Reviewer’s report

Title: A novel cognitive behavioural intervention with Theory of Mind (ToM) training for children with epilepsy: protocol for a case series feasibility study

Version: 0 Date: 26 Sep 2018

Reviewer: Cheney Drew

Reviewer's report:

Thank you for the opportunity to review this manuscript, however, it has been a length process as it is an incredibly long paper. I would agree with the authors that the social aspects of epilepsy are a neglected in terms of treatment and care and that interventions addressing this are welcome. However, I have several comments regarding the manuscript and study design which should be addressed prior to publication.

Overall this manuscript strikes me as two separate publications. One should focus on the intervention development and the second should focus on the protocol for testing the feasibility of the intervention, this would reduce much of the confusion reading the manuscript where methods for intervention development and feasibility testing have the same sub-headings. I would suggest that the section on intervention development is not within the remit of Pilot and Feasibility Studies and the authors should seek alternative journals for publication of this work. To that end, my review has concentrated on the feasibility testing section of the manuscript.

In general, the manuscript could be improved by removing extraneous detail and shortening significantly.

Below are some more detailed comments and questions for the authors.

Introduction: This could be significantly shortened and tightened up by removing the background on intervention development.

I do not think Figure 1 adds any additional information or clarity of information to what is already in the text. It would be sufficient to refer to the unamended figure of the complex intervention lifecycle taken from the MRC guidance.

Methods: In the manuscript the methods section describe general study aims; these are then listed in the SPIRIT checklist as objectives. Aims and objectives are not the same thing- and they should be called one or the other.

Recruitment: The authors do not give a rationale for why only children with GGE or TLE are going to be recruited to the study. Why exclude children with other forms of epilepsy as surely
they are subject to the same issues of poor social functioning? Please include an explanation of this inclusion criteria.

Please could the authors detail what they mean by the inclusion criteria "currently controlled seizures with medication". Does this mean that the children must be seizure free, or are currently experiencing a stable seizure frequency? If so, how will this be assessed? What does it mean for eligibility of the child has recently undergone. Is undergoing active AED changes? Or is there a seizure frequency cut-off? This criterion needs additional clarity.

The last sentence in the paragraph regarding inclusion criteria (p.20) - "Children who are currently engage in concurrent group or individual treatment with a psychologist will not be recruited..." should be included in the following paragraph as a specific exclusion criterion.

There is repetition of criterion between the inclusion and exclusion sections. If an inclusion criterion is "a current diagnosis of GGE or TLE", then an exclusion criterion of "no longer meet criteria for GGE or TLE" is not required. Any similar repetition of criterion between the two sections should be removed.

I am struggling with the concept of evaluating the feasibility and acceptability of the intervention by asking clinicians to review the intervention and provide opinion. This seems more like part of intervention development in that the expert clinician opinion would provide feedback on the potential feasibility and acceptability of the intervention. In an evaluation/trial setting, one would expect clinician rated acceptability of the intervention to be provided by clinicians/allied healthcare professionals responsible for delivering the intervention. The way the case series has been designed, there would be a limited sample of clinicians delivering the intervention to provide data on acceptability of the intervention in practice.

The fine detail on the materials for the intervention and how cognitive behavioural skills, language instruction, executive functioning strategies and theory of mind training are incorporated into the intervention could be included in a separate intervention development paper. This manuscript could then focus on the design and methods for the piloting and feasibility of the intervention. The level of detail (provided there were an additional intervention development paper) given in the SPIRIT checklist would suffice.

With regards to the home-based learning tasks, how will the fidelity/adherence to these tasks be assessed? The text on p.28 says that home based tasks will be reviewed at each subsequent session, but does this not need to be formally assessed to ensure consistency of delivery of the intervention between participants?

On p. 18 and in the SPIRIT checklist the study is described as having a double baseline design, however, Figure 3 and the accompanying text suggests that there will only be one baseline measure taken. There is some further detail in the analysis section which suggests that multiple baseline measures will be taken. It is unclear as to whether these are multiple measures assessed
at a single time point or specific measures repeated across multiple timepoints. I think it is the former, but could the authors please clarify. The manuscript would be strengthened by clarifying how the 'double baseline' part of the study will be achieved.

Assessments: With the weekly on-line questionnaire- it is not clear if this will be completed by parents and children or by parents or children. Please clarify.

Outcome Measures: the authors state that the primary outcomes are feasibility and acceptability which are to be measure in a myriad of ways, including responses from independent clinicians, but in some instances this is not applicable to testing the feasibility of the intervention, for example the use of the BTPS by independent clinicians (point 5, p.34) will not provide specific barriers and facilitators to the delivery of the intervention in question. Going back to one of my earlier remarks, I suggest the authors consider removing the sections relating to independent clinician review from this manuscript and putting that as part of intervention development.

The discussion should come after the data management, risk/ benefit, adverse events sections.

The list of abbreviations does not contain all the abbreviations used in the manuscript. All the abbreviations used for the outcome measures have been omitted.

TiDIER Table

This is a completed TidIER table, but is not actually a TiDIER checklist as the authors suggest

Both the TiDIER table and the table summarising the studies evaluating Theory of Mind interventions in children are both labelled as table 1.

Section 2: This should be written as the aims/ rationale for the intervention, not for the feasibility study

Section 4: This should be written to include what procedures are included as part of the intervention, not as procedures for the case series evaluation.

Section 6: More detail on number and length of sessions should be included in this section.

SPIRIT Checklist

Details should be included in the body of the manuscript and not just in the SPIRIT checklist - i.e. the data management details should be written out in the new manuscript. Generally, the SPIRIT checklist just needs to be completed with the relevant page number where each item is described in the manuscript. The detail of the manuscript does not need to be re-produced in the checklist.
I have a minor concern about the lack of Sponsor for this trial. This may be due to a lack of familiarity with trials regulations in Australia, but in my experience in is mandated by ethics committees that a sponsor should be in place to ensure maintenance of standards and regulatory adherence. Please can the authors clarify this?

**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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No