Author’s response to reviews

Title: An iterative design process to develop a randomized feasibility study and inform recruitment of minority women after stillbirth

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Response to Reviewers

Reviewer #1: Comments

GENERAL OVERALL COMMENTS:

* It was a pleasure reading this manuscript on a very important and under-researched topic
* Strong use of current evidence (Lancet series articles 2011 & 2016)
* Well designed study with rigorous evaluation methods
* Clearly written with the purpose of the research well identified. The importance of the need for interventions targeting physical and mental wellbeing for women who have experienced stillbirth was clearly highlighted.

* The term 'post-traumatic stress' is used throughout the paper yet in the study protocol (reference 25) 'post-traumatic stress disorder' was used and abbreviated to PTSD. It is not clear why the authors switched from using the term PTSD to using post-traumatic stress? Please clarify.

Post-traumatic stress disorder (PTSD) is an actual mental health diagnosis that can only be made through an evaluation by a trained mental health provider that includes assessment as well as context. Given that, we have tried to be more circumspect and nuanced with the nomenclature. Post-traumatic stress is a cluster of symptoms associated with PTSD and probabilistic of PTSD.
but it is not an actual diagnosis, and thus PTS is more accurately represented by the sole use a psychometric measure.

* The study protocol clarifies why yoga in particular may be a suitable intervention to improve both the emotional and physical well being of women who have experienced still birth however this is not explained in the current manuscript. It would be beneficial to have one sentence linking yoga to improved emotional and physical well being in the perinatal population.

We have added two sentences to the end of page 2.

BACKGROUND

The following revisions are recommended:

Lines 10-12:

Please consider rewording the following sentence: "These risks may persist years after the baby's death, with one-third of grieving mothers demonstrating clinical levels of post-traumatic stress at 18 years since after loss"

We have modified this sentence to: Approximately 44% of mothers who have stillborn babies exhibit symptoms of PTSD, which may last anywhere from two months to 18 years.

Lines 23-25:

When reading this sentence, it appears slightly awkward. Perhaps delete the word 'are' before the word reluctant: "Many mothers express a strong interest in home-based treatments as they do not want to encounter other babies in public and support groups are not effective for post-traumatic stress or women reluctant to communicate with others".

We modified this sentence to make it less awkward.

Lines 26-27:

For the phrase many are interested in conceiving again (50-98% conceive again), what is the reference for the 50-98% statistic?

We have added references.

METHODS

Lines 67-69:
Please reward the phrase "an advertisement that included language for African American and/or Hispanic women". It is not clear what this means and could be misinterpreted by readers.

We have modified this to make it more clear.

Lines 74-80:

Thank you for providing a clear rationale as to why two distinct groups of non-pregnant women were recruited.

You are welcome.

Lines 98-99:

What were the key components of the videos selected by the research team that you believed would cultivate emotional regulation and self-compassion? This is valuable information that could help future researchers.

We have added these to page 3.

Lines 113-121:

It is important that participant burden to complete questionnaires was considered before and after the yoga sessions. Please clarify if the research team felt the two, 1-item questionnaires for ER and SC (pre and post self-compassion and emotion regulation assessments) that were created to reduce participant burden measured what they intended to measure? For question 1, how did women in the non-stillbirth group perceive the term: understanding toward yourself and your grief if this group had not experienced a stillbirth. Did they wonder what this meant? Was question 2 clearly understood by participants or did they require clarification what the question was asking?

The questions were 1. How much self-compassion do you feel (i.e., self-kindness, understanding toward yourself and your grief, common humanity, mindfulness) right now? and 2. How much do you feel that you are able to be with your emotions (i.e., consciously stay with your emotions or mood) right now? Women were not asked specifically about their grief (i.e., those that hadn't had a stillbirth) as that was an example given to them in addition to the others such as self-kindness. Thus, some of the examples pertained and some did not. The research team thoroughly explained the questions and made sure women understood before answering. All women answered them without concerns or questions.

RESULTS
Reviewer #2:

Thank you for asking me to review this paper. It reports on the development phase of a NIH funded 2-phase feasibility study to examine an online yoga intervention to reduce symptoms of post-traumatic stress in mothers after stillbirth.

The paper describes an iterative design to i) inform the development of the online yoga intervention and ii) inform recruitment strategies to enrol minority women into phase 2.

The study included ten mothers (5 stillbirth mothers with no yoga experience and 5 non-stillbirth mothers with yoga experience) who were asked to participate in a series of selected yoga videos and assessed for self-compassion and emotional regulation.

Additionally a group of five minority women who had experienced a stillbirth were interviewed on the telephone about cultural barriers to recruitment and their perceptions/opinions of yoga.
My comments on this paper are restricted to the qualitative elements of the study (interviews with minority mothers).

Introduction - this is well described

Thank you.

Methods - generally well described, although I would like to see a little more detail on the selection of the yoga videos (l 97-103) If some videos were identified during beta testing what was the rationale for adding in additional ones that the research team felt might be suitable?

We have added information about the rationale for choosing videos that would cultivate emotional regulation and self-compassion.

Recruitment and analysis all described adequately.

Results

p. 13/4. I'm somewhat confused by the filming of additional yoga videos. The results indicate that these were developed, added to the sequence but not reviewed by study participants. Could authors provide more detail as to the rationale for these additions and why they were not reviewed in this phase of the study?

On page 7 we provided information about the videos and their purpose of being integrated into the prescription for phase 2 along with the tested videos. The design of these videos was based on feedback from a previous beta-test (published) of an online yoga intervention in women with stillbirth. These videos were filmed also because Udaya videos are made for the general public and we wanted videos specific to the population. The requirements for what the yoga instructors had to do to develop the videos (under the direction of the research team) is on page 9 (filming of additional yoga videos).

We have added some terminology to the results refering the reader "above" to clarify this information.

Interview results

These are well described and provide useful insights into the barriers to involving minority women in a yoga intervention study. In particular they provide insights into cultural barriers (p.16) and preferred environment for practicing yoga. The interviews provide useful insights into effective recruitment methods, highlighting the value of using social media routes using trusted sources of information. Participants were also asked about the most appropriate time to approach mothers after a stillbirth. There was wide variation in their answers (from a week to no time limit). Insights were also provided on the design of recruitment materials and incentives.
Thank you!

Discussion

The discussion is well structured with reference to relevant literature. However a couple of points that need addressing:

I am again confused by the development of the new yoga videos (l.446). If these were in response to feedback and results from this phase of work that would make more sense, but this is not clear from the paper.

We have information about this on page 7 and added referral to this in the results on page 8 where the videos are mentioned again.

As acknowledged, this is a very small study. There is detailed reporting of findings from the interviews with little overall evidence of thematic synthesis. But if the intention is to inform the next phase of the overall project these insights are no doubt valuable. It is not clear from this paper if and how the insights from minority women, in particular around recruitment materials and barriers to yoga uptake, have been integrated into the next stage of the study. More details on this are needed in this paper.

We appreciate this comment and are grateful that you believe that the insights we have shared are valuable. We are currently conducting data analysis from Phase 2 of the study. We will be sharing the methods that were conducted based on this paper in that paper. I have added two sentences to the conclusion with examples of some of the methods in the approach based on our findings (i.e., fliers with ethnically diverse women, reaching out to groups that cater to ethnically diverse women to advertise, monetary incentive, and recognizing the birthday of the stillborn child during the study). We hope we have addressed what you are asking for.