Reviewer's report

**Title:** An explanatory randomised controlled trial of a nurse-led, consultation-based intervention to support patients with adherence to medication taking for type 2 diabetes

**Version:** 1 **Date:** 23 January 2012

**Reviewer:** Justin Beilby

**Reviewer's report:**

Review

My comments have been linked to Headings but are all Minor Essential Revisions.

An explanatory randomised control trial of nurse-led consultation based intervention (Farmer et al).

**ABSTRACT:**

The abstract is appropriate for the paper and provides the summary of the findings as per expected. I note the comment re the need for an important longer term study to assess clinical and cost-effectiveness outcomes. I would prefer they add over “a longer period of time” in this abstract. I think it is a key point for future studies.

**BACKGROUND**

I have no comments on the background except to note the importance around looking at medication, adherence and relying on self report. The other point around self adherence is the length of time the intervention is used. I think this should be discussed as part of the introduction.

**METHODS**

The method are well defined and the intervention model outline. The randomisation model is noted and primary care setting in 13 general practices. In describing the intervention I like the information around the time the nurses were involved with the patients and more importantly the time required to do the training. One of the issues around this type of intervention is the cost effectiveness required in a larger study. I note the intervention for the clinic nurse across the 13 practices lasted approximately 30 minutes and data collection 20 minutes. Is there any other studies that have looked at the time for training and intervention in the area of medication adherence.?

**RESULTS**

The mean difference between the groups in the percentage of days of correct number of doses taken was 8.4% with the P-value of 0.044. This improvement is illustrated in Figure 2 and I am not totally convinced re thus figure should remain
or at least “lines of best fit”/trend added. Figure 2 does outline the sustained effect really began from day fourteen as I understand the graph, although this will need further information for the reader to follow.

There were no significant differences for secondary outcomes. Importantly the authors comment in the results the intervention may have been larger for those with better glycaemia control, older age and higher self adherence at baseline. I note the mean total of time difference between the intervention group of 74 minutes versus 42 minutes is 31 minutes. An intervention facilitator spent an average of 2.3 hours per patient listening to tape recordings compared to 1.2 hours in standard care. This time required to deliver the intervention needs further discussion in the final version of the paper...These are significant time imposts in a busy GP practice.

DISCUSSION

The authors make the valid point that the study effect was over 12 weeks and there is no doubt we need longer studies. Follow up to look at the true effect of adherence and whether a one off affect and the sustainability can be clarified. The only other comment is the need for a larger study to look at both cost effectiveness and clinical outcomes. The time required to train nurses to complete this intervention and then involve the patients is substantial and it maybe useful to spend a little bit of time discussing how to create the sustainability of this in a broader practice based intervention. This is probably the key point that is missing with the discussion.

In summary this is a useful explanatory study that is well constructed and implemented.,

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

No conflict of interest.