Author's response to reviews

**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

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Reviewer reports:

Reviewer #1: 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.

R1 It would help if the title indicated this was a protocol.

The title has been changed to –

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

R1 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 background section including the second paragraph has been rewritten to include reviews of art therapy studies. See lines 57-95.
R1 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.

The three referenced papers have led to a ‘working manual’ that has not yet been published. Wording on lines 93-95 has been changed accordingly to... 'This preliminary work has led to the development of a working manual for interpersonal art psychotherapy that is being considered in this study.'

R1 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 art therapy application in this population?

The background section has been rewritten to place the therapy in a wider context of literature and systematic reviews of art therapy studies. See lines 57-95.

R1 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.


R1 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.

Additional explanation has been added to lines 184-187 and 203-206 regarding the therapy aims in relation to the session schedule.

Explanation: as a result of this feasibility study findings a full Logic Model will be devised prior to a pilot trial / RCT.

R1 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.

Specific reference to NIHR-funded evidence synthesis in relation to attention control has been removed and this section has been re-worded to closely relate to specific recommendations in the reference document. See lines 107 to 119. (I would be happy to receive suggested references for ‘intention to fail’ should the reviewer wish me to refer to this specifically in addition to the revised text).

R1 Most of the paper then goes on to describe an individually-randomised RCT of art therapy + TAU Versus TAU. The important behavioural inclusion criterion is not standardised - it should be stated how it will be identified and by whom;
To clarify this, the wording ‘(As identified by the clinical team)’ has been added on line 273 for clarification. This inclusion criteria is based on the subjective opinion of the clinical teams in the participating sites. This is the first study of its type and standardised behavioural inclusion criteria will be generated from this study.

R1 Detail is needed about how randomisation will be undertaken and by whom; Elaine McColl is an author - is the Newcastle CTU managing this?

Explanation: The CTU is not managing this study although Elaine is an author. The section on randomisation has been amended to include how randomisation and allocation will be undertaken and by whom, see lines 282 to 289.

R1 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.

A sentence about independent ethical approval has been added on line 291 – 292. Explanation: As stated in the text, participants are given a minimum of 2 days after they receive study information in order to make their decision independently of research and ward staff.

R1 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?

Explanation: Consent forms are presented in simplified language. It is a weakness of the study that provision was not made for people who can give consent but cannot sign.

R1 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.

The reviewer’s comments are appreciated. The wording in this section has now been changed explaining that the small sample size reflects the resources and time available, amongst other things, to conduct the study. See lines, 326 -333.

R1 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?

The number of therapists at each centre has been added in line 180.
R1 I couldn't see when (in relation to randomisation) outcome measures were to be taken, nor by whom.

Wording to line 289 has been amended to include - Participants can be then informed if they have been assigned to either interpersonal art psychotherapy or to the waiting-list and re-assessed at four months by a research assistant.

R1 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; 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?

Explanation: To inform future study design, potential primary outcome measures and their standard deviation estimates obtained will be used to investigate a possible sample size calculation. Decisions around a clinically important difference will be based on clinical opinion or available literature at the time. Data from this, admittedly small study will form the best available evidence of variability on these potential primary outcome measures in this population.

R1 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.

A reference for Thematic Analysis has been added to line 257-258.

R1 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.

Information about the case-series has been separated from the section on ‘Sample size’ for the main trial. See, 329-330.

Reviewer #2: Secure provision for people with learning disabilities are currently in transition - this is a contextual factor but raises certain issues - perhaps the role of art psychotherapy for those with an offending background, particularly around aggression, but currently cared for in community settings, might be worth considering as part of the study. If not, then better justification of the sample selection, and non-inclusion of those in non-NHS settings, or on Community Treatment Orders or subject to Guardianship, is probably necessary.

Explanation: The study is now open to recruitment. The scope of this study is to look at the feasibility of running a trial in secure settings. I will note the reviewer comments for a possible future study.
R2 The literature review could demonstrate better understanding of art psychotherapy, particularly to justify the selected approach, since the effectiveness of this treatment might be most effectively determined through qualitative or mixed research methods. Some discussion, for example, of art psychotherapists' criteria for success would be useful and might differ from the information provided by other methods. Not the clearest read but an interesting proposed study.

The background section on art psychotherapy has now been amended to include a number of systematic reviews (See comments in response to reviewer #1, point 2)

R2 I'm not sure why the authors use the title of Interpersonal Art Psychotherapy when all AT is by definition interpersonal i.e., between client/s and therapist.


R2 I also feel there needs to be a clearer explanation of the Manualised Art Psychotherapy the study is going to be considering - perhaps even examples to illustrate - as far as I'm aware, this is not a common practice or approach.

I hope this has now been addressed in response to reviewer #1 in point 2.

R2 I did wonder on p7 whether the battery of validated measures would negatively impact or undermine the effectiveness or benefits of the AT sessions (which need time to unconsciously or non-consciously be processed).

Explanation: Historically, questions in relation to this issue have been made by art therapists about using measures in clinical practice. However, measures are now routinely used in many clinical settings in relation to current art therapy practice. The feasibility study objective 3 requires assessment of the burden of outcome measures on participants and they have been included for this reason.

R2 Some of the referencing appears incomplete (nos 4 and 5) but this may be pedantic…

Thank you, all referencing has now been revised and corrected.