Author's response to reviews

Title: The contribution of qualitative research in designing a complex intervention for secondary prevention of coronary heart disease in two different healthcare systems [ISRCTN24081411]

Authors:

Mairead Corrigan (m.corrigan@qub.ac.uk)
Margaret E Cupples (m.cupples@qub.ac.uk)
Susan M Smith (susmith@tcd.ie)
Molly Byrne (molly.byrne@nuigalway.ie)
Claire S Leathem (c.leathem@qub.ac.uk)
Pauline Clerkin (pauline.clerkin@nuigalway.ie)
Andrew W Murphy (andrew.murphy@qub.ac.uk)

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Author's response to reviews: see over
Dear Editor

We would like to thank the reviewers for their most helpful comments about the paper. We wish to re-submit our paper for publication in the journal BMC Health Services Research. We have addressed the reviewers’ comments with a point-by-point response to them and have revised our manuscript accordingly, details of which are described below. We have also cited, in the revised paper, Murchie P, Campbell NC, Ritchie LD, Thain J. Running nurse-led secondary prevention clinics for coronary heart disease in primary care: qualitative study of health professional perspectives. BJGP 2005, 55:522-528. We have revised our paper in accordance with the guidelines on reporting qualitative data. We have also ensured that the files are correctly formatted.

Yours Sincerely,

Mairead Corrigan
Reviewer Gene Feder –
In response to the general point that the qualitative data could be combined with process data from the pilot in the same paper, details of how the intervention was developed and refined and an outline of the contribution of qualitative research have been reported in a paper by Byrne M et al entitled ‘Development of a Complex Intervention for Secondary Prevention of Coronary Heart Disease in Primary Care Using the UK Medical Research Council Framework’ which was recently published by The American Journal of Managed Care 2006. The process has been reported in detail but the qualitative research has not been. We considered that it was not possible to combine the detail of the qualitative analysis with a detailed description of its application to the development of the intervention in a single paper. We have included a reference to the above paper in the revised manuscript, Reference 29 on Page 23 (7 lines down).

In response to the general point that the qualitative data could be combined with survey data from the pilot in the same paper, the survey which was referred to in the paper was a brief staff evaluation of the training they received as part of the study. We have included more detailed information about the staff evaluation in the Discussion under Standardisation and Tailoring Page 23 (10 lines down) -

‘We also conducted objective staff evaluations of training delivered in the intervention through questionnaires which related to the appropriateness and clarity of its content and suitability of location and training. These did not reveal the depth of information gathered through this qualitative work, for example how the training could be made more relevant to particular practitioners, practices and patient needs; background information about staff in respect of ability and training received; and detailed information about organisational difficulties and staff-patient relations.’

In response to the general point that we did not show how we integrated data from the qualitative study into the theoretical framework of the intervention, we identified through the qualitative research the need for training and approaches to behaviour change to be based on theoretical frameworks. We have included this information in the revised manuscript in Results, Application of findings to intervention design Page 21 (2nd paragraph, 10 lines down) –

‘The qualitative research highlighted the need for the training and the approach to behaviour change to be considered within specified theoretical frameworks which addressed aspects of patient and staff motivation, and patient health beliefs using practical examples of application of theory and case-based learning. A full discussion of the behaviour change theories used in the intervention have already been reported [23].’

Minor Essential Revisions -
We did not include patients with angina because of a lack of standardisation of diagnostic criteria and difficulty confirming the validity of the diagnosis. We have revised the manuscript to include this information, Methods, Participant Selection Page 7 (2 lines down) -
'We did not include patients whose records indicated a diagnosis of angina because of difficulty confirming the validity of this diagnosis.'

Reviewer Graham Watt (Minor Essential Revisions) –

- We have changed sentences to reflect Data as plural.

