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Effectiveness of Trauma-Focused Art Therapy (TFAT) for psychological trauma: Study protocol of a multiple baseline single case experimental design

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Abstract

Introduction. Although treatments like EMDR or (narrative) exposure therapies are common treatments of first choice in psychological trauma, art therapy is also often used daily practice although sound evidence is lacking. Patients seem to benefit from art therapy because of its more indirect, nonverbal, experiential approach. This protocol paper describes a study to examine the effectiveness of a 10-week individual Trauma-Focused Art Therapy (TFAT) intervention.

Methods and analysis. A mixed method multiple baseline single case experimental design (MBSCED) will be conducted with 25-30 participants with psychological trauma. They will be randomly assigned to a baseline period lasting 3-5 weeks, after which the TFAT intervention starts (10 weeks), with a follow-up period lasting 3 weeks. Quantitative measures that are completed weekly are: the Beck Depression Inventory (BDI-II), the Mental Health Continuum Short Form (MHC-SF), the Resilience Scale (RS), the Rosenberg Self-Esteem Scale (RSES), and the Self-expression and Emotion Regulation in Art Therapy Scale (SERATS). The PTSD Checklist (PCL-5) is only completed at week 1 and week 10. Qualitative instruments are a semi-structured interview with both the patient and the therapist, and a short evaluation for the referrer. Artwork will be used to illustrate the narrative findings. Quantitative outcomes will be analysed with linear mixed models using the MultiSCED web application. Qualitative analyses will be performed using thematic analysis with Atlas.TI.

Ethics and dissemination. This study has been approved by the ethical committee of the HAN University of Applied Sciences (ECO 394.0922). All participants will sign an Informed Consent and data will be treated confidentially. Study findings will be published Open Access in peer reviewed journals.

Trial Registration. This study has been registered at http://www.ClinicalTrials.gov (trial registration number NCT05593302.

Strengths and limitations

+ This study uses both quantitative and qualitative outcomes
+ Beyond decreasing trauma related symptoms, this study also focuses on positive mental health outcomes
+ This study uses a Multiple Baseline Singe Case Experimental Design (MBSCED), which requires fewer participants and is therefore a feasible alternative for a Randomised Controlled Trial (RCT)
– Participants cannot be kept blind for the intervention. This might cause bias in completing the questionnaires
– Because (art) therapy always requires individual attunement to each patient's needs and process, the executed protocol might slightly differ in exact execution

Introduction

About eighty percent of people experience one or more shocking event in their lives. Ten percent of them subsequently develop a Post-Traumatic Stress Disorder (PTSD) (1). PTSD is a trauma and stress-related disorder (2), characterised by severe symptoms of re-experiencing, avoidance and arousal. PTSD is diagnosed if symptoms last longer than one month. The disorder causes significant distress and impairment in social, occupational, and other areas of functioning (2).

According to Clinical Practice Guideline for the Treatment of PTSD (3) and NICE Guidelines (4), Cognitive Behavioral Therapy (CBT), Narrative Exposure Therapy (NET) and Eye Movement Desensitisation and Reprocessing (EMDR) are treatments of choice for PTSD. However, these interventions do not work for everyone – more than a third of patients do not benefit (5). This includes those with severe traumatisation, with a poor verbal memory and patients who find it difficult to talk about traumatic experiences.

For these patients, visual art therapy (AT) may offer a promising treatment, because the visual, tangible and experiential character of AT fits well with the often wordless, visual and sensory nature of traumatic memories (6). AT is one of the creative art therapies (CATs): The treatment tradition of CATs spans about a century and includes the disciplines of art, drama, dance, and music therapy. In AT, numerous art materials, art therapeutic methods and techniques are used to give meaning to events in the past and to get a better grasp on one's own life. AT distinguishes itself from other treatments by its experiential approach and by the visible and tangible nature of the process and art product. Acting, doing and experiencing with visual art materials can counter the feeling of powerlessness and increase the feeling of control and self-esteem. Using art materials in AT triggers emotions: it enables access to traumatic memories (7; 8). AT makes it possible to

give shape to traumatic memories in the artwork in a safe and phased way (9; 7). The result of the artwork is visible, tangible and has a lasting character. As a result, one can literally distance oneself from the emotion, share with the art therapist what is made, to finally integrate it psychologically and give it meaning (10; 8). Taken together, this enables processing and integrating traumatic experiences. AT shows promising results according to patients and professionals but still requires substantiation by scientific evidence.

