Author's response to reviews

Title: Psychological Advocacy Towards Healing (PATH): randomised controlled trial to determine the effectiveness and cost-effectiveness of a psychological intervention delivered by domestic violence advocates

Authors:

Gwen Brierley (gwen.brierley@bristol.ac.uk)
Roxane Agnew-Davies (roxanedavies@aol.com)
Jayne Bailey (jayne.bailey@bristol.ac.uk)
Morgan Fackrell (chiefexecutive@cardifffomensaid.org.uk)
Giulia Ferrari (giulia.ferrari@bristol.ac.uk)
Sandra Hollinghurst (sandra.hollinghurst@bristol.ac.uk)
Louise Howard (Louise.Howard@iop.kcl.ac.uk)
Alice Malpass (alice.malpass@bristol.ac.uk)
Carol Metters (carol.metters@missinglinkhousing.co.uk)
Tim Peters (tim.peters@bristol.ac.uk)
Fayeza Saeed (fayeza.saeed@bristol.ac.uk)
Gene Feder (gene.feder@bristol.ac.uk)

Version: 2 Date: 18 April 2013

Author's response to reviews: see over
April 16th 2013

Editors

Trials

Dear Editors

Psychological Advocacy Towards Healing (PATH): randomised controlled trial to determine the effectiveness and cost-effectiveness of a psychological intervention delivered by domestic violence advocates (Manuscript ID 166885169864324)

Thank you for your positive response to this manuscript and sending us the comments of the reviewers. We have responded to their queries and useful suggestions below. Changes in the manuscript are highlighted in yellow. I hope these responses and the changes in the paper make it fit for publication.

One additional change in the manuscript is the addition of another co-author, Lyn Marie Sardhina.

Yours sincerely

[Signature]
Reviewer: Michele Kiely

1. I found the description of the sample size and power misplaced. It seemed to belong much earlier in the manuscript (I thought it belonged before the description of the intervention).

   *We think it makes more sense to specify and justify the sample size after the outcomes have been described, although we have moved the section above that describing the nested qualitative study.*

   In reviewing the manuscript when addressing reviewer’s comments, we realized that we had incorrectly reported the sample size calculation. In fact we would have 96% power to detect an effect size of 0.52 with 125 women recruited and a 20% loss to follow up and 81% power to detect an effect size of 0.4 with the same number recruited and attrition. We have amended the text accordingly (p 6 para 5)

2. Were there any restrictions in the randomization, such as blocking?

   Yes. *The randomization programme applies stratification with random blocking. Within each stratum, participants are assigned to treatment or control in randomly chose blocks of 2, 4 or 6. We have amended the text accordingly (p 4 para 3)*

3. I thought the roles of members of the research team should have been made more explicit. The only person explicitly described were the Specialist Psychological Advocate and the clinical psychologist who supervised them.

   *We weren’t sure what the reviewer means by the “research team.” We described the role of the SPAs and the psychologist providing their clinical supervision because they are part of the intervention. What would be the rationale for specifying the roles of the principal investigator (GF), trial managers (GB and JB), research associates (FS, EN,LM), economists (SH, GFerr), statistician (TP), co-investigator (DS), site managers (MF,CM), social scientists (ME and AM)? If the editors want us to do that, of course we will.*

4. I was unclear why the researchers, unless they were the ones providing the intervention, were privy to the randomization group.

   *From our pilot study we ascertained that it was impossible to keep the research associates blinded to randomization group status of participants in the course of one year follow up. They became un-blinded either from inadvertent information from the intervention site or from the participant. Therefore we had to accept that this was not achievable in the main trial. By the same token, it was neither feasible nor desirable for the social scientists conducting interviews with the participants to be blinded, as one of their major objectives was to understand the participants’ experience of the intervention or usual care within the domestic violence agencies.*

Discretionary Revisions

5. What is the plan if a participant does not attend the CBT sessions?

   *If a participant in the intervention group misses an appointment, the SPA will contact them to arrange another one. If a participant declines to attend any of her sessions, she will continue to receive advocacy support. The primary analysis will be on an intention-to-treat basis so non-attenders will be included.*
Major Compulsory Revisions

1. The study design cannot adequately test the hypothesis with an Attention Control group. Much has been written over the last 20 years regarding the importance of an Attention Control group to control for the "attention" offered to the intervention group. Without an attention control group the hypothesis cannot be tested with any degree of validity.

*This was designed and funded explicitly as a pragmatic (effectiveness) not explanatory (efficacy) trial, building on previous trial evidence for the effectiveness of psychological and advocacy interventions. Therefore it is legitimate to have a treatment as usual rather than an attention control group. We will collect data on contact time between advocates and participants in both arms and will use that in our interpretation of the findings.*

2. An effect size of .5 is projected. Data is needed to justify the .5 effect size on populations of abused women.

*With regards to the CORE-OM, which has not been used as an outcome measure in populations of women experiencing abuse, an effect size of 0.5 is very modest compared to that measured in trials as well as pre/post study studies of psychological therapies.*

*With regards to the PHQ-9, an effect size of 0.5 is consistent with the effects of psychological interventions for depression.*

*For example, in a primary care based trial of collaborative care for patients with depression, using the PHQ-9 as an outcome measure, the effect size was 0.61, albeit with wide confidence intervals (0.19 to 1.07). Moreover that effect size is also consistent with some trials of psychological interventions for women who have experienced domestic violence. (see appendix 7.5 in our systematic review of interventions.) For example, Kubany and colleagues' two trials of CBT for women diagnosed with PTSD following intimate partner violence, reported effect sizes of 0.9 and 0.33 respectively for PTSD and 0.4 and 0.25 for depression outcomes. Labrador reported effect sizes of 1.23 and 1.77 for PTSD and depression outcomes respectively; Reed and Enright reported effect sizes of 2.33 and 1.55 for PTSD and depression respectively. We have amended the text accordingly (p 6 para 6, p7 para 1).*

Minor essential revisions:

(1) It is stated that researchers continue to prompt women (or their locators) for the return of the questionnaire until week 12 after posting. What does 'continue' mean and after how many times will 'continue prompting' stop?

*We have provided more detail regarding the prompting of non-responding participants. (p 4 para 4)*

(2) What exactly does the participant receive in the 8 SPA sessions? Are the materials repeated 8 times? Or are there specific topics for each of the sessions?

*We have added more detail about the intervention to the text (p.5, para 2)*


