Author's response to reviews

Title: Impact of telemonitoring home care patients with heart failure or chronic lung disease from primary care on healthcare resource use. The TELBIL study. Results of a randomised controlled trial.

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Author's response to reviews: see over
Dear Professor Franklin,

Please find below our response to the Reviewers of our paper ‘Impact of telemonitoring home care patients with heart failure or chronic lung disease from primary care on healthcare resource use. The TELBIL study. Results of a randomised controlled trial.’ MS: 2073455349851613.

We thank the Reviewers for carefully reading our paper and for providing very supportive comments on our manuscript. The following is our reply to the specific points raised by the Referees. We have grouped the response to some of the suggestions in order to facilitate the reading. Note that in what follows the bold text indicates a comment/suggestion of the Reviewer, whereas italicised text is used for our response.

We have also made significant modifications to the manuscript so as to improve the style and clarity of the text. Finally, we have added subheadings to the methods and results sections to facilitate the reading of the paper.

We believe that the modifications made to the text have greatly improved the manuscript. We would be very grateful if you considered our paper for publication in BMC Health Services Research.

Looking forward to hearing from you.

Yours sincerely,

Dr. Iñaki Martín-Lesende
Responses to Comments of the Reviewer

*R1 (Referee 1, Kavita Radhakrishnan) R2 (Referee 2, Robyn Clark)*

Editor: Figure titles. All figures must have a figure title listed after the references in the manuscript file. The figure file should not include the title or number.

*Figure legends have been listed after the reference list and the title/number has been removed from the figure files as stated in the instruction for authors.*

**Title**

*R1 (discretionary revision). The title of the study could reflect the setting (primary health center) of the tele-monitored patients.*

*The title of the manuscript has been modified to reflect the primary care setting of the study and the fact that it is a randomised controlled trial has also been highlighted following the CONSORT guidelines.*

**Abstract**

*We have extensively modified the abstract of the manuscript so that it follows the CONSORT guidelines for reporting randomised controlled trials in journal abstracts.*

*R1 (minor essential revision). Abstract, results, 2nd sentence: P value missing for result (RR and CI provided). R2. All results should include number percentage (or both) RR 95% CI and p value.*

*As suggested by the Reviewers, we have modified the results section of the abstract, including all frequency, percentages, RR, 95% CI, and p-values for categorical variables, and mean, SD and p-values for continuous variables.*

*R2. The methods section of the abstract does not include details of design.*

*Details about the design of the study have been included in the abstract.*

*R1 (minor essential revision). Abstract – Conclusion: The results showed a trend to reduce all-cause and cause-specific hospitalizations (since not statistically significant). Please revise Conclusion, 1st sentence to reflect so.*

*Following the Reviewer’s comment, we have modified the abstract conclusion to reflect a trend more than the evidence based on our results regarding hospital admissions.*

*R1 (discretionary revision). Abstract – Conclusion: What are the Implications of increasing telephone contacts and decreasing home nursing visits, how does it affect the care provided?*  

*The implications of increasing telephone contacts and decreasing home nursing visits have been discussed in the discussion section rather than in the abstract due to word limit constrains.*

**Background**

*R2. Background: Every sentence in the first 2 paragraphs should be referenced. The background should include details of the trajectory of each disease and expected outcomes for both.*
This is a valid point. We have added more references to the first two paragraphs, and modified the background text to improve the clarity of this section. Details of the trajectory of the targeted diseases have been included in paragraph 6, together with information on the evolution of these conditions and the importance of controlling the basal status of the patient.

Methods

R1 (minor essential revision). Methods - Statistical Analysis, 1st para: A better word for qualitative variable would be categorical variable, and continuous for quantitative variables

The terminology ‘categorical variable’ and ‘continuous variable’ has been used throughout the text instead of ‘qualitative’ and ‘quantitative variables’, as indicated by the Reviewer.

R2. inclusion criteria should state that these were Adult patients.

The inclusion criteria have been correctly worded both in the abstract and methods section to reflect the fact that the patients included in the trial were adult patients.

R2. Please describe how the data was secured

Patients’ identity was preserved at all times during the course of the trial and this has been properly stated under the “Ethics approval” subheading of the methods section. Further details concerning data security can be found in the published research protocol and we mention so in the text.

R2. What was the risk management for this study. Were patients monitored 24/7 or only during business hours.

R1(minor essential revision). 3) Methods – Paragraph 3 – intervention consisted of not in daily transmission

We would like to clarify this point. Patients transmitted data 7 days a week, but professionals checked this information from Monday to Friday during business hours. We have included this information in the methodology section under the ”Description of the intervention” subheading.

R2. Usual care is not described

A description of the usual care has been included in the second paragraph of the ”Description of the intervention” subheading.

R1 (major compulsory revision). Statistical Analysis section: Comment on whether a power Analysis conducted to estimate sample size?

R2. The report does not present a power calculation and although a detailed methodology paper has been published previously the paper would benefit from including CONSORT criteria for reporting RCTs. There is no power analysis or rationale for not having power analysis.

The Reviewers are correct that a power analysis should be conducted and clearly stated in the methodology section. We are very thankful for this comment which has been addressed in full. Details on initial power estimation are described in the published study protocol and have also been included in the methodology section. However, there has been a deviation in the initially estimated power due to the occurrence of more losses than expected and a lower reduction in the number of hospital admissions than previously envisaged. Following the reviewers comments, we have included the initial power estimation in the methods section and further discussed the initially calculated power deviation under the” Study limitations” subheading in the discussion section. We have recalculated the statistical power based on the results obtained in the present study.

