Author’s response to reviews

Title: Developing stepped care treatment for depression (STEPS): protocol for a mixed methods study involving a pilot randomised controlled trial and qualitative interviews

Authors:

Jacqueline J Hill (j.j.hill@exeter.ac.uk)
Willem Kuyken (w.kuyken@exeter.ac.uk)
David A Richards (d.a.richards@exeter.ac.uk)

Version: 4 Date: 12 October 2014

Author’s response to reviews: see over
Dear Editors-in-Chief

MS: 3946234651319425

We thank the Editorial Team and reviewer for their comments on our study protocol paper entitled, ‘Developing stepped care treatment for depression (STEPS): protocol for a mixed methods study involving a pilot randomised controlled trial and qualitative interviews.’ We are pleased to respond.

Editorial Requests

1. Email addresses

   1.1. Please include the email addresses of all authors on the title page.

      Email addresses have been added.

2. Date of trial registration

   2.1. Please include the date your study was registered with the trial registration number at the end of the Abstract.

      We have added this date.

3. Ethical bodies

   3.1. Please include the names of all ethical bodies that approved your study in the various centres involved, in the Methods section. If you do not wish to list them all in the Methods section, please include the list as an additional file and refer to this in the Methods section.

      We have listed the names of all ethical bodies that approved our study i.e. NRES South West – Frenchay, Devon Partnership Trust and the School of Psychology at the University of Exeter. This information is provided in the Ethical issues sub-section of the Method.
Referee 1

Minor essential revisions

4. In the Introduction

4.1. The uncertainties regarding the effects of stepped care are well documented in the introduction. This makes the need for this study clear. However, it would be helpful for the reader if you restructure your introduction. The main research questions may be introduced earlier and more clear in order to lead the reader through the introduction. It is also unclear whether you need to differentiate between your own work and the literature in general.

We agree with the reviewer’s comment and have restructured the Introduction. We have introduced our main research questions earlier - see The need for a mixed methods feasibility study. We no longer differentiate between our own work and the literature in general. We believe that our main research questions are now clearer: under Uncertainties we have removed our emphasis on the diverse ways in which stepped care is implemented given that we do not aim to test alternative forms of stepped care. We more carefully distinguish between uncertainties associated with stepped care that will ultimately be addressed in a large RCT (equivalence, efficiency – see Uncertainties) and the aim of the current study i.e. to test methodological and procedural uncertainties associated with the conduct of a large RCT including what people think about stepped care to inform a clinical protocol for use in a large trial (see The need for a mixed methods feasibility study). We have amended the Abstract to reflect these changes.

5. In the Methods / Design

5.1. Setting. The IAPT service selected is not described. As IAPT services differentiate regarding the proportion of patients being stepped up and not (0-50%) it would be interesting and relevant to know the “culture” for stepping up at the specific IAPT service. Please describe the setting in further detail.

Trial participants will be recruited via an IAPT service but treated at the University of Exeter AccEPT Clinic. Hence the “culture” for stepping at the IAPT service will not influence clinical practice in the current study. To help make this clear, we have inserted a new sentence under Setting and participants to say that patients who have been recruited via IAPT will be treated at the AccEPT Clinic. Under Trial Interventions we describe the AccEPT Clinic in more detail; we comment that it has not previously delivered stepped care. We have inserted a new line in the Abstract to clarify that all patients will be treated at the University of Exeter.

5.2. Stepped Care. The evidence for the guided self-help material is unclear as the references refer to computerized interventions. Please clarify.

We have amended our description of the Stepped Care intervention to clarify that the Guided Self-Help material will be an offline version of the online Wellbeing Course developed by the Centre for Emotional Health at Macquarie University. In some cases, the Centre for Emotional Health supplies course material by post and patients are supported by
a therapist via the internet or by phone. With the permission of Macquarie, we have adapted the Wellbeing Course for a UK patient population. Course material is otherwise unchanged and we will replicate the weekly delivery of the online course in how we provide patients pdf and paper documents. (Note - we have replaced our references on the effectiveness of the Wellbeing Course with three that are more up to date.)

5.3. Quantitative analysis. In the text it is stated that data will be analysed with an intention-to-treat approach. In the Figure it is stated that only patients with available data at follow-up will be analysed. Please clarify.

We have clarified our use of the term ‘intention to treat’ (ITT) - participants will be analysed in their original assigned groups. We will not impute missing data; we will report outcome data that are missing in both intervention groups and, to the extent that we are able, reasons for missing outcomes. We have left Figure One unchanged.

6. In the Discussion

6.1. Potential strengths and weaknesses in the design should be discussed.

We have modified the Discussion in line with the reviewer’s comment. We have kept our discussion relatively brief as we anticipate that a report / paper on study outcomes will also discuss strengths and weaknesses.

Discretionary Revisions

7. Setting

7.1. IAPT services differentiate regarding the proportion of patients being stepped up and not (0-50%). As this variability is acknowledged, I wonder if you may consider recruiting two IAPT clinics, one at each extreme on the stepping-up scale? This would inform a future large scale RCT and make the pilot study an even greater contribution to the existing knowledge-base.

We thank the Reviewer for her suggestion. However, we will not work in IAPT services (see 2.1). Rather we have defined a stepped care clinical protocol for therapists to follow at the AccEPT Clinic. The progress of all stepped care patients will be assessed using the same stepping criteria. In line with the purpose of a feasibility study, we will ask patients and therapists for their views and experience of how the criteria are implemented. This information will inform a stepped care clinical protocol for a proposed large RCT.

8. Stepped care

8.1. Patients may decide that all guided self-help consultation may be face to face. To our clinical experience therapists’ preference may be as significant as patients’ preferences when it comes to preferring face-to-face contact during guided self-help and regarding stepping up or not. In this trial this is especially relevant to the two groups of patients where stepping up may be decided based on patients’ wishes. Information about the therapists’ wishes is to our experience also relevant.

We agree with the Reviewer’s comment. Semi-structured interviews with therapists will explore what they thought of face to face versus telephone consultation; we have amended
our description of the interviews to note this. We will probe for an understanding of how therapists’ views of the mode of therapy affected their implementation of stepped care, including the stepping criteria.

Thank you for the opportunity to revise our manuscript for Trials. We look forward to your editorial decision and stand ready to respond to any further issues raised should this be required.

Yours faithfully

Jacqueline J Hill
Exeter Graduate Fellow