

A randomised controlled trial of cognitive behaviour therapy for women with problematic menopausal hot flushes: Trial protocol

Reviewer 1: Slade, Pauline

The Study	Yes	No
Is the research question clearly defined?	✓	
Is the overall study design appropriate and adequate to answer the research question?	✓	
Are the participants adequately described, their conditions defined, and the inclusion and exclusion criteria described?	✓	
Are the patients representative of actual patients the evidence might affect?	✓	
Are the methods adequately described?	✓	
Is the main outcome measure clear?	✓	
Are the abstract/summary/key messages/limitations accurate?	✓	
Are the statistical methods described?	✓	
Are they appropriate?	✓	
Is the standard of written English acceptable for publication?	✓	
Are the references up to date and relevant? (If not, please provide details of significant omissions below.)	✓	
Do any supplemental documents e.g. a CONSORT checklist, contain information that should be better reported in the manuscript, or raise questions about the work?		✓

If you answered No to any of the above, please supply details below.

RESULTS AND CONCLUSION (For articles reporting research findings only)	Yes	No
Do the results answer the research question?		
Are they credible?		
Are they well presented?		
Are the interpretation and conclusions warranted by and sufficiently derived from/focused on the data?		
Are they discussed in the light of previous evidence?		
Is the message clear?		

If you answered No to any of the above, please supply details below.

REPORTING AND ETHICS**Yes No**

Is the article reported in line with the appropriate reporting statement or checklist (e.g. CONSORT)?	✓
Are research ethics (e.g. consent, ethical approval) addressed appropriately?	✓
Is the article free from any concerns about publication ethics (e.g. plagiarism, fabrication, redundant publication, undeclared conflicts of interest)?	✓

If you answered No to any of the above, please supply details below or contact the editorial office.

req BMJ Open uses compulsory open peer review. Your name and institution will be returned to the authors and will be published with this review if the article is accepted. Therefore please sign your review in the box below. Include your name, position, institution and country. Please also include a statement of competing interests. If you have filled out an ICMJE Conflicts of Interests form - please attach this using the box beneath instead.

This is a well designed trial addressing a neglected area which causes significant distress and has major adverse implications for wellbeing in midlife women. It is particularly timely because of women's recent concerns relating to hormone replacement therapy.

Methodologically it is sound and impressive in including both psychological and physiological assessments. It will provide high quality evidence about the effectiveness of two forms of delivery of cognitive behaviour therapy against usual care for women with hot flushes/night sweats

My points are only those where the protocol could have been further developed: I would have liked to have seen a little more on the interview process and analysis in terms of women's experience of the interventions particularly if there is dropout.

There could have been some consideration of health economics including any implications for time off from employment although it may be that samples are too small to address this. Night sweats certainly have implications for fatigue and hot flushes can be highly stressful for some women in the work environment.

The only other query I have concerns the criterion for inclusion; 4 weeks of hot flushes/night sweats seems quite brief but it may be that an argument for early intervention so that beliefs and responses do not become entrenched could easily be made.

The protocol is fluent, clear and well written.

req Recommendation

- ✓ Accept
- Minor Revision
- Major Revision
- Reject

Would you be willing to review a revision of this manuscript?

- ✓ Yes

No

Authors Response to Decision Letter for (BMJ Open.2010.000047)

A randomised controlled trial of cognitive behaviour therapy for women with problematic menopausal hot flushes: Trial protocol.

Thank you for the opportunity to revise our manuscript. Please find our responses to the reviewer comments below:

Reviewer comment:

1. I would have liked to have seen a little more on the interview process and analysis in terms of women's experience of the interventions particularly if there is dropout.

The following has been added under the heading 'Treatment Evaluation' (page 19):

"This includes their perceptions of any symptom, cognitive or behavioural changes occurring during treatment or in the follow-up period, as well as their thoughts on the group sessions/self-help booklet and how well CBT treatment fits with their lifestyle. The interviews will be conducted, transcribed and analysed by an independent researcher using Interpretative Phenomenological Analysis (IPA)."

Reviewer comment:

2. There could have been some consideration of health economics including any implications for time off from employment although it may be that samples are too small to address this.

We have included questions relevant to health economics, such as use of services, medication and major changes to lifestyle, which includes other health problems, stresses and changes in employment (page 13).

Reviewer comment:

3. The only other query I have concerns the criterion for inclusion; 4 weeks of hot flushes/night sweats seems quite brief but it may be that an argument for early intervention so that beliefs and responses do not become entrenched could easily be made.

Findings from previous work (Hunter & Liao, 1995) suggest women who seek help for menopausal symptoms have often experienced hot flushes and/or night sweats for approximately 5 years. However, we wanted to include women across the menopausal transition and therefore decided to include those who had experienced symptoms for at least 1 month but who were experiencing at least 10 hot flushes and/or night sweats a week. This would ensure women who had just begun to experience symptoms but who found them quite problematic and frequent would not be excluded from treatment.

We hope the manuscript is suitable for publication in BMJ Open.

Yours sincerely,

Dr Beverley Ayers, Dr Eleanor Mann and Professor Myra Hunter