PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of Trauma-Focused Art Therapy (TFAT) for psychological trauma: Study protocol of a multiple baseline single case experimental design
AUTHORS	Heijman, Jackie; Wouters, Hans; Schouten, Karin Alice; Haeyen, Suzanne

VERSION 1 – REVIEW

REVIEWER	Moss, Marc University of Colorado Denver - Anschutz Medical Campus, Medicine
REVIEW RETURNED	03-Dec-2023

GENERAL COMMENTS	Thank you for asking me to review the study protocol manuscript entitled, “Effectiveness of Trauma-Focused Art Therapy (TFAT) for psychological trauma: Study protocol of a multiple baseline single case experimental design”. This is an important area of research that could eventually result in novel treatments for patients with PTSD. I do have a few concerns about the protocol. Major Comments: 1. Regarding the eligibility criteria, it would be helpful to define the three following criteria more definitively: A. dealing with trauma related symptoms, B. suitable for individual art therapy C. and/or not benefiting enough from regular ongoing therapy. For example, what criteria or survey instruments will be used to define the presence of these criteria. 2.Since “not benefiting from regular ongoing therapy” is an inclusion criterion, will participants that have not engaged in other forms of therapy be eligible for the study? 3. Will the TFAT intervention be conducted in person or virtually? This should be explicitly stated. 4. It might be beneficial to include the actual interview guides for the participants and therapists as a Table in the manuscript. 5. From a safety perspective, how will the study monitor the development of suicidal thoughts that could be provoked by study participation? What are the safety protocols if one of the study participants develops severe suicidal ideas? This information should be included in the protocol paper. 6. The sentence on page 11 lines 25-30 “based on a power analysis for the MBSCED…” should be moved to the analysis of data section,

	6. It appears that the sample size for the study is only 12 subjects? Is the study adequately powered with this sample size? The analysis of quantitative data section only states that an alpha of 5% will be adopted. The manuscript should include more information about the effect size. 7. In addition, the article should clearly state what is the primary outcome variable, even though it is mentioned in the summary in Appedice A. 8. The planned dates that the study will be conducted should be included in the manuscript. Minor Comments: 1. Line 8-9 should add the word “in” before daily practice so that it reads “often used in daily practice”. 2. Line 20, please spell out the acronym for “NICE” i.e National Institute for Health and Care Excellence.

VERSION 1 – AUTHOR RESPONSE

Thank you for submitting your manuscript entitled "Effectiveness of Trauma-Focused Art Therapy (TFAT) for psychological trauma: Study protocol of a multiple baseline single case experimental design" (manuscript ID bmjopen-2023-081917.R1) to BMJ Open. This has been returned to you to address the following issues before it can be assigned to the Editor.

1. Funding Information:
- You have indicated a funder/s for your paper. Please ensure to provide an award/grant number for your funder/s in the main document file and in ScholarOne.

As we have gained funding from a private organisation, we have not received a grant number. We have now added the CoC number and contract date in the manuscript:

“This study is funded by the Care and Cure by Creativity (CCC) Foundation; CoC number 41189407 (www.stichtingcccfoundation.nl), which seeks to enhance treatment and therapy. No grant number was issued (contract date 09-06-2022)."

2. Embedded supplementary appendix:
- Kindly remove all your Supplementary Appendix in your Main Document and upload it separately under file designation "Supplementary File" in PDF Format.

We have now removed all our supplementary files and added those as seperate supplementary files in PDF Format.

3. Confirm file if supplementary:
- We have noticed that you have uploaded the file "Interview guide TFAT English" under 'supplementary file'. However, we can't see any citation for this file within the main text. If this file needs to be published as supplementary file, please cite it as 'supplementary file' in the main text and upload it in PDF format. Or you can change the file designation into “Supplementary file for Editors only”.

We have now

Reviewer: 1
Dr. Marc Moss, University of Colorado Denver - Anschutz Medical Campus
Comments to the Author:

1. Thank you for asking me to review this study protocol manuscript. I would consider having an editor review the manuscript to ensure that the English is acceptable for publication, and that a statistical editor review the manuscript as the statistical analysis is very rudimentary.

We appreciate this advice. We concur that this is a new methodology and have now provided more specific information about the statistical analysis (p. 15-17). Specifically, we will use MultiSced. This is an application built with Shiny a framework to create interactive web applications that provide an interface to the R functionality (R Core Team, 2013). We also refer to Declerq et al. (1) for a detailed description and tutorial of MultiSced.

In addition, we have sent our manuscript to an unaffiliated professional native English speaker, who has reviewed and refined the manuscript for us, which has resulted in improvements in the English text.

Thank you for asking me to review the study protocol manuscript entitled, “Effectiveness of Trauma-Focused Art Therapy (TFAT) for psychological trauma: Study protocol of a multiple baseline single case experimental design”. This is an important area of research that could eventually result in novel treatments for patients with PTSD. I do have a few concerns about the protocol.

Thank you for recognising the importance of our area of research. Below, we address your concerns.

Major Comments:

1. Regarding the eligibility criteria, it would be helpful to define the three following criteria more definitively: A. dealing with trauma related symptoms, B. suitable for individual art therapy C. and/or not benefiting enough from regular ongoing therapy. For example, what criteria or survey instruments will be used to define the presence of these criteria.

