Reviewer's report

Title: Randomised controlled trial of an automated, interactive telephone intervention (TLC Diabetes) to improve type 2 diabetes management: Baseline findings and six-month outcomes

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Reviewer: Rachel Jordan

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Randomised controlled trial of an automated interactive telephone intervention (TLC Diabetes) to improve type 2 diabetes management: baseline findings and six-month outcomes

PEER REVIEW

Summary

The authors report on a randomised controlled trial of an automated interactive telephone-delivered system designed to improve type-2 diabetes self-management. The paper reports the 6 mth results for the primary outcomes: HbA1c and HRQL. 120 adults with type 2 diabetes from a range of sources and also having HbA1c levels >7.5% were randomised to the intervention or the usual care control arm. In the intervention arm patients were asked to call the system weekly and were given feedback/encouragement tailored to responses and baseline information. Behaviours were: blood glucose testing, nutrition, physical activity, medication-taking.

Is the question original, important, well defined?

Self management is an important issue for diabetics and newer and more effective delivery is required. There are a number of studies of telephone-based care but few which are automated.

Are the data sound and well controlled? Are the methods appropriate and well described? What are the strengths and weaknesses of the methods?

MAJOR COMPULSORY REVISIONS

1. I am most concerned about the balance of characteristics between the two arms. Even though there may be no statistical differences except in one or two variables, there are clinically important differences in major confounding factors such as age, levels of education, self care etc which may affect the results such that it explains the apparent benefit of the self management arm. It is essential that a statistical reviewer comment on this and that these factors are explored in adjusted analyses to see if they affect the results.

2. Although the text states that there were no significant differences between the 2 arms except the glomerular filtration rate, the values given in the table do appear to show material differences in many variables eg education, levels of
depression, physical activity, adherence to guidelines etc which may not be significantly different, but which show a trend to the intervention group being more healthy and better at adherence etc. This section should be looked at by a statistician and a decision made about whether these differences may affect the results, and what measures should be taken to try to adjust for them.

3. This should also be described and discussed appropriately in the text of the results and discussion. It is dealt with only briefly and inadequately in the text of the results.

4. The clinical reasoning behind adjustment for glomerular filtration rate is not evident.

5. METHODS: The allocation ratio, method of allocation and allocation sequence generation are not stated. Even if these were in the protocol publication they should also be in the report.

6. Table 2 provides a comparison of the 2 arms. The text provides a description of the overall sample which is not reflected in the table. The table should also have a column which describes the overall sample, and the text should describe any differences between the two arms.

MINOR ESSENTIAL REVISIONS

METHODS

7. Blinding: were their usual care providers blinded to their allocation?

8. Please make the intervention section clearer by including appropriate sub-headings for each topic eg Overall aims of the intervention; baseline visit; weekly telephone calls; topics/responses; follow-up etc

9. Outcome variables: please provide more information about the blood tests. Were these distinct from the weekly blood glucose testing fed back to the TLC? Where were they undertaken and by whom? Were they fasting?

10. In the statistical analysis section there is a sentence describing Table 1 which should be in the results section and also labelled Table 2.

RESULTS

11. In table 3 and the text it must be made clear that this is an ITT analysis and give the numbers analysed for each group.

12. Why is the difference presented as a ratio? And should this have a %? This is confusing.

13. We need p values and confidence intervals in the text to describe % achieving recommended HbA1c levels etc.

14. Comparing with AUSDiab: There is no table 4 – do you mean table 2? Please correct this.

ABSTRACT

15. The abstract needs to include the fact that diabetes patients were required to have HbA1c > 7.5% and also in the results that the physical HRQL was
unaffected.

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

**Quality of written English:** Acceptable

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

**Declaration of competing interests:**

We received financial support from Pfizer Health Solutions and Birmingham East and North PCT for the evaluation of Birmingham Own Health telephone care management service. However, the interpretation and conclusions contained in that study were those of the authors alone. This work did not influence my decisions on this peer review which are based purely on the methodology and not the results.