Reviewer's report

Title: The face of equipoise: a qualitative study of the experiences of deliverers of a structured education programme within a randomised controlled trial in type 2 diabetes

Version: 1 Date: 25 August 2013

Reviewer: Sean F Dinneen

Reviewer's report:

Summary

The authors describe a qualitative study undertaken within a RCT comparing 2 different methods of self-monitoring of glucose delivered as part of the DESMOND self-management education programme. The focus of the research is on the attitudes of the educators involved in delivering the protocol. In particular the authors were interested in whether the educators' personal views on urine versus glucose monitoring influenced their delivery of the protocol and (potentially) the outcome of the trial. Based on a series of focus groups held before and after educator training and follow-up interviews held 2 years later the authors report that educators were not in "individual equipoise" but were aware of the need for new evidence in this area of clinical practice. The authors claim that this awareness of the need to answer an important question along with a sense of professionalism and "concessions in the trial protocol" helped educators deliver the intervention in an unbiased manner.

Major Compulsory Revisions:

As mentioned in the Background section of the manuscript the issue under scrutiny in this qualitative study (ie, DESMOND educators' attitudes towards the protocol they are asked to deliver) can influence more than just their delivery of the intervention. The other obvious area that can be influenced by educators' attitudes is recruitment into the study. It would be helpful to have some more information on the status of the main RCT and whether there were any difficulties with recruitment. This would help with readers' interpretation of the findings of the current qualitative work.

The authors refer to treatment fidelity being assessed during the RCT as part of the DESMOND Quality Development system. Given its relevance to the topic under scrutiny here it would be helpful to have some idea of what the QD exercise demonstrated. Were educators true to the delivery of the intervention as called for in the protocol? If output from the QD exercise is not available this should be stated.

It is not clear why the interview and focus group data were anonymised. It would be helpful for the authors to explain the rationale behind this decision. Surely a design that enabled the researchers to track (potential) changes in attitudes at an
individual level would have been more helpful.

Minor Essential Revisions

An explanation of the term "equipoise" early in the manuscript would be helpful.

It is not clear what the authors mean by the phrase "concessions in the trial protocol" used in the Abstract (Results, last sentence). This should be explained.

Background section; para 3 opening sentence: the word "levelled" should be replaced by "reduced"

Discussion section; para 2; opening sentence: "unsurprising" should be replaced by "not surprising".

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I have no conflicts or competing interests with the subject of this manuscript.