PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Bathing adaptations in the homes of older adults (BATH-OUT): Protocol for a Feasibility Randomised Controlled Trial (RCT)
AUTHORS	Whitehead, Phillip; James, Marilyn; Belshaw, Stuart; Dawson, Tony; Day, Miriam; Walker, Marion

VERSION 1 - REVIEW

REVIEWER	Dr Catherine Haighton Lecturer in Public Health Institute of Health and Society Newcastle University Baddiley-Clark Building Richardson Road Newcastle upon Tyne NE2 4AX UK
REVIEW RETURNED	22-Jul-2016

GENERAL COMMENTS	This is a well written protocol of a fully funded ethically approved trial so it has already been through a substantial peer review process. I do however have one or two comments for improvements in reporting: The abstract is well written but it is unclear in the introduction section as to what the services were meant to prevent deterioration in. The method would be improved with a clearer justification for the sample of 40-60 people for the feasibility trial see Billingham, Sophie AM, Amy L. Whitehead, and Steven A. Julious. "An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database." BMC medical research methodology 13.1 (2013): 1. The description of the study design could make it clearer that this is a single (researcher) blinded trial. More details are need of the qualitative interviews. What is the purpose/aim of them and how will they be analysed? Again could the proposed sample size be justified? Detail is also needed regarding the proposed statistical analysis of outcome measures for the intention to treat analysis.

REVIEWER	Dr Jennifer Wenborn Division of Psychiatry, University College London, England Senior Clinical Research Associate – Occupational Therapist
REVIEW RETURNED	05-Aug-2016

GENERAL COMMENTS	The aim of this study is to test the feasibility of running a fully

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	powered RCT in the future. It will therefore assess the feasibility of conducting the study processes; delivering the intervention delivery and completing the outcome measures in practice. The authors explain the practice background well; highlight the paucity of robust evidence in this area of practice; and emphasise the need for this feasibility study, especially in view of the lack of RCTs to date of housing adaptations. The study therefore addresses an important topic bearing in mind the potential impact on the physical and mental health of recipients as well as their carers, plus the anticipated economic benefits. The research team is experienced in conducting trials of complex interventions and includes members with practice experience within social care. I am happy to recommend for publication pending clarification of the queries below: 1 The intervention under consideration is the installation of an accessible showering facility in a participant's own home. This is indeed a complex intervention to deliver, dependent as it is on the individual's needs, abilities, and motivation; the suitability or otherwise of the physical environment to be adapted; the ownership of the property and funding of the adaptation. A social care occupational therapist initially identifies the need and then the adaptation process is completed by the Adaptations and Renewals Agency. It would be usual in a RCT of this nature to include a more detailed description of the intervention, or refer to an intervention protocol or manual; as well as outlining a process to assess the fidelity of the intervention being provided. Whilst I appreciate that this level of detail cannot be included in a manuscript of this length some mention should be made of these aspects. From the current description it is not clear how much variety there may be in the actual intervention delivered, for example, it is stated that the provision of an accessible showering facility '..usually involves the removal of an existing bath and replacement with a flush floor anti-slip walk in 'level-access' shower'. At what point would a bathing adaptation be deemed as not meeting this definition and therefore render the client ineligible to take part? 2 The inclusion criteria are necessarily broad to reflect the population under consideration. Those who have been referred for any additional adaptations will be excluded, but presumably those referred for additional equipment will not? I wonder if the sample will prove to be too heterogenic but this of course is the purpose of conducting a feasibility study. 3 The process of obtaining valid informed consent needs to be explained more accurately as the current sentence does not make sense – why would the investigator or their nominee need to provide informed written consent? It should be noted that a Consultee cannot consent on another individual's behalf, their role is to express an opinion / sign a declaration as to whether they consider the individual would have agreed to take part had they still had the capacity to state their own preference. 4 The online programme that will be used to randomise participants and the electronic database should both be named / referenced. 5 I note that participants' ability to manage daily living activities will be measured using the Barthel Index. Are the authors confident that this measure is sufficiently sensitive to measure change over time in basically just one activity, ie: bathing? 6 A major challenge in complex intervention RCTs is maintaining masking of research staff. The authors rightly state that the participants cannot be masked and so of course there is always the BMJ Open review: Whitehead et al., August 2016 2

