Reviewer's report

Title: Effect of telehealth on glycaemic control among patients with type 2 diabetes: findings from the Whole Systems Demonstrator cluster randomized trial

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Reviewer: Geert Goderis

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Effect of telehealth on glycaemic control among patients with type 2 diabetes: findings from the Whole Systems Demonstrator cluster randomized trial
13/3/2014
Geert Goderis

1. General Comments. This is a well written manuscript, part of a larger trial with already some excellent publications.
The article is important in its field. Most of my questions consider minor items and deal with clarifications.

2. I have one major compulsory remark that deals with the statistical analyses. I recommend the authors to analyze the difference in change in HbA1c before and after the start of the trial between intervention and control group. As stated now, the conclusion of the manuscript “telehealth led to improvement in glycaemic control” is technically spoken not supported by the analyses because the analyses only compared intervention and controls after the start of the trial. Difference in change (before/after start of the trial between intervention and control) can be analysed using a longitudinal mixed linear regression model (eventually with three levels: level1= practice ; level2= individual ; level 3= time) and thus 2 cluster levels, using splines with the starting point of the trial as defined spline.

Same remark for analyses of dichotomous outcomes

Minor remarks

3. Please fill in the consort statement for Cluster RCTs (and eventually that of pragmatic RCTs) to make lecture of reviewer and reader more comfortably.


Methodology (& results & discussion)

4. Effect of patient recruitment on results (possible bias): Less than 5 diabetes patients per practice were recruited

4a. Some questions:
4a1. What was the average number of Type 2 diabetes patients per practice (minimum/maximum)
4a2 What was the minimum and maximum number of included patients per practice?
4a3. Are there significant differences in patient characteristics between participators and non participators
4a4 What were the reasons for the very high refusal rate of patients?
4a5. How did recruitment happen? Were all eligible patients contacted? Or did recruitment stop after obtaining sufficient numbers? If yes, did recruitment happen randomly or sequential or…?

4b. Remarks & discussion: Strictly spoken, the findings are not generalizable to the whole diabetes patients but only to those patients who accepted to participate. There may be an important inclusion bias and the results may only applicable to those patients willing to adhere to that kind of intervention/care. Please comment this in the discussion section. The discussion section only deals with the cluster effect on inclusion bias. This is too limited.

5. P. 7 the read codes: what are these codes, diagnostic code is not ICPC-2. Proper to EPR?

6. p.11 Repeated Measure model: was this an ANOVA? (I do not think so because measures are time-varying). Was it a mixed linear model with random effect? Random slope? Please specify (see also first major remark about longitudinal analyses).

7. p. 12 in order to summarize HbA1c, why did the authors use the mean value? I would have taken the last HbA1c value because 1. HbA1c is already a parameter that indicates the glycaemic levels during the last three monthts prior to the measure (e.g. Goderis G, Van PG, Truyers C, Van C, V, De CE, Van Den Broeke C et al. Long-term evolution of renal function in patients with type 2 diabetes mellitus: a registry-based retrospective cohort study. BMJ Open 2013; 3(12):e004029.) 2. The problem with the 12-month average is that it may smooth the effect of the intervention. (you should not mention this reference, its only to stimulate the debate about choices to make in the case of multiple measures). It may be helpful to conduct these supplementary analyses using the last available HbA1c value.

Results
8. p.13 please be consequen in reporting e.g. first intervention then control, or vice versa, but do not mix both.

9. p.14 (+ discussion): proportion of patients under or above certain cut-off values (7.5%, 6.72%, 9.85%)

9a. why 6.72% / 9.85%? were these values calculated in order to obtain a significant difference?

9b. again, difference in change should be analysed. If these differences were present before start of the trial, no real change happened. (method, longitudinal logistic regression with splines).

Discussion

10. What about the Hawthorne effect? The authors only deal with this problem with relation to the act of measuring HbA1c. But when patients are supposed to make self control measures 5 times a week, the act of measuring happens 5 times a week and thus intervention patients are definitely aware that they are participating to a study…. That’s the Hawthorne effect. Please mention in the discussion section.

11. What about sustainability of the findings?

12. Please explicit mention “weaknesses of the study”.

Level of interest: An article of importance in its field

Quality of written English: Acceptable

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

Declaration of competing interests:

I declare not having any competing intrest