Trauma-Focused Art Therapy provides access to memories and emotions, enables to externalise these in artwork, and can help to put these into words. It may be a possible pre-therapy for other trauma-focused treatments (such as EMDR, CBT, NET). Experienced experts (11) underline the importance of the availability of trauma treatment based on AT because they believe it to offer an essential alternative to the usual verbal, cognitive approaches. The Posttraumatic Stress Disorder Improvement Report (12) also mentions more people with PTSD receiving trauma-oriented treatment as one of the most important focus points for improvement.

Schouten (13) developed the Trauma-Focused Art Therapy (TFAT) protocol. In a pilot study with patients with PTSD due to multiple and long-term traumatisation, this protocol has been tested and proved to be acceptable, feasible and applicable (14). Preliminary results show decreased PTSD symptom severity in some patients and adherence to treatment and treatment satisfaction of participants. This intervention is suitable for transferring this method between art therapists but has not yet been further investigated for effect or implementation in practice.

The developed TFAT intervention offers opportunities to improve the accessibility, quality and efficiency of trauma treatment, because patients who would otherwise not be treated or receive long-term treatments without results, now receive potentially effective treatment (14). The intervention is a short-term, individual and ambulatory trauma-focused art therapy consisting of

10 sessions (lasting 60 minutes each) in three phases (I Stabilisation and symptom reduction; II Trauma processing; III integration and meaning making). After the first phase of getting acquainted, creating safety and determining a list of memories, the second phase focuses on expressing and shaping positive and negative memories and associated feelings and thoughts. The third phase focuses on: reordering and merging the artwork and completing the AT (see Intervention).

Problem

Treatment guidelines for psychotrauma and stressor-related disorders in the Netherlands (15) state the following: "A survey among experienced experts shows that people are unanimously positive about AT and regard it as valuable, especially if patients are not yet well being able to talk about their traumas." A meta-analysis of dropouts in treatments for PTSD confirms this (16). Recounting traumatic memories in exposure-based talk therapies in detail was found to be poorly tolerated by patients. The goal of this research is to contribute to the development of evidence of AT for psychological trauma.

Research question

The main question in this study is: *Is the Trauma Focused Art Therapy (TFAT) intervention effective for treatment of trauma-related symptoms (including direct trauma symptoms, depressive symptoms, decreased well-being, decreased self-esteem, decreased resilience and decreased self-expression)?*

Additionally, the following question will be explored: *What is the perceived experience of the TFAT intervention according to patients, therapists and treating clinicians?*

Goals

The aim of this study is to gain insight into the effectiveness and functioning of trauma-focused AT to increase the quality and availability of trauma treatment. Consequently, the aim is to provide trauma treatment in line with the need of patients to work on personal recovery in a different way than usual, talk therapy. Upon findings in support of the effectiveness, the intervention will be further disseminated and implemented so that patients who are otherwise not treated or who receive long-term treatments without results, may now receive appropriate treatment.

Hypotheses

The hypotheses in this study are as follows:

The TFAT intervention is effective for treatment of trauma-related symptoms:

1. TFAT reduces trauma symptoms
2. TFAT reduces depressive symptoms
3. TFAT enhances self-confidence/ self-esteem,
4. TFAT enhances mental resilience
5. TFAT enhances self-expression and emotion regulation in AT

Regarding the perceived experience of TFAT by patients, therapists and treating clinicians, no hypotheses are made, as we aim to avoid confirmation bias in thematic analysis of interviews.