- Changes to Tables –
  We have removed the footnote in Table 1 and the totals in Table 2 as this duplicated the information in Table 1. We amalgamated Tables 3 and 4 and placed the information about patients’ age and months since diagnosis in the main text. We removed Table 5 and included these data in the main text. Deleted data from the Tables may now be found under Methods, Data Collection

Page 7 (6 lines down) -

‘As it was only possible to carry out the focus groups during the day most of the patients who attended were between 48-74 years of age and were retired from work. Their length of time since diagnosis varied from 3-238 months.’

Page 8 (7 lines down)

‘17 patients participated, ranging from 49-80 years of age and 4-274 months since diagnosis (Table 3). In each practice a GP, nurse and practice manager were interviewed except in one practice where the nurse had left and in another where the practice manager was not available for interview (N=10).’

- We have removed the reference to funding in the final sentence of the Conclusion Page 26 and replaced it with - ‘The findings highlight how qualitative research may be a valuable component of the preparation for complex interventions and their evaluation’ as recommended by the reviewer.
Reviewer Peter Murchie –

We have made reference to the differences in attitude engendered by the different healthcare systems under Discussion, Strengths and Limitations Page 25 (1st sentence, 2nd paragraph) -

‘A particular strength of the study would be its indication of the differences in attitudes engendered in staff and patients by different healthcare systems.’

1. Methods Page 7 (Setting)
   In response to the need for the authors to reflect in the discussion about the typicality of the practices chosen, we have extended the relevant sentence in the Discussion (Strengths and Limitations) Page 24 (3rd line down), which now states that ‘To overcome these limitations the practices were chosen to include small and large practices in rural and urban locations to reflect the diversity of practices in both healthcare systems’. Detailed information about the characteristics of the practices are included in Table 1 that should help the readers to judge whether or not the practices were typical. We have expanded a discussion of the implications of the practice characteristics for our conclusions in the Discussion, Strengths and Limitations Page 24 (9 lines down) –

   ‘Moreover the fact that they were all teaching practices might suggest that the findings represent the “best case scenario” for delivery of secondary prevention. Therefore it is important to place these findings within the context from which they were derived.’

2. Methods Page 6 (4 lines down) (Participant Selection)
   We have extended the relevant sentence to explain why -

   ‘Different patients were selected for the two phases of data collection in order to minimise the potential for bias and to facilitate access to a greater breadth of opinions about the intervention.’

3. Methods Page 9 (Data Collection)
   We would like to refer to reference 18 in the section Discussion (Strengths and Limitations) Page 25 (4 lines down) as evidence of the inhibiting nature of work-based focus groups. We explain in more detail in the Methods, Data Collection section the reasons why focus groups were used for patients and interviews for staff, Page 8 (1st line, second paragraph) –

   ‘Data were collected in focus groups because of the strength of focus groups for generating new ideas through group interaction [18] and for facilitating access to the diverse opinions of a number of patients in a short space of time. Semi-structured interviews were used because only a small number of staff in each practice were involved in administering the intervention in the
exploratory phase and they facilitated detailed descriptions of GP and nurse consultations with patients.’

We also justify in Point 12 below our reasons for using interviews with the staff.

4. Methods Page 9 (Data Analysis)
We had mistakenly omitted that analysis was facilitated by a computer software programme and have inserted a sentence to this effect and removed the reference to manual analysis, see Page 9 (1st sentence) –

‘Data analysis was conducted using the qualitative computer software programme NUDIST (N6). MC and PC initially analysed the transcripts separately to identify the main issues.’

5. Methods Page 9 (Data Analysis)
We have revised the sentence on pages 9-10 to explain how data saturation had been achieved –

‘Both researchers agreed that there were no new issues in the data collected from the fourth practice and that data saturation had been reached.’

6. Methods Page 9 (Data Analysis)
We have included examples of how symbolic interactionism influenced the data analysis on page 11 (2nd paragraph, 6 lines down) –

‘This theory led us to explore, for example, the social and cultural influences on patients’ health beliefs and behaviours, and how staff related their relationship with patients to their motivation in pursuing secondary prevention with them.’

