Reviewer's report

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

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Reviewer: Jeremy Dale

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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.

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.

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 purposefully 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.

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.

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.

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.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

Discretionary Revisions (which the author can choose to ignore)