Reviewer’s report

Title: Training attention control of very preterm infants: protocol for a feasibility study of the Attention Control Training (ACT)

Version: 0 Date: 16 Jun 2019

Reviewer: Raff Calitri

Reviewer's report:

I very much enjoyed reading this protocol and recognise that the planned research, should it progress to a definitive trial and be successful, has the potential to support the development of very premature babies. This is a valuable research agenda. The protocol is well written; it is very clear what the processes/procedures will be for participants.

They authors however do not provide very much information about the governance and management of the trial. I would have expected to see a clear statement as to who the trial sponsor is along with their role/responsibilities. Similarly, the authors should report whether there has been the institution of a trial management group, trial steering committees, and data monitoring committee. It might be that the team felt these groups were not necessary -I would argue that they are essential for a trial - if this were the case, they should please explain why.

It is considered good practice to report at this early stage your data management plan. You will be collecting eye tracking data from VP babies and questionnaire and some qualitative data from parents/guardians. How will you be managing this data? How will you anonymise the data? What are your storage plans - how long will you store the data for and you will be able to access it? Essentially there needs to be some comments as to whether you will be adhering to the GDPR and Data Protection Act 2018.

Similarly, it would be helpful to know what plans you have for managing qualitative data. What will you do with the audio recordings? Will they be deleted once verbatim transcription has been carried out? How will you ensure that parents (and babies) remain anonymous when reporting findings?

There must be some comment on potential harms/ adverse event (AE) monitoring. Even if the trial is considered to be low risk this needs to be explicitly stated. Do you have an AE reporting procedures in place? If not, please say why it is not necessary.

Additional points:

i. Please clarify whether consent is verbal or written consent?

ii. Please clarify who will perform the statistical analyses (e.g., a statistician independent from eth trial team)? Will they be blind to trial arm?
iii. Just out of interest - will you capture whether parents/guardians and Experimenter 2 guessed outcome allocation? Asking experiments at eth end of testing and parents at the end of the final outcome assessment would help us understand whether blinding worked.

Level of interest
Please indicate how interesting you found the manuscript:

An article of importance in its field

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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