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: 05 Apr 2017

Reviewer: Neil Wright

Reviewer's report:

This manuscript describes the protocol for a pilot trial investigating the use of creative music therapy (CMT) for preterm infants. CMT is hypothesised to improve brain growth and development in the short term and cognitive, behavioural and motor development in the longer term. The authors provide a detailed background and justification for a randomized controlled trial of this intervention.

This study is described as a pilot trial, but the objectives are not clear. There is no indication of the areas of uncertainty to be investigated in preparation for a full scale trial. The authors provide hypotheses on the effects of the CMT intervention, and state this is the first trial to examine "short- and long-term effects". However, a pilot trial is not suitable to address these hypotheses or investigate effectiveness of an intervention.

The authors describe statistical analyses, including providing a level for statistical significance. A focus on significance testing is unlikely to be appropriate in a pilot trial with no sample size calculation. It would be more suitable to report results that would be useful for planning a full scale trial. The authors also state that infants in the control (standard care) group who are exposed to music from parents will be excluded from the analysis. Although estimation of a treatment effect is not the purpose of a pilot trial, it is worth noting that this prevents an intention-to-treat analysis and could introduce bias in estimating a treatment effect.

It would be useful to have more specific descriptions of the outcomes listed in manuscript. The authors could include the exact measurement or scales as well as the method of collection (e.g. what will be measured in the "Visual and hearing exam"). The outcomes should also match what is provided in the ClinicalTrials.gov registration record. Follow-up for the trial extends to 5 years of corrected age for the participants. It is not clear why long term follow-up is required for this pilot trial.

The authors provide a good description of the CMT intervention. A minimum of 10 sessions of CMT are to be delivered, but it might be useful to record the number and length of the sessions received. This would be useful, when reporting the trial, to provide detail on the extent of the intervention delivered.

The authors should provide some justification for the sample size of 60 (30 per treatment group), related to the objectives of this pilot study.
The title of the manuscript should indicate that this is a protocol for a pilot trial.

In Table 1 it would be helpful to label the rows, to clarify what is shown in each row.

Further minor suggestions:

In the 'Background' section of the abstract, the end of last sentence should be: "… will have developmental benefits in short- and long-term brain function."

In sub-section "Neurobiology of music during early life", sentence 3 should start: "This is particularly important following preterm birth …"  

In the second paragraph of the sub-section "Neurobiology of music during early life", the end of the first sentence should be: "… into the newborn period and through early neonatal life" or "… into the newborn period and during early neonatal life."

In the sub-section "Potential benefits of creative music therapy (CMT)", the fifth sentence should read: "… tailored to the infant's needs …"

In the sub-section "The intervention", the second sentence appears to have a missing reference "(REF)".

In the sub-section "Outcomes", the sentences after the lists of secondary endpoints should start: "Additionally a parental questionnaire …"

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