PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Experiences of patients and professionals participating in the HITS home blood pressure telemonitoring trial: a qualitative study
AUTHORS	Hanley, Janet; Ure, Jenny; Pagliari, Claudia; Wild, Sarah; Sheikh, Aziz; McKinstry, Brian

VERSION 1 - REVIEW

REVIEWER	Miss Michelle Beynon - Research Assistant Dr. Martin Cartwright - Research Associate Health Services Research School of Health Sciences City University London England
REVIEW RETURNED	28-Feb-2013

THE STUDY	There is no considered distinction between the experiences of control versus intervention participants, the minimum suggestion would be to (i.) include the trial arm allocation alongside the patient ID under each quotation, e.g. “Patient 20, usual care” or “Patient 14, telemonitoring”; (ii.) highlight any important similarities or differences between control and intervention participants. If quotations from control participants are not used at all and if there are not important differences in the interviews with control and intervention participants then there is an argument for removing all references to the 5 control participants from the manuscript. Prior experience of home BP monitoring should also be included as a descriptor alongside the patient IDs under the quotations (e.g. “Patient 14, telemonitoring, no prior BP monitoring”). Page 5, lines 23-25: “Patients who had… were not included”. ‘Not included’ is not necessarily the same as ‘excluded’ – the former may mean that you didn’t actively try to recruit such patients but some patients recruited on other criteria may have happened to have one or more of the listed conditions; the latter means that the listed conditions were checked for all potential patients and were a definite exclusion criteria. Please clarify. Page 5, line 52: Data saturation is a contentious issue in qualitative research as there debates around the definition, operationalization and implementation, as well as the degree and nature of the evidence need to demonstrate that data saturation has been achieved (e.g. Kerr, Nixon & Wild, 2010; Francis et al, 2010; Guest, Bunce & Johnson, 2006). While it may not be possible to achieve best practice retrospectively, the authors should provide sufficient detail so that the processes followed for determining data saturation are transparent, replicable and allow readers to make a judgement

	about these processes are likely to have been adequate. Page 5, Sampling and recruitment: Were participants newly diagnosed as having above target BP (i.e. were patients assessed specifically for the purposes of establishing eligibility for the study) or had they previously been assessed as such? Page 6, Date handling and analysis: Please provide the timeframes for the qualitative data collection (either in terms of start/ end dates or the overall duration in months) and give more detail about what aspects of data analysis (or number of interviews) were done during that data collection period and what aspects were done retrospectively. There is an implication in the text that some analysis was done during data collection in order to feed into subsequent interviews but without further detail it is not possible to judge whether this claim is feasible. Page 7, The description of the participants is minimal. If further data were collected in the qualitative study or the parent RCT that could be used for descriptive purposes, additional salient demographics such as marital status, general health or the presence of other comorbidities, and an indication given of how long they have been treated as hypertensive for, this should be included. There is still an inconsistency between the themes reported in the body text versus the themes in the table in the appendix. Page 11 details the theme 'Using the telemonitoring system' in the table in Appendix 2 the theme is 'Using the telemetry service', page 13 has the theme 'Adjusting to new responsibilities and new ways of working' in the table this is 'Adjusting to new roles and responsibilities'. The authors should ensure that all inconsistencies of this nature are checked and corrected, or explained if the renaming was deliberate.
RESULTS & CONCLUSIONS	This is only a partial No. Page 8, lines 24-34: It is possible, as the authors suggest, that higher concerns about BP (as inferred from prior self-monitoring of BP) had some direct effect on the trial outcomes. There are alterative or elaborated interpretations of the observation. For example, it could be that patients who previously performed regular BP monitoring were in some sense more skilled at taking BP measurements (e.g. they may have been more consistent in the way that they measured their BP) thus providing more accurate data on which to base medical management decisions. Alternatively, prior exposure to regular BP monitoring may have extinguished much of the anxiety about the process leading to greater compliance with the trial protocol and, in turn, better outcomes. The author may wish to consider these or other alternatives when offering an explanation for the observation of a relationship between prior BP monitoring and trial outcomes. Page 8, lines 34-35: Referring to the sentence "It also suggests that the telemetry and communication with the practice contributed to the outcome rather than just home monitoring". We are not clear how the authors reached this conclusion from the evidence they presented immediately before – have we misunderstood something obvious or is there a missed explanatory step? Page 15, Discussing patients who owned home monitors prior to the trial and the greater improvement in their BP, this result is