We agree with this comment and have now specified the eligibility criteria. In Dutch mental health institutions, it is often determined by a multidisciplinary team of psychologists/psychiatrists/art therapists if a patient is eligible for a certain treatment. Patients will be enrolled when they meet the following eligibility criteria: 1) aged between 18-65, 2) dealing with trauma-related symptoms (i.e. nightmares, flashbacks, persistent fatigue or depression, anxiety in regards to specific triggers, sleep disorders), 3) being suitable for individual AT and/ or not benefiting enough from regular ongoing therapy, and 4) having motivation to work on traumatic memories. The meeting of the criteria will be based on the discretion of the patient's' multidisciplinary treatment panel (consisting of a psychiatrist, psychologists, sociotherapists, and art therapists), and in consultation with the patient itself. Acute psychosis or crisis are exclusion criteria, as well as intellectual disabilities, as to be able to complete and understand all questionnaires.

We have not selected criteria on instruments to define the presence of criteria, since, in our experience, trauma-related symptoms can occur in diverse shapes and forms. We want to include a broad variety of patients. At the end of our study, we will hopefully be able to comment on the differences in results in patients who score higher or lower on the baseline PCL-5.

2.Since “not benefiting from regular ongoing therapy” is an inclusion criterion, will participants that have not engaged in other forms of therapy be eligible for the study?

The criterion states: and/ or not benefiting enough from regular ongoing therapy. Therefore, participants who have not engaged in other forms of therapy but are eligible for art therapy and have trauma-related symptoms, will be eligible for the study as well. We will record the usual care that a patient has received. In this way, we will be able to examine the additional value of art therapy for patients with and without other earlier care.

3. Will the TFAT intervention be conducted in person or virtually? This should be explicitly stated.

Thank you for pointing this out. The intervention will be conducted in person, which we have now added at p. 11 (Intervention).

4. It might be beneficial to include the actual interview guides for the participants and therapists as a Table in the manuscript.

Thank you for this suggestion. As per request by the editor, we have now added our semi-structured interview guides as a supplementary file.

5. From a safety perspective, how will the study monitor the development of suicidal thoughts that could be provoked by study participation? What are the safety protocols if one of the study participants develops severe suicidal ideas? This information should be included in the protocol paper.

This is a very important comment which we will take seriously during our study. We will monitor this by instructing the therapists to inspect the BDI-II questionnaire weekly (question 9), which focuses on suicidal thoughts. When a participant scores 2 or 3 on this question, the art therapist is instructed to confide this in us, and to consult the main practitioner on their estimation of the patient's suicidality before continuing their intervention. The main practitioner, art therapist and patient will then engage in a 3-way conversation in which it is discussed if these feelings are new to the patient, if they know why they started, and if it is wise to continue the treatment. When the patient, art therapist or main practitioner estimates that the treatment should be terminated, it will. We do not have a specific score (i.e. '3' on the BDI-II), which will end the treatment, but will always discuss this matter in a personal way because suicidal thoughts are not uncommon in patients with PTSD (2). We want to confide in the clinicians' (and patients') knowledge and estimation of the situation, to decide what is best for a patient. We have described this on page 17 of the manuscript.

6. The sentence on page 11 lines 25-30 "based on a power analysis for the MBSCED…" should be moved to the analysis of data section

We have now moved these lines to the analysis of data section (p. 15).

6. It appears that the sample size for the study is only 12 subjects? Is the study adequately powered with this sample size? The analysis of quantitative data section only states that an alpha of 5% will be adopted. The manuscript should include more information about the effect size.

*We use the innovative MBSCED design. Herein, patients are their own "control" and are repeatedly measured over 16-18 weeks. This yields 192-216 data points in total (I.e. 12 participants * 16-18 measurements). Bouwmeester et. al (3) has previously stated that a minimum of 12 subjects will indeed adequately power a MBSCED design.*

In addition, we have now provided a more detailed explanation on the study design and the statistical power of our study (p. 15-17).

7. In addition, the article should clearly state what is the primary outcome variable, even though it is mentioned in the summary in Appendice A.

Thank you kindly for this comment. In the registry, we first selected the SERATS and the PCL-5 as our primary outcomes. However, the PCL-5 will only be measured twice in this design: it is a questionnaire focusing on trauma-related symptoms. Hence, it would be too burdensome for patients to complete this trauma-related questionnaire weekly. In contrast to other questionnaires, the PCL-5 is therefore not included in the MBSCED design. Consequently, we have removed the PCL-5 as our primary outcome and have now selected it to be a secondary outcome next to other negative symptoms (depression) and positive mental health outcomes; this concurs with the new two-continuum model, where we see that positive outcomes must be treated alongside negative symptoms. Now, there is no hierarchy in importance in our symptom-related outcomes. The SERATS is the only primary outcome, which focuses on self-expression and emotion regulation in art therapy; which is precisely our main area of interest: art therapy.

We have stated this explanation in our manuscript now (p. 15-17).

8. The planned dates that the study will be conducted should be included in the manuscript.

We have now added the planned dates to our manuscript (Study setting, p. 9)

Minor Comments:

1. Line 8-9 should add the word “in” before daily practice so that it reads “often used in daily practice”.

Thank you for this detail: we have now added the word “in”.

2. Line 20, please spell out the acronym for “NICE” i.e National Institute for Health and Care Excellence.

Thank you for this suggestion. We have now spelled out the acronym.

References

1., Jamshidi L, Heyvaert M, Declercq L, Fernández-Castilla B, Ferron JM, Moeyaert M. A systematic review of single-case experimental design meta-analyses: Characteristics of study designs, data, and analyses. Evid Based Commun Assess Interv. 2022;1–25.

2., Sareen J, Houlahan T, Cox BJ, Asmundson GJG. Anxiety disorders associated with suicidal ideation and suicide attempts in the national comorbidity survey. J Nerv Ment Dis [Internet]. 2005;193(7):450–4. Available from: http://dx.doi.org/10.1097/01.nmd.0000168263.89652.6b

3., Bouwmeester S, Jongerling J. Power of a randomization test in a single case multiple baseline AB design. PloS One. 2022;15(2).