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@cardiffwomensaid.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 J Peters (tim.peters@bristol.ac.uk)
Fayeza Saeed (fayeza.saeed@bristol.ac.uk)
Lynnmarie Sardhina (Lynn.Sardinha@bristol.ac.uk)
Gene S Feder (gene.feder@bristol.ac.uk)

Version: 3 Date: 31 May 2013

Author's response to reviews: see over
May 29th 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 the additional consideration you have given this manuscript and for the further comments of a reviewer. We have responded to the points you raise below:

- Please ask the authors to add discussion of the point raised about the use of an attention control group by the referee in both the first and second rounds of review.

We have now added our response to the manuscript:

“We are not using an attention control group, as this trial is 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.”

We respectfully disagree with Judy McFarlane that a pragmatic trial testing this psychological intervention is not legitimate before an efficacy trial has been conducted. There is sufficient evidence, in our opinion, for this type of intervention to be trialed without an attention control, not least because we are including a cost-effectiveness analysis. To play devil’s advocate here, let us suppose that a possible effect is due to additional attention from a domestic violence advocate, not the specific programme given in the intervention arm. If the intervention was cost-effective, would it matter that we could not disentangle the effect? The additional training and supervision costs are greatly outweighed by the salary costs, which would be the same if the advocates simply spent more time with the client rather than provided a psychological intervention. Finally, the trial design was endorsed by 10 external peer reviewers, including trialists, as part of the funding process by the National Institute of Health Research.
In addition, can the authors recheck the sample size calculation and how it is described please as it differs between the responses to the referees and the manuscript.

Done. We have now referred consistently to the total sample size (250) rather than the size of each arm (125)

Editorial requests:

1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?__________________ study protocol for a randomized controlled trial.?  
Done  

2) Please include a title page as page 1. The title page should include the title, authors, author affiliations and corresponding author details.
Done

3) Please ensure the abstract is on a separate page, this should follow the title page.
Done

4) Please include a trial status section. This should state the status of the trial at the time of manuscript submission. The journal considers study protocol articles for proposed or ongoing trials provided they have not completed patient recruitment at the time of submission.
Done

5) Please include a competing interests section at the end of the manuscript, before the reference list. If the authors have no competing interests, please state: "The authors declare that they have no competing interests."
Done

6) Please include an Authors? Contributions section at the end of the manuscript, before the reference list. We suggest the following kind of format (please use initials to refer to each author’s contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.
Done