	considered to be consistent with the Health Beliefs Model and perceived severity of the condition. However, the decision to have a monitor previously may simply reflect individual differences in need for information regarding their BP. The link to the HBM seems too speculative and is not grounded in either the qualitative or quantitative data reported. This linkage could either be removed or replaced with reference to a model that more closely links to the observation that some patients monitored BP regularly beforehand and some did not. If the aim is to link to a model of (health) behaviour then it would be better to go for something where the speculative leap is not so great (e.g. the distinction between dispositional avoidance and approach coping, or the closely related monitors vs blunters).
GENERAL COMMENTS	A few further minor revisions. In several places the authors refer to the "success of the intervention", referring to the parent RCT. The word 'success' is ambiguous in the current context as it could refer to the effectiveness of the intervention (i.e. did it change the outcomes it was supposed to change, in the expected direction, to a clinically meaningful degree?) or it could refer to the success implementation of the telemonitoring intervention in usual care (regardless of whether or not it delivered to hypothesised effects). It would be preferable to avoid the word 'success' and distinguish between the two different potential meanings throughout. (effectiveness / implementation) Page 7, lines 14-15: It is mentioned that where it was possible to triangulate findings this was done. It would be useful to have all instances where triangulation was conducted specified. Pages 14-17, Discussion: This section is well written as does a good job of highlighting the mains finding, comparing with other research, discussing strength and limitations, and suggesting implications for future research/ practice. One criticism of the discussion is that there is a little too much repetition of certain points. A more concise discussion with less repetition would be stronger. General point: The participant quotes reported are by-and-large excellent and really help to support the authors interpretations. However, some of the quotations are difficult to make sense of as presented and a judicious use of punctuation (commas, "…", hyphens) could help to convey the meaning for readers. The authors have clearly considered all reviewers' comments (from Round 1) carefully and have done an excellent job of addressing the concerns raised. The revised paper is much improved. It is clear, consistent and highlights valuable lessons learned from the experience of conducting an RCT of telemonitoring of BP for hypertension in a usual care (i.e. primary care) context. Notably, there is now a clear distinction between the views and experiences of patients and professionals, several contradictions, ambiguities and inaccuracies have been resolved, and subtle changes in the structure (e.g. describing the key findings from the parent RCT in the Introduction rather than later in the manuscript) greatly improve the narrative of the article. The integration of selected quantitative data into the main body of the manuscript (rather than as a separate 'Triangulation' section) helps to support and contextualise the qualitative findings (though a purist qualitative research perspective

	would object to its presence!). The minor concerns which have been listed should be relatively simple to correct. If the authors are able to address these issues satisfactorily, we would have no hesitation in recommending the article for publication.

VERSION 1 – AUTHOR RESPONSE

We have listed the comments which required a response and the responses belowThere is no considered distinction between the experiences of control versus intervention participants, the minimum suggestion would be to (i.) include the trial arm allocation alongside the patient ID under each quotation, e.g. “Patient 20, usual care” or “Patient 14, telemonitoring”; (ii.) highlight any important similarities or differences between control and intervention participants. If quotations from control participants are not used at all and if there are not important differences in the interviews with control and intervention participants then there is an argument for removing all references to the 5 control participants from the manuscript. Prior experience of home BP monitoring should also be included as a descriptor alongside the patient IDs under the quotations (e.g. “Patient 14, telemonitoring, no prior BP monitoring”).
Control patients were interviewed because it was possible that their treatment may also have been different during the trial – directly randomising patients in a practice was a considered risk taken in this trial although given the high prevalence of hypertension, we thought contamination of the control group would be unlikely. Fortunately there was no evidence from the interviews that this had happened so this negative point has been added to the paper. Some quotes from the control patients have been used, but the labelling has been extended as suggested.

Page 5, lines 23-25: “Patients who had… were not included”. ‘Not included’ is not necessarily the same as ‘excluded’ – the former may mean that you didn’t actively try to recruit such patients but some patients recruited on other criteria may have happened to have one or more of the listed conditions; the latter means that the listed conditions were checked for all potential patients and were a definite exclusion criteria. Please clarify.
A more detailed description of the trial inclusion and exclusion criteria has been added to the paper, which also addresses the second comment below

Page 5, line 52: Data saturation is a contentious issue in qualitative research as there debates around the definition, operationalization and implementation, as well as the degree and nature of the evidence need to demonstrate that data saturation has been achieved (e.g. Kerr, Nixon & Wild, 2010; Francis et al, 2010; Guest, Bunce & Johnson, 2006). While it may not be possible to achieve best practice retrospectively, the authors should provide sufficient detail so that the processes followed for determining data saturation are transparent, replicable and allow readers to make a judgement about these processes are likely to have been adequate.

Page 5, Sampling and recruitment: Were participants newly diagnosed as having above target BP (i.e. were patients assessed specifically for the purposes of establishing eligibility for the study) or had they previously been assessed as such?
No participants were newly diagnosed, they were all recruited from existing primary care hypertension registers and had uncontrolled hypertension based on their surgery readings in the last 6 months (see inclusion criteria). They were then further assessed for eligibility using daytime ambulatory blood pressure monitoring. The description of the trial has been altered to clarify this.