7. Results Page 11 (Time and Money)
We have now referenced the study by Murchie et al (Reference 22) in the Results, Application of Findings to Intervention Design Page 20 and in the Discussion, Strengths and Limitations Page 24.

We have moved this paragraph out of the discussion to Results Pages 20-21.
Please see our response to Gene Feder.

10. Discussion (Page 23) Strengths and Limitations
We have clarified how our study is in accordance with the MRC Framework by inserting
the following sentence into the Introduction Page 4 (4 lines down) –

‘A framework for the development and evaluation of such programmes has been
proposed by the Medical Research Council (MRC) [7]. This describes a phased
approach which begins with a theoretical phase exploring the literature and
progresses to a modelling phase which confirms the relevance of components
identified from the literature, followed by an exploratory phase to refine the
programme design before performing a randomised controlled trial.’

We have also replaced the words ‘pilot’ or ‘initial’ with the words ‘modelling /
exploratory phases’ throughout the paper.

We have clarified how saturation was achieved in the Discussion, Strengths and
Limitations Page 24 (paragraph 1, 3rd last sentence) –

‘However there was consensus amongst the research study team that data
saturation had been achieved as no new issues had emerged from the interviews
in the fourth practice.’

Please also see our response to point 5.

We have clarified how the researchers’ different interpersonal skills may have influenced
the data collected on Page 24 (2nd paragraph, 1st line) –

‘The amount and type of data that were collected may also have been influenced
by how well the researchers interacted with the respondents during the interviews
that may reflect their different interpersonal skills.’

11. We have removed the sentence referring to the researchers’ non-clinical background
as we recognise that this is a judgemental statement.
12. Reference 18 provides evidence of how hierarchical relations may inhibit focus group discussions. We have included more information to justify our use of interviews Page 25 (paragraph 1, sentence 1) -

‘However hierarchical relations within the group may censor some participants [18] and justified the individual interviews in the exploratory phase. Analysis of the focus group transcripts confirmed the researchers’ observations that discussions tended to be dominated by the GPs, nurse practitioners or practice nurses and practice managers while the treatment room nurses and receptionists were more silent.’

We have expanded the sentence to demonstrate how discussions between the research nurse and practice staff were separate from the focus groups, Page 25 (paragraph 1, last sentence)

‘However, separate informal discussions between CSL and practice staff revealed no new issues.’

The discussions between the research nurse and practice staff were previously mentioned under Data collection Page 10 (7 lines down) –

‘CSL, who liaised with staff to facilitate the smooth running of the study, also made contemporaneous written records of her observations of the administration of the practices and individual discussions with staff in relation to their needs and experiences of the pilot trial.’

13. Page 25 Conclusions
We agree that we will only be able to confirm Gunn et al after the main trial, the new sentence now reads Pages 25-26 –

‘We have shown that qualitative findings in the development of a complex intervention contribute to refinement of the design detail by identifying and addressing barriers and facilitators to implementing the intervention in the main trial in a way that is acceptable to staff and patients [29].’

**Minor Essential Revisions**

Heartwatch – this has been an initiative involving only a small and limited number of practices which will not extend to more practices and so will not interfere with the delivery of the main trial of the intervention. In respect of the different structures of the RoI practices we feel that awareness of these do allow the intervention to be tailored for delivery. We have referred to the differences between the two systems in respect of access to care and payment for prescriptions in the Discussion, Strengths and Limitations Page 25 (last sentence) –
‘The implications of charges for visits to practice and prescriptions in the RoI will be taken account of in the main trial.’

We have replaced the word ‘definitive’ with ‘main’ in the Discussion Strengths and Limitations Page 25 (paragraph 2, 3 lines down) so that the sentence now reads –

‘The changed arrangements for payment for management of CHD may impact on the intervention in the main trial but the current findings and awareness of the impact of background policy should assist in our interpretation of the findings.’