acceptable

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
None

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
None
Discretionary Revisions (which the author can choose to ignore).
See the comments related to the Discussion - can show the link with the phases of the study thus far. Also the differentiation of current project with work by Lorig and colleagues might need further clarification.
Accept after discretionary revisions

Author response to Reviewer One
The above comments were welcomed by the authors. A more recent paper by Lorig et al has been included in the paper. The discussion has been expanded and a title and abstract have been added.

Reviewer Two report

General
The article addresses an important topic, self-management in diabetes, and reports the development stages of an innovative peer support intervention for use in a complex RCT. The study has followed the phases of the MRC framework for the design and evaluation of complex interventions. Overall, the paper is well presented, but in many places it needs to be strengthened with greater detail to allow assessment of the study’s rigour.

Background: It would be helpful if the scale of the problem against which the intervention is targeted were presented: e.g. diabetes prevalence, diabetes complications and health policies etc, together with a brief description of the design of current health care for diabetics in the health care system being studied. The rationale for considering peer support as an element of this system of care needs to be stronger.

Author response:
National prevalence estimates and prevalence data from general practice have been included in the Background.
Figure 1 has been included in the background to describe the current health services available to people with type 2 diabetes in the Republic of Ireland (page 2)

Methods: The methods section lacks adequate detail. Although the MRC framework that guided the research is explained, in many places it is unclear how this was applied. Specifically, the phases lack clear set of aims/objectives, and without these the appropriateness of the methods cannot be judged.

Author response:
Aims and objectives have been clarified on page 2

Specifically, in Phase 1 it should be clear (either in the main text or in a table) how many informants were invited and how many participated in each aspect of data collection. With regard to phase 2, the aims and objectives include testing feasibility, including such issues as sample size calculations, acceptability of the intervention for both the participants and the peer supporters, issues regarding acceptability of the randomisation, outcome measures, optimum frequency of meetings, testing of data collection – see Lancaster et al, 2004. These should be spelt out and justified. In addition, the approach to
purposely selecting patients for participation in Phase 2 should be described. There also needs to be a description of how data in Phase 2 were analysed. Details of topic guides for the focus groups and interviews etc should be provided, together with where, when and how they were conducted.

Author response:
Details of the participants have been included in Table 2 on page 6. Details of the focus groups have been documented on pages 3. Data analysis has been described on page 3.

We never intended phase 2 to incorporate testing of our sample size as it had been based on a larger sample of patients with type 2 diabetes in the same setting. Numbers involved in phase 2 were not large enough to facilitate testing these previous calculations, which have already been peer reviewed during the grant application process when we were applying for funding for this study. Other methodological issues in relation to the RCT will be presented in a companion paper on the pilot study, which is being submitted to a peer review journal at present.

Results:
Pre-clinical phase – in my opinion, the results (together with the description of the methodology used) of the pre-clinical phase belong in the background rather than the results section. This would improve the flow of the paper, strengthen the background and provide justification for the rest of the study.

Author response
This has been a challenging paper to write as it does not fall neatly into the standard format for scientific papers and we have had considerable discussion in relation to where each component of the model would be presented. While we accept that literature findings may be placed in the background or introduction section, the MRC Framework specifically highlights the importance of the literature review in the pre-clinical phase so we have presented the main findings from this stage within the results section in order to be consistent throughout the paper.

Phase 1
- A description of participants in the focus groups should be given (e.g. age, sex, type of diabetes, duration of diabetes, complications etc), which would inform discussion of the extent to which they reflect the target population for the intervention
- It is unclear how what emerged from Phase 1 was used to contribute to the definition of the preliminary peer support intervention (i.e. the extent to which there was consensus over the key elements of the intervention, and what these elements were; the target population for the intervention; criteria for selecting peer supporters; training issues; the delivery of the intervention etc etc). This should be described as Phase 1 findings – not as part of the results for Phase 2 which is where they currently appear - The process through which these findings were used to develop the content of the training and support materials etc for the peer supporters should be described, including the extent to which users were involved in this process, their refinement and validation etc.
Author response:
Details of the positive response to the concept of peer support among the focus group participants are highlighted on page 5. The training and support for peer supporters was identified through focus groups and meeting with experts in the area as a vital part of the intervention. This has been clarified on page 5.

Phase 2:
- This section describes what was done (much of which belongs under Phase 1 findings, as above), but lacks detail about what was found from applying these criteria, procedures and processes. This should include descriptions of the characteristics of the peer supporters, the patients recruited, participation rates, attendance rates at meetings, acceptability etc. Specifically, the findings should reflect the aims/objectives for this Phase which as described above should have been made explicit in the methods
- Details should be given about how the Phase 2 study was used to test outcome measures for use in the main trial, to inform sample size calculations etc

The discussion could be strengthened by including more consideration of the limitations/difficulties associated with the MRC framework in relation to the aims of this study, and of any issues that might limit the generalisability and applicability of the intervention that has emerged from applying this approach to intervention development.

Author response:
Descriptions of the patients and peer supporters that participated in the pilot study are now detailed in Table 2 on page 6.

As mentioned above the study protocol has been written up in detail and is being submitted to a peer review journal at present. This paper details issues such as outcome measures and sample size calculations, which were based on data from previous work conducted in the Republic of Ireland. The current paper focuses on the utility of the MRC Framework in relation to the development of the peer support intervention.

References