Author’s response to reviews

Title: Home-based versus hospital-based cardiac rehabilitation: Literature review, study design and rationale of the Birmingham Rehabilitation Uptake Maximisation Study (BRUM): a randomised controlled trial (ISRCTN72884263)

Authors:

Dr Kate Jolly (C.B.Jolly@bham.ac.uk)
Gregory YH Lip (gregory.lip@swbh.nhs.uk)
Ms Josie Sandercock (J.Sandercock@bham.ac.uk)
Dr Sheila M Greenfield (S.M.Greenfield@bham.ac.uk)
James P Raftery (J.P.Raftery@bham.ac.uk)
Dr Jonathan W Mant (J.W.Mant@bham.ac.uk)
Dr Rod S Taylor (R.S.Taylor@bham.ac.uk)
Kaeng Wai Lee (kaeng.lee@swbh.nhs.uk)
Deirdre Lane (deirdre.lane@swbh.nhs.uk)
Andrew J Stevens (A.J.Stevens@bham.ac.uk)

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PDF covering letter
Dear Ms Veitch

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Home-based versus hospital-based cardiac rehabilitation after myocardial infarction or revascularisation: Design and rationale of the Birmingham Uptake Maximisation Study (BRUM): a randomised controlled trial (ISRCTN72884263)

I am attaching a revised version of the paper which addresses the comments made by the reviewers. I have amended the title in line with the instructions for authors. The changes made are highlighted by a point by point response below.

Reviewer 1 – DRT

2.i Exercise-based has been removed from the abstract.
2.ii The reference numbers were incorrect and have been amended.
2.iii The paper by Gray et al has been referenced in the section ‘cost and cost-effectiveness of CR’.

Reviewer 2 – HMA

Compulsory revisions:

1. The cardiac rehabilitation being used in this trial is that of a comprehensive multifactorial intervention. As comprehensive CR has an exercise component we feel it would be inappropriate to exclude all exercise-based CR trials. To reduce any confusion we have removed the term “exercise-based” from the abstract and added “exercise-only” when referring to these trials in the text.

2. The study includes a cost-effectiveness trial, which means that the effectiveness needs to be established first. To highlight the importance of the effectiveness element this has been inserted into the abstract so this now reads: “This trial evaluates the effectiveness and cost-effectiveness of home-based compared to hospital-based cardiac rehabilitation.”

3. The primary and other outcome measures are clearly stated in Box 2. The reference to Box 2 has now been inserted into the text in the section on outcome measures.
In the background section we have added the appropriate time frame over which mortality reductions have been observed.

The reference to Beckie’s study has been removed.

The paper by Arthur has now been referenced in the section on effectiveness of CR after revascularisation.

One of the objectives of the BRUM study is to look at uptake. We have discussed the difficulty of measuring uptake of a home-based intervention, but have included an activity questionnaire at 6, 9 and 12 weeks as a proxy for uptake. Whilst this is an imperfect measure of uptake it will give a self-reported measure of the amount of activity undertaken by the home-based and hospital-based participants. The BRUM study is taking place in an inner city, multicultural environment and seeks to explore whether the home-based programme is more acceptable to people who are known to be poor attenders (women, the elderly and people from ethnic minority groups). We feel that the section on uptake is relevant to the study.

Most trials of cardiac rehabilitation have recruited predominantly white middle income participants. Whilst we have provided special materials for the most predominant ethnic minority group, people from other groups who speak adequate English are eligible, and the area has a significant proportion of Afro-Caribbeans. The area is thus multi-ethnic. We agree that the term South Asian is more accurate and have changed the term “Asian” to “South Asian”.

We have amended the section describing the home-based programme to clarify when the visits and telephone contact takes place.

The modified Godin will be used as a proxy for uptake. The sentence in the section on outcome measures has been amended to read “Patient completed activity questionnaires (modified Godin at 6, 9 and 12 weeks) are used for both groups to provide a comparison of activity.

See point 3 above. There are 5 primary outcome measures, with no one outcome having primacy, which we feel is appropriate given the broad objectives of cardiac rehabilitation. The outcome measures are detailed in Box 2. To improve the clarity of the paper, details about data collection have been moved to the section on outcome measures.

Patients are recruited to the trial approximately 4 days post-MI which is too early to be undertaking an exercise test. As the Heart Manual programme commences in hospital it is not possible to use as a baseline measure the exercise capacity at the start of a rehabilitation programme, which is the solution used by many hospital-based CR trials. We have included a statement in the statistical analysis section, which reads: “Baseline measurements for exercise capacity will not be available as patients are randomised approximately 4 days post-MI and the day after PTCA which is too early to undertake an exercise test. As the sample is large and randomised we would not expect baseline differences between the groups. The lack of a baseline measure reduces the available precision, but this was taken into account in the power calculation.”

The comment about detecting the direction of treatment effects is in a paragraph describing the analysis of sub-groups. There is still insufficient data
about the effectiveness of home-based CR in different subgroups. The subgroup analyses are pre-specified but not powered for, which is the reason for the cautious argument made for this part of the analysis.

14. In the section about the qualitative study we have retained the analytic method as grounded theory, but have clarified the fact that we will be aiming to generate a theory of adherence to CR as an outcome of that analysis.

Discretionary revisions:

1. Box 1, which describes the inclusion criteria, has been amended to clarify that patients are eligible with first or subsequent events.

2. In the “participants and sampling” section of the qualitative study the definition of patients who decline or do not adhere has been included.

I have checked through the formatting list and believe that the manuscript conforms to all the points.

I trust that we have addressed all the reviewers points and look forward to your response.

Yours sincerely

Kate Jolly