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	risk that they will unmask research staff. I would suggest including more detail about the strategies to be employed to reduce the risk of unmasking as there are numerous other ways in which research staff could be unmasked. Surely one very likely risk is that research staff will notice the change to the home environment – especially if they need to visit the bathroom whilst there? Consideration needs to be given as to how to collect accurate data on health and social care service usage without participants unmasking the research staff. I suggest that research staff routinely record their perception / knowledge of the participants' allocation following each follow-up so that the rate of unmasking can be calculated (see Minns Lowe et al., 2011 for more detail). 7 The main end point is to determine the feasibility of conducting a fully powered study and certainly the statistical analysis will enable a sample size calculation to inform this. I would suggest that, in addition, relevant criteria against which to evaluate the practicality and success of the study processes are predefined, for example: in terms of recruiting participants –how long did it take to recruit the desired number of participants? What was the conversion rate of eligible participants to those consented? Were certain areas / teams more successful in recruiting participants than others? How user friendly was the recruitment documentation? How user friendly was the paper CRF and subsequent process of transferring data into the database? 8 One minor editorial point – spelling varies between randomised and randomized, this obviously need to be consistent throughout depending on the journal's preference.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1
1. The abstract has been updated to reference 'health and social care services'. Further details about the preventative effect on particular services is included in the first paragraph of the introduction.
2. Additional information has been added (page 9) to justify the planned sample size and we have included the suggested reference.
3. A sentence has been added to the description of the study design (page 6) to make clear that the outcome assessor is masked. This information was already included in the section on randomisation, but we agree that including this earlier improves the clarity.
4. Additional information has been added regarding the purpose and aim of the qualitative interviews. The interviews will be analysed using thematic analysis – information and an appropriate reference has been added to the text. The sample size is in order to gain a range of interviewees across both groups in the feasibility RCT and this has now been referenced in the text.
5. We believe that we have included sufficient detail in the section 'Data Collection, Management and Analysis' regarding the analysis of outcome measures. We are not proposing to carry out any hypothesis testing but we will calculate the between group difference and the 95% confidence interval for the purpose of informing our effect estimate and sample size calculation for a further study. We believe this is appropriate level of detail and analysis for a feasibility study.

Reviewer 2
1. We have included additional text (page 7) to clarify the types of accessible shower/ showering alterations which would be included and to state under the exclusion criteria that alterations to baths will be excluded.
2. It is correct that participants may have received items of equipment provided by the social care occupational therapist. This will usually have been provided prior to the referral for the level access shower. With regard to bathing, referral for an accessible showering facility is usually based upon the

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criterion that bathing equipment has been deemed to be unsuitable. It is possible that participants may have received other items of equipment to help with other ADLs – for example a bed lever to assist with bed transfers, and we would expect this to be the same in both groups. We will collect information on use of equipment as part of our health and social care resource use questionnaire.
It is possible that the sample may be heterogeneous; however, we have attempted to minimise heterogeneity by restricting the eligibility criteria to older adults and bathing adaptations only. This will be one of the determinants of feasibility.
3. We have revised the section on consent (page 9) to clarify points about informed consent and the role of the consultee in the process.
4. We have added a reference to the online randomisation programme (page 9) and the electronic database (page 10).
5. Part of the rationale for focussing on bathing adaptations is that disability in bathing may precede disability in other ADL. Therefore the Barthel Index is included as a standard measure of personal ADL ability; it is included to record outcomes across other ADL within the home. With regard to bathing, we are also planning to analyse the bathing question from the Barthel Index as a separate standalone outcome. Additionally, we also have a scale measure (0-100) recording participants' perceived disability in bathing to capture the specific effect on bathing. However, this information was not included in the manuscript and we have now added this (page 8).
6. We have included additional detail on (page 10) regarding the strategies for maintaining the masking of the outcome assessor. Although the original manuscript included details of our intention to monitor this we have included further information to increase clarity.
7. Information for evaluating the success of the study in terms of feasibility are included in the study objectives. These are "to recruit 40-60 participants within the recruitment period (eight months); recruit a minimum of 50% of those eligible, provide 70% of adaptations within the specified timescales; follow-up a minimum of 70% of participants at the 6-month time point; and achieve a minimum of 80% completeness of data". NB. These figures have been altered slightly from the original manuscript, following further consultation with our collaborators. We are willing to include this information again under the section about the study endpoints but believe that this would be a little repetitive; thus we have not done this.
8. We have amended this and changed all to 'randomised'.

Additional changes
The following changes have also been made:
1. The word 'feasibility' has been added to the title to make clear that this is feasibility RCT.
2. A sentence has been added to the first paragraph to state that 'adaptations' may also be referred to as 'modifications' to make this explicit for international readers.
3. References have been included for each of the outcome measured to be used.

VERSION 2 – REVIEW

REVIEWER	Katie Haighton Newcastle University, UK
REVIEW RETURNED	26-Aug-2016

GENERAL COMMENTS	I am satisfied that the authors have made the suggested revisions and the manuscript is now improved.

REVIEWER	Dr Jennifer Wenborn Division of Psychiatry, University College London, England. Senior Clinical Research Associate - Occupational Therapist
REVIEW RETURNED	05-Sep-2016

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GENERAL COMMENTS	Thank you for the opportunity to review this resubmitted manuscript. I am satisfied with the amendments made in response to my review of the earlier version and am happy to now recommend for publication.

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