R1 (major compulsory revision) statistical Analysis, para 2, last sentence: Describe how you estimated the number needed to treat (NNT), in terms of provision of telemonitoring support, to prevent one hospital admission in a year.

R2 No details of how the NNT was calculated
We have included a brief description on how the NNT was calculated and added a reference in this regard.

R1 (minor essential revision). Methods, Para 2: Need a brief description of the primary health care center setting. What was the average composition of health care providers across the health care centers? Is a healthcare center synonymous with a primary care clinic?
R2. Please give more details of the characteristics and qualifications of the “health professionals” delivering this intervention. Please provide details of the primary care physicians

Following the Reviewer’s comments, we have briefly described the composition and characteristics of Bilbao Primary Care Health District in the methods section under the “Study design and setting” subheading.

Results

R1 (major compulsory revision). Results, para 3: Which adjustment variables were considered as independent variables in the logistic regression analysis of Incidence ratios

Details on the adjustment variables in the logistic regression analysis are given in the methodology section. We carried out a logistic multivariate regression analysis, but it showed that the independent variable (i.e., lack of social support) was non-significant. Thus, the aforementioned multivariate model was not considered for subsequent analysis and we state so in the results section under the “Effect of home telemonitoring on hospital admissions” subheading.

R1 (minor essential revision). Results, para 3, Table 2: Please provide the RRs and CIs in Table 2

Following the Reviewer’s suggestions, we have included RRs and 95% CIs in Table 2.

R1 (discretionary revision). Results: Figure 2: Comment on why home visits by doctors trended to be more in IG than CG

We think that the very slight increase in home visits by doctors in the IG may be due to a closer delivery of care and increased initial actions undertaken by doctors, until the participating GPs became accustomed to the telemonitoring process. We have included a few lines in the 7th paragraph of the discussion section regarding this issue.

R2. Results: More details on the interpretation of the Charlson index and Barthel index scores

As suggested by the Reviewer, we have included further details on how the Charlson and Barthel indexes are interpreted.

R2. Sub-analysis by demographic group would be interesting.

We agree with the Reviewer on that a sub-analysis by demographic group would be very interesting. However, considering the sample size limitations of the present study, undertaking the aforementioned sub-analysis would be very complex as the number of patients in each of the sub-groups would be too small to draw solid conclusions.

Discussion

R1 (discretionary revision). Discussion, para 7: “On the other hand, it is equally important as an indicator of the impact of changes in care practices on primary care, the setting in which the technology is managed.” What does this mean? What kind of impact is being indicated, besides cost savings?
The Reviewer is right that the mentioned lines require further explanation. We think that the increase in telephone calls and the decrease in home nursing visits could have a significant impact on the way primary care professionals work, leaving more time for nurses to spend on other relevant tasks that could improve the management of this type of patients. However, the evaluation of the effect of telemonitoring on such operational modifications has not been directly addressed in this study and requires further investigation. We have modified the text in the discussion 7th paragraph to clarify this issue.

R1 (discretionary revision).Discussion, para 8: “82.4% of alerts were reviewed with any further action being taken” – Why did the alerts not require any action? Were the alerts false alarms? How did the providers decide if a alert required any action or not? R2. Was there a relationship between alerts and outcomes.

Following the Reviewer’s suggestion, we have further explained this point in the methods section under the “Description of the intervention” subheading. In this regard, we would like to clarify that healthcare professionals assessed the alerts in the context of the rest of the clinical parameters and the health status questionnaire received through the telemonitoring system. Therefore, even if an alarm was triggered for a specific clinical parameter, it was the patient’s overall health status that was taken into consideration by healthcare professionals, before taking any further action.


We thank the Reviewer for reminding us of the work conducted by Wakefield and colleagues. The article has been included to the reference list and referred to in the discussion.

R2. Discussion: These patients were very old. This needs to be discussed in more detail in the context of previous research.

We have reworded the first paragraph of the discussion section to address the point raised by the Reviewer.

R2. Is there a planned cost analysis for this study. Please discuss.

A cost-effectiveness analysis of the TELBIL study was undertaken in 2012. We expect the work to be published at the end of 2013. We have included the provisional reference related to the economic analysis in the reference list.

R2. What is different about primary care telemonitoring? Please discuss.

We have further explained this point in the discussion section paragraph 9. In this respect, we think that having primary care professionals in charge of the telemonitoring intervention is particularly important, since these are the healthcare professionals that routinely carry out the follow-up of in-home patients and, thus, telemonitoring could have a greater positive impact than when applied to hospital-based interventions.

References

The following four references have been added to the reference list:


**Figures and tables**

R2. **Figure 1: Study Flow should follow CONSORT GUIDELINES**

We have modified Figure 1 and adapted the flow of patients through the study according to the CONSORT guidelines.

**Figure 2: Needs to be reformatted. Remove numbers. A similar Figure could be presenting analyzing the resource use by diagnostic group**

*Following the Reviewer’s advice, we have reformatted Figure 2 removing the numbers from the columns. Presenting the resource use by diagnostic group as suggested by the Reviewer would be interesting. However, 50% of the participating patients had both diseases simultaneously, and, therefore, we would need to represent the results categorised into three different groups and the resulting graphical representation can be confusing. Instead, we have created another graph (Figure 3) representing the variables in which telemonitoring had a greater impact (i.e., home visits and telephone contacts), categorised by diagnostic group for the patients in the intervention group.***

**Table 1: Explain “Other” living arrangements**

We have changed the words “living arrangement” for “living with” in Table 1, and specified what we mean by “others”.

**Table 2.**

*As suggested by the Reviewers, we have included RRs and 95% CIs in Table 2.*