Page 6, Date handling and analysis: Please provide the timeframes for the qualitative data collection (either in terms of start/ end dates or the overall duration in months) and give more detail about what aspects of data analysis (or number of interviews) were done during that data collection period and

what aspects were done retrospectively. There is an implication in the text that some analysis was done during data collection in order to feed into subsequent interviews but without further detail it is not possible to judge whether this claim is feasible.
The timeframes have been added to the document.
Page 7, The description of the participants is minimal. If further data were collected in the qualitative study or the parent RCT that could be used for descriptive purposes, additional salient demographics such as marital status, general health or the presence of other comorbidities, and an indication given of how long they have been treated as hypertensive for, this should be included.
These data were not collected, although, as descibed, those with previous stroke/ TIA or diabetes (the most common co-morbidites) were excluded

There is still an inconsistency between the themes reported in the body text versus the themes in the table in the appendix. Page 11 details the theme 'Using the telemonitoring system' in the table in Appendix 2 the theme is 'Using the telemetry service', page 13 has the theme 'Adjusting to new responsibilities and new ways of working' in the table this is 'Adjusting to new roles and responsibilities'. The authors should ensure that all inconsistencies of this nature are checked and corrected, or explained if the renaming was deliberate.
This was not deliberate and the document has been amended

Page 8, lines 24-34: It is possible, as the authors suggest, that higher concerns about BP (as inferred from prior self-monitoring of BP) had some direct effect on the trial outcomes. There are alterative or elaborated interpretations of the observation. For example, it could be that patients who previously performed regular BP monitoring were in some sense more skilled at taking BP measurements (e.g. they may have been more consistent in the way that they measured their BP) thus providing more accurate data on which to base medical management decisions. Alternatively, prior exposure to regular BP monitoring may have extinguished much of the anxiety about the process leading to greater compliance with the trial protocol and, in turn, better outcomes. The author may wish to consider these or other alternatives when offering an explanation for the observation of a relationship between prior BP monitoring and trial outcomes.

Page 8, lines 34-35: Referring to the sentence "It also suggests that the telemetry and communication with the practice contributed to the outcome rather than just home monitoring". We are not clear how the authors reached this conclusion from the evidence they presented immediately before – have we misunderstood something obvious or is there a missed explanatory step?

Taking these two points together - we agree that the use of home monitoring prior to the trial as an indicator of concern is not direct and there could be other explanations for the trial data, although the two suggested are unlikely (there is no clinical evidence that practice has any effect on the accuracy of measurements using automated systems, and the trial paper shows that compliance with home monitoring was high). More importantly, however, the use of these data in this context seem to be making the second point, the impact of the telemetry as opposed to just home monitoring, difficult to understand. The analysis of the trial data is a key point here, it is comparing like with like – people who had previously self monitored and were now using the telemonitoring system with people in the control group who had previously self monitored with no telemetry and presumably continued to do so throughout the trial. Thus the telemetry side of the system is adding something which simple self monitoring did not.
We have tried to reduce this confusion by dropping the use of self monitoring as a potential indicator of concern (the qualitative data is clear anyway) and moving the comparison to a little later in the results section.

Page 15, Discussing patients who owned home monitors prior to the trial and the greater improvement in their BP, this result is considered to be consistent with the Health Beliefs Model and

perceived severity of the condition. However, the decision to have a monitor previously may simply reflect individual differences in need for information regarding their BP. The link to the HBM seems too speculative and is not grounded in either the qualitative or quantitative data reported. This linkage could either be removed or replaced with reference to a model that more closely links to the observation that some patients monitored BP regularly beforehand and some did not. If the aim is to link to a model of (health) behaviour then it would be better to go for something where the speculative leap is not so great (e.g. the distinction between dispositional avoidance and approach coping, or the closely related monitors vs blunters).

Given that the use of trial data to support this argument has now been dropped, this part of the discussion has also been removed.

A few further minor revisions.

In several places the authors refer to the “success of the intervention”, referring to the parent RCT. The word ‘success’ is ambiguous in the current context as it could refer to the effectiveness of the intervention (i.e. did it change the outcomes it was supposed to change, in the expected direction, to a clinically meaningful degree?) or it could refer to the success implementation of the telemonitoring intervention in usual care (regardless of whether or not it delivered to hypothesised effects). It would be preferable to avoid the word ‘success’ and distinguish between the two different potential meanings throughout. (effectiveness / implementation)
This has been reviewed and ‘effectiveness’ substituted for success where appropriate

Page 7, lines 14-15: It is mentioned that where it was possible to triangulate findings this was done. It would be useful to have all instances where triangulation was conducted specified.

This list has been provided in the text