Reviewer's report

Title: Creative music therapy to promote brain structure, function and neurobehavioral outcomes in preterm infants: a randomized controlled pilot trial protocol

Version: 0 Date: 22 May 2017

Reviewer: Margarita Corry

Reviewer's report:

Thank you for the opportunity to review your protocol.

In general it is a well written paper and the study is theoretically based. It is a new area of research as the authors state that it is the first in the world.

I have just a few points that the authors might consider:

Sample size: I understand that a sample size calculation is not appropriate for a pilot study but I am left wondering why you have chosen a sample size of 30 in each group? You can justify that using the literature on pilot studies (see reference 32 and 34 in a study by Pincus T., Anwar S., McCracken L., McGregor A., Graham L., Collinson M. & Farrin A.J. (2013) Testing the credibility, feasibility and acceptability of an optimised behavioural intervention (OBI) for avoidant chronic low back pain patients: protocol for a randomised feasibility study. Trials 14(1), 172-176).

Statistical analysis: In line with best practice you need to be clear on the purpose of the statistical analysis and what results will be generated and reported.

Page 6 line 23 - REF - what does this mean? As this is not blind peer reviewed it is appropriate to include the reference even if it identifies the authors.

Page 6 - is the music therapist the primary author. If the music therapist (the interventionist) is part of the research team how will the risk of bias be minimised, especially if that person is the one recording the data in relation to parental involvement and environmental influences.

Page 7 line 8 and 9 - will you use a standardised form to record this data and who will record it.

Page 7 line 19 - I think it is important for transparency to state what 'third party' will do the central randomisation. As the study is ongoing this information is available.

Page 7 - line 53 and 54 - Is it necessary to repeat the hypothesis here in this section is on data analysis. If you wish to do so it might be useful to link it more eg. In order to test the null hypothesis that ........................... the following statistical analysis tests will be conducted: and then outline the tests.
Titles and legends for table and figure: I note a title for both at the end of the reference list. To me the title does not reflect the content. The table is more than the course of the music trial as it also includes outcome measures and the Figure is not the formulation of the hypothesis - perhaps it is more correctly 'Factors leading to the development of the hypothesis'

Table 1, needs a legend to explain the abbreviations. I note a list of abbreviations but for the reader a legend with the relevant abbreviations makes it easier to read.

Just an observation: I note that the study has been recruiting since Jan 2015 and it is now 2017. The protocol is written in the future tense which is as expected in a protocol but it feels a little strange to read what you will do when you are actually doing it.

As the study is recruiting for two years now and is still on-going it would be helpful to the reader to know more about the study site. How many pre-term births are in the unit (on average) every year? What is the expected duration of this study? Has feasibility work been done prior to the pilot study? If it takes so long to recruit why haven't the authors considered extending the study to other sites?

I note that you state that preterm babies who are not stable enough are excluded as they may be over stimulated but what about the study participants. Are you collecting data on possible adverse events in the study group? How do you know that some of them will not be over stimulated? I note you will monitor for safety of all participants but what will be considered an adverse event of this intervention as opposed to a preterm's reaction to something else in the environment? Is there a particular time of day for the delivery of the intervention eg. morning, afternoon or evening?

I hope these comments are helpful.

Kind regards

Margarita

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