Reviewer’s report

Title: Conducting a pilot randomized controlled trial of community-based mindfulness-based stress reduction versus usual care for moderate-to-severe migraine: protocol for the Mindfulness and Migraine Study (M&M)

Version: 0 Date: 09 Dec 2018

Reviewer: Monica Busse

Reviewer’s report:

This manuscript describes the study protocol for feasibility trial of mindfulness based stress reduction compared to usual care for moderate to severe migraine. The manuscript is generally well written however there are major concerns in relation to the feasibility design. There are also references to a feasibility/pilot study. It is important to define what the specific study design is. A feasibility study will test specific feasibility questions whilst a pilot study is a smaller version of the proposed efficacy trial. Pilot studies can be considered a sub-set of feasibility studies and as such the feasibility questions need to be much clearer. The focus on efficacy outcomes and mechanism needs further consideration.

The authors should refer to the CONSORT extension for pilot and feasibility studies (http://www.consort-statement.org/extensions/overview/pilotandfeasibility) They must and need to ensure consistency in definitions and clear definition of feasibility outcomes as well as progression criteria. Of particular relevance is the guidance provided by NIH National Centre for Complementary and Integrative Health who appear to be the funders here: https://nccih.nih.gov/grants/whatnccihfunds/pilot_studies

The authors could also refer to the work of Eldrige at el. (Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework as https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4792418/) as the manuscript requires detailed review and amendment to ensure that it fully describes and documents the feasibility nature of the protocol.

Introduction

The authors need to expand more on the necessity for the feasibility trial in particular they should discuss the paper by Wells et al 2014 who conducted a trial to assess the safety, feasibility, and effects of the standardized 8-week mindfulness-based stress reduction (MBSR) course in adults with migraines (https://www.ncbi.nlm.nih.gov/pubmed/25041058).

Methods/Design
The intervention description should be sufficiently detailed to be able to complete a TIDIER checklist. Whilst this is a manualised intervention, it is also a pragmatic delivery. This will mean that perhaps some aspects of the intervention may be modified for setting and population. There is no information on this. There is also no information on any efforts to capture usual care and any potential contamination.

Analyses is currently heavily focused on efficacy outcomes. There is little specific detail provided on feasibility outcomes, fidelity assessments or process evaluation. The Spirit Figure is lacking in specific detail in relationship to intervention records and usual care recording as well as individual outcome assessments. There is also reference to digital data to study mechanism. All together this is an impressive battery of outcomes.

Sample size: Whilst it is not appropriate to provide sample size calculations in relation to efficacy there should be a clearer rationale for chosen sample size in relation to feasibility objectives for example which proportions (and 95% CI) they would be able to detect (e.g. recruitment, retention).

Discussion

There should be some discussion how information gathered in this trial would facilitate progression to a full trial.

References

References need to be reviewed for formatting and consistency as well as accuracy. For example, reference 12 does not seem to have any relationship to the topic of the introduction where it is cited (Cattaneo MG, Yafuso C, Schmidt C, Huang CY, Rahman M, Olson C, et al. Farm-scale evaluation of the impacts of transgenic cotton on biodiversity, pesticide use, and yield. Proc Natl Acad Sci U S A. 2006 May 16; 103:7571-6.)

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