Reviewer’s report

Title: Interpersonal Art Psychotherapy for the treatment of aggression in people with learning disabilities in secure care: A protocol for a randomised controlled feasibility study

Version: 0 Date: 10 Jun 2017

Reviewer: A.O. House

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The paper describes the protocol for an individually randomised RCT. I gather that the project is funded as part of the academic training of the first author (SH) and that it is already underway. My suggestions about improvements therefore should be dealt with either by modification of the presentation (for example to clarify or provide missing information) or by an extension of the discussion about limitations.

1. It would help if the title indicated this was a protocol.

2. I didn't find it easy initially to work out what art therapy was aimed at achieving. The second paragraph in Background is unhelpfully vague; the sessional account that describes the specific intervention is clear and easy to follow but none of the three references appears to be to the manual cited in the text. More generally, it would help to have a clearer pointer to the status of this therapy in the wider art therapy world. Is the therapy itself innovative or unusual, or is the innovation more about an art therapy application in this population? All three references in the methods are to the first author's own work, and the only reference to theory is to a textbook I couldn't readily access. As described, the art seems like a technique for elicitation and facilitation of therapeutic discussion, and a clearer explication of the theory or logic model would help.

3. In the last paragraph of Background the authors say that NIHR-HTA recommend consideration of attention controls or active comparators, citing an NIHR-funded evidence synthesis. In fact the standard NIHR disclaimer makes it absolutely clear that attributing NIHR endorsement to outputs like this is not appropriate. Not all therapists agree about the place of attention controls and some describe the approach as "intention to fail" because of the absence of therapist expectation of benefit; reference to this argument would help.

Most of the paper then goes on to describe an individually-randomised RCT of art therapy + TAU Versus TAU.

1. The important behavioural inclusion criterion is not standardised - it should be stated how it will be identified and by whom;

2. Detail is needed about how randomisation will be undertaken and by whom; Elaine McColl is an author - is the Newcastle CTU managing this?
3. The section on capacity and consent is detailed but even so would be helped by a sentence, especially for a non-UK audience, about how independent ethical approval is required and obtained in the NHS. Many (all?) of the participants will be subject to compulsory detention and I could have done with a little more clarity about how independent support for autonomous decision-making was ensured.

4. Presumably, accessible versions of participant information sheets and consent forms were generated and it would be good to see them in supplementary materials. What will happen about people who give consent but can't sign?

5. The section on sample size cites Teare et al as suggesting a suitable sample size and says that the current study is less than 20% of the size recommended. In fact the paper cited suggests N=70 so the present study is nearer 30% of that. I couldn't really follow the argument about why the study is designed to be too small. Is the truth of it that the budget (which is often constrained for training fellowships) won't stretch? That's fair enough if true; what's then needed is some explanation of how the study will nonetheless be able to answer the feasibility questions.

6. How many art therapists have been trained and are delivering therapy? In considering the likely effect of clustering by therapist, what consideration has been given to the question of No. participant per therapist or number of therapists per centre?

7. I couldn't see when (in relation to randomisation) outcome measures were to be taken, nor by whom.

8. The analysis plan could make clearer what will be taken as criteria for feasibility of a definitive trial - for example in terms of recruitment rates (given what is known about the size of the target population), fidelity to therapy and outcome recruitment rates;

9. In relation to sample size for a definitive study (a follow on from my earlier point), the study will obtain a pooled estimate of mood (sd) for four subscales of the proposed primary outcome (MOAS). Given that, presumably, all participants will not score high on all subscales, what score will drive the sample size estimate, is enough known about clinical importance of change, and is N=20 likely to yield a precise enough estimate?

10. There is a fair bit of non-structured and qualitative data collection, but the handling of data and analysis plan is not clearly described and nor is there an indication of how it will drive the design of the main trial.

As a presentational matter, I thought it would help if the small case series to evaluate the attention-control idea were pulled out and described in a separate section. I found it a bit confusing to have it interleaved with the main trial report.

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