Methods and analysis

Design

This is a prospective mixed method study which combines quantitative and qualitative methods. The quantitative part of the study consists of a multiple baseline single case experimental

design (MBSCED). Herein, the effectiveness of the TFAT intervention can be evaluated. Participating patients are randomised for the time at which they start with the TFAT intervention. Effectively, this results in baseline periods which vary for participating patients between 3-5 weeks. Subsequently, all patients start with the intervention which lasts 10 weeks and a follow-up of 3 weeks. The MBSCED is a feasible design in which participants are followed closely over time at a substantial number of repeated measurement occasions. Quantitative results are measured weekly per person. With the randomisation of the baseline period, each participant functions as its own control, which provides the opportunity to isolate treatment effects (17). The MBSCED adequately deals with threats to the internal validity (e.g., maturation, history, and regression to the mean as rival explanations for improvement instead of the TFAT intervention). Measurements in the intervention period will be compared to measurements in the baseline, and follow-up period. The implementation of the TFAT protocol shall be concluded with in-depth qualitative interviews in which potential perceived effects by therapists and patients are investigated (see Figure 1).

Figure 1. Visualisation of study design and procedure.

[Insert Figure 1]

Note. Visualisation of the MBSCED design with patient 1 having a 3-week baseline and patient 2 having a 5-week baseline. This graph represents fictious examples with the ideal improvements in mental health outcomes increase in the intervention period which stay relatively the same in the follow-up period.

Study setting

This study will be conducted during 24 months in at least four different mental health facilities in the Netherlands in at least three different settings, including psychiatric hospitals, psychiatric forensic facilities, a refugee psychiatric facility, and/or general psychiatric departments. At least four art therapists will be selected to avoid that results can be ascribed to

specific factors of one therapist. Art therapists will be selected purposefully for working in varying fields of trauma-related populations (e.g., refugees, veterans, (sexual) abuse survivors, etc.) to account for the spectrum of trauma-related issues. It should be noted that one art therapist can provide multiple cases of patients. Only clinics with eligible participants will be selected, as to achieve adequate participant enrolment.

Eligibility criteria

Patients will be enrolled purposefully through art therapists and clinicians. Patients will be enrolled when they meet the following eligibility criteria: age between 18-65, dealing with trauma-related symptoms, suitable for individual art therapy and/or not benefiting enough from regular ongoing therapy. Acute psychosis or crisis are exclusion criteria. Based on a power analysis for a MBSCED, expecting a medium effect size (Cohen's d = .6), adopting an alpha of 5%, inclusion of twelve participants yields 80% power (18). Treatment as usual will be continued with the AT as add-on component. It is monitored which other psychological treatment each patient gets.

Procedure

Art therapists that carry out the TFAT need to have a certified degree in AT and are working in mental healthcare clinics or in private practices. Art therapists are recruited by snowball effect via the researchers' networks. They are offered a presentation on the study, including: the content of the AT intervention, the data collection methods and our instructions. They will then be invited to participate in the study. Participating art therapists will be provided with the TFAT intervention, questionnaires and a week-by-week guiding file. In this guiding file, therapists will record notes on the patients' sessions from their Electronic Health Record (EHR). All participating art therapists will be asked to join online supervision sessions to discuss occurring insights and

problems. After completing a TFAT intervention with a patient, a semi-structured interview with the art therapist will be conducted, focusing on experiences with the TFAT intervention and on perceived effects of the TFAT regarding the patient.

Patient participants will be recruited by their treating clinician on an indication for trauma treatment. They will then receive a full explanation of the study by the corresponding art therapist. No treatment and screening will start before patients sign an informed consent, in which data collection, ethics and data management are explained. Upon starting, patients will receive a patient number and a computer-generated, randomised baseline period lasting 3-5 weeks, after which the TFAT intervention starts (10 weeks), ending with a follow-up period of 3 weeks. The allocation sequence is designed by a researcher who is not involved in the data collection and briefing regarding the intervention. Another researcher assigns the generated starting points. Each week, patients will complete the selected questionnaires. At the start of the TFAT and after the final week of the therapy sessions, the PTSD Checklist (PCL-5) will also be completed. Questionnaires will be completed without the art therapist being present. After finalising the follow-up, an interview with the patient will be conducted by one of the researchers, focusing on perceived effects of the TFAT. Finally, the treating clinician will be asked to give their opinion on the perceived effects of TFAT by answering three short written questions by e-mail. Figure 2 represents a visualisation of the study procedure.

Figure 2. Visualisation of the study procedure.

[Insert Figure 2]

Intervention

The TFAT intervention is a 10-session short-term individual therapy in which each session lasts 60 minutes and are held once a week. These sessions are specifically aimed at processing trauma in AT. Each session includes an introduction, an art-therapeutic method (making artwork) and a verbal reflection. The TFAT intervention consists of three phases. Phase I: Stabilisation and symptom reduction: four sessions focused on acquaintance, stabilisation and exploration of traumatic and positive memories. Art therapeutic methods focus on depicting a lifeline and/or depicting a safe place. During the fourth session, the patient makes a list of negative and positive memories. Phase II: Expressing and shaping memories: five sessions in which the chosen memories are depicted with pencil, chalk, paint, clay, or other material of choice. This can be done with either sensory, kinaesthetic, affective or symbolic artwork using imagery exercises or with, for example, photos or objects that fit the specific memory of the patient. If necessary, a return is made to the 'safe place' assignment or to a positive memory. The therapist makes maximum effort to tailor well to the needs and possibilities of the patient. Phase III: Integration and meaning making: one session in which the completed artworks are arranged and put together (for example in a book or collage). The focus in this session is looking back together at the recent process in the TFAT and on the here and now: how does the patient experience the memories when viewed now?

Measures

Quantitative measures

Trauma-related symptoms will be measured two times (T0 and T10) using the Post-traumatic stress disorder Check List (PCL-5) (19); this questionnaire consists of 20 items, measuring twenty symptoms of PTSD according to the DSM-5. Items are scored on a 5-point Likert scale (Not at all - Extremely). An example item is: In the past month, how much were you been bothered by: "Repeated, disturbing, and unwanted memories of the stressful experience?"

The PCL-5 shows excellent internal consistency (Cronbach's α = .95) and strong convergent and divergent validity (20).

Mental health will be measured using the Mental Health Continuum Short Form (MHC-SF) (21); this questionnaire consists of 14 items aimed at positive mental health and measures three dimensions of wellbeing: emotional, psychological and social well-being. Items are scored on a 6-point Likert scale (Never - Every day) with the main question "In the past week, how often did you feel…" and the sample item: "...that you were happy?". The total score of the MHC-SF has sufficient to high internal consistency. Cronbach's α ranges from .76 - .91 across studies (22). Confirmatory factor analysis (CFA) confirmed the 3-factor structure in emotional, psychological, and social well-being and these three dimensions showed convergent validity (23).

The ability to express oneself and to regulate emotions through art therapy will be measured by the Self-expression and Emotion Regulation in Art Therapy Scale (SERATS) (24); this questionnaire consists of 9 items and is specifically aimed at measuring emotional self-expression and emotion regulation in AT with items such as "In art therapy I can express my feelings" and a 5-point Likert scale ((Almost) never true – (Almost) always true). One total score is calculated. The scale showed a high internal consistency (Cronbach's α = .94) (23). SERATS showed high convergent validity (24).

Depressive symptoms will be measured with the Beck Depression Inventory (BDI-II) (25); this questionnaire gives a total score for estimating the severity of depressive symptoms and a score for three sub-scales of depression: affective, cognitive and somatic. The questionnaire consists of 21 items that are scored on a 4-point scale with items such as "Gloom, sadness" and response options "I don't feel down – I feel so down or unhappy that I can't bear it". The cutoff scores for interpretation of the severity of depressive symptoms are as follows: 0-13 represents

minimal, 14-19 represents mild, 20-28 represents moderate and 29-63 represents severe depressive symptoms (26). Osman and colleagues (27) report a high internal consistency (Cronbach's α = .90) for the total BDI-II score, indicating high reliability. Content validity, convergent validity and divergent validity are all rated as positive.

Resilience will be measured by the Resilience Scale (RS) (28); this questionnaire measures mental resilience (how one deals with setbacks, challenges and difficulties). A total score is calculated and sub-scores for the sub-scales Personal Competence & Acceptance of Self and Life. The RS consists of 25 statements with a 4- point response scale (Strongly agree - Strongly disagree). An example item is: "I can deal with unexpected problems." The RS has sufficient to high internal consistency (Cronbach's α ranges from .72 to .94 in different studies, indicating sufficient to high reliability (29). The Dutch RS (RS-nl) revealed acceptable construct validity (28).

Self-esteem will be measured by the Rosenberg Self-Esteem Scale (RSES) (30); this questionnaire consists of 10 items and focuses on measuring self-confidence, with items such as "On the whole I am satisfied with myself" and a 4-point response scale (Strongly agree – Strongly disagree). One total score is calculated. The RSES shows sufficient to high internal consistency (Cronbach's α ranges from 0.77 – 0.90). The scale has good internal and predictive validity (31).

Qualitative measures. Semi-structured interviews will be held with both patients and art therapists. These interviews will be based on the *change interview*, focusing on identifying change processes in therapy (32). The interview guide consists of a topic list which will be used to prevent important topics from being neglected. The aim of the interviews is to enhance the interpretation of individual effects by using the patients' perspective and professional expertise. Example questions are 'Did you notice any positive or negative changes in your mental health during the

therapy?', 'Did you see any changes in the patient during the therapy?', 'How, do you think, did these changes occur?', and 'How did you experience the art therapy?'. At the beginning of the interview, the artwork will be presented as a prompt to help the conversation to remain specific. Each interview will last about one hour.

Data management

Researchers from the Research Group Arts & Psychomotor Therapies in Health Care will manage the data according to the 'FAIR Guiding Principles for scientific data management and stewardship'. A data management plan was assessed and approved by the ethics committee (ECO 394.0922) of the HAN University of Applied Sciences. In this data management plan, it is explained that data will be stored on a secured Research Drive. Data will be entered twice, to assure data quality. Informed consents will be kept secure at the patients' treatment facility. The research team only has access to participants data according to their participant number. Only the research team will have access to the final data set.

Data analysis

Demographic and clinical characteristics of participating patients will be summarised with descriptive statistics (means and standard deviations for interval variables, median and interquartile range for ordinal variables and numbers and percentages for nominal variables). The following demographics will be reported: age, gender, type of trauma (Acute / Complex / Chronic), general content of trauma (War / Violence / (Sexual) Abuse / Bullying / Neglect / Other) and diagnosis (PTSD / Personality Disorder / Anxiety Disorder / Depressive Disorder / Bipolar Disorder / Eating Disorder / Developmental Disorder / Other).

Analysis of quantitative data. Linear mixed models will be used to analyse the quantitative data. A random intercept and slope will be included to account for the dependence of 'observations within participants at different timepoints'. Mean differences of outcomes between the baseline period, intervention period and follow-up period will be calculated. Linear mixed models are well equipped to handle missing data under the assumption of 'missing at random' (MAR). In an intention to treat analysis all participants will be regarded, regardless of treatment fidelity, therapy compliance and regardless of being lost-to-follow-up. In a secondary analysis those participants will be regarded whose treatment fidelity and compliance were secure. In a sensitivity analysis the robustness of the findings will be analysed by repeating the analysis with only those participants without missing data (complete case analysis) and without multivariate outliers (Mahalanobis distance). An alpha of 5% will be adopted. Assessing the quantitative effect of the TFAT will be done by analysing single-case experimental data (MultiSCED). With this program, both linear mixed models and individual trajectories can be analysed. Visual displays of outcomes of individual trajectories, as well as overall outcomes will be shown in graphs.

Analysis of qualitative data. The interviews will be audio-recorded and transcribed verbatim and analysed using thematic analysis (33) in ATLAS.ti Windows (Version 23.0). Consistent with the principles of thematic analysis, we will apply three coding steps (i.e., open, axial and selective coding) to the interview analysis. All codes are summed up in a code tree (i.e., a list of codes). Through comparative analysis, we will rename existing codes to develop core- and sub-categories of themes.

Integration of quantitative and qualitative results. We will place individual MBSCED trajectories next to interview outcomes. Inter- and intrapersonal similarities and differences in outcomes will be researched. Based on these findings, the effectiveness of the TFAT intervention

will be assessed and recommendations will be made regarding using the TFAT intervention in clinical practice.

Monitoring

This study has an external advisory board consisting of the protocol developer (KS), a health insurance policy maker (JC), two patient representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies (JZ and PU) (11) and a professor in Psychology of University of Twente (GW) who advises about the research design and related statistics. This external advisory board meets the principal researcher (SH) each four months during the project.

One executive researcher (JH) of the research team functions as monitor. This researcher has overview of the status of each trajectory, keeps in contact with art therapists and manages the data on the Research Drive. This researcher also provides therapists with clear instructions on how to monitor questionnaires during baseline, intervention and follow-up. Adverse events and difficulties in therapy will be monitored in supervision sessions held once every three months. In these sessions, art therapists can exchange their experiences and experienced barriers. Patients' wellbeing will be monitored by the performing art therapists. Therapists will be asked to monitor BDI question number 9 on suicidality. When patients fill out a 2 or 3 (indicating moderate to severe suicidality), art therapists will be asked to contact the treating clinician and the research team. It will then be discussed whether the TFAT intervention should be continued and if other measures should be taken. Finally, therapist's adherence to the intervention will be monitored by the week-by-week guiding file, in which art therapists will explain what they did every therapy session. Important life events and (changes in) treatment of the patient are also registered by the art therapists in the patients' guiding file.

Patients and Public Involvement Statement

Patients' representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies (11) were involved in the development of the study idea and the research questions. One of these representatives is also monitoring the research process. Patients' experiences and preferences are investigated in this study protocol with interviews. Their experiences will be incorporated into the TFAT protocol and are of the utmost importance to the research team. The burden of this intervention was assessed by patients and approved. The results of the study will be disseminated to the study participants if desired by them.

ETHICS AND DISSEMINATION

The local medical ethical committee (METC Oost-Nederland) stated that this research was not subject to the Dutch Medical Research Involving Human Subjects Act (2022-15780). Following this approval, this study was ethically approved by the ethics committee of the HAN University of Applied Sciences (ECO 394.09/22). Relevant amendments will be communicated with the medical ethical committee and reapproval will be awaited. The trial registration clinicaltrials.gov will be amended accordingly. This trial was registered two days after enrolment of the first participant, due to our part-time operation. The first participant was enrolled by our executing researcher on Monday. The epidemiologist responsible for registering the study worked the following Wednesday (see Appendice A). Study findings will be published Open Access in (a) peer reviewed journal(s). Metadata will be accessible by request for the public.

Funding

This study is funded by the Care and Cure by Creativity (CCC) foundation (www.stichtingcccfoundation.nl), which main purpose is the enhancement of treatment and

therapy. No grant number available. The study funder is not involved in the execution of the study and in data analysis and interpretation or in the decision to submit results.

Competing interests statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author contribution statement

SH and KS conceived of the presented idea. *SH, JH* and *HW* contributed to the design and the writing of the study protocol. *JH* and *HW* carried out the ethical procedures. *SH* and *JH* take care of the implementation of the research. *JH* monitors the therapists' procedures. *HW* verified and conducts the statistical analysis. *SH* is principal investigator, supervises the research process and connects with the advisory board. *KS* commented on the final draft of the paper. All four authors contributed to the final manuscript of this work.

Date and version Identifier

The TFAT protocol was developed by Karin Alice Schouten in 2015 (13).

Word Count: 3998 (Introduction-Acknowledgements).

APPENDICES

Appendice A: Summary of clinical trial registration

Data category	Information[32]
Primary registry and trial identifying number	ClinicalTrials.gov NCT05593302
Date of registration in primary registry	Oktober 12, 2022
Secondary identifying numbers	Unique protocol ID: TFAT SU1424 -101
Source(s) of monetary or material support	Care and Cure by Creativity (CCC) foundation
Primary sponsor	Care and Cure by Creativity (CCC) foundation
Secondary sponsor(s)	-
Contact for public queries	*Dr. Suzanne Haeyen*, [suzanne.haeyen@han.nl]
Public title	The Effectiveness of Trauma Focused Art Therapy (TFAT)
Scientific title	The Effectiveness of Trauma Focused Art Therapy (TFAT): a Multiple Baseline Single Case Experimental Design
Countries of recruitment	The Netherlands
Health condition(s) or problem(s) studied	Psychological Trauma
Intervention(s)	Trauma-Focused Art Therapy (TFAT)
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no Inclusion criteria: adult patient (≥ 18 years), being eligible for art therapy on discretion of multidisciplinary treatment panel (consisting of a psychiatrist, psychologists, sociotherapists, and art therapists), PCL < 33 points.

	Exclusion criteria: insufficient command of the Dutch language, intellectual disability (precluding the filling out of questionnaires).
Study type	Interventional Allocation: patients randomised for the time at which they start the intervention: CONSORT recognises this design as an N=1 Trial, please refer to https://www.consort-statement.org/extensions/overview/n-of-1 Intervention model: Multiple baseline single case experimental design Masking: None (Open Label) Primary purpose: Treatment Phase: N/A
Date of first enrolment	October 10, 2022
Target sample size	12
Recruitment status	Recruiting
Primary outcome(s)	- PCL-5 - SERATS
Key secondary outcomes	- RSES - RS - BDI-II - MHC-SF

Appendice B: Sponsor contact information

Trial Sponsor: HAN University of Applied Sciences

Contact name: Suzanne Haeyen

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Telephone: (024) 35 31 575

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Appendix C: Organisational structure

Principle Investigator and research team

This research is led by the research group "Arts and psychomotor therapies in health care" from the HAN University of Applied Sciences.

Tasks of this research group include:

- Setting up the study
- Preparation of study protocol
- Managing the execution of the study protocol
- Data management
- Analysing results
- Publication of study reports

The research group is led by Suzanne Haeyen, the main applicant. In authors contribution, other group members' contributions can be viewed.

GGNet Scelta

GGNet Scelta is an expert centre for diagnosis and treatment of personality disorders and an important collaborative partner. At GGNet, several patients will be selected to participate in this trauma study.

ARQ Psychotrauma centre

Karin Alice Schouten, art therapist at ARQ psychotrauma centre, has originally created the Trauma-Focused Art Therapy protocol and has a supervising role in this research. She will join in the supervision sessions with therapists.

Appendix D: Patient Consent Form

Participant Information Form

Research: Trauma-focused art therapy

Dear Sir / Madam,

We ask you to participate in a study into the effect of trauma-oriented art therapy. Participation is voluntary. Your written permission is required to participate.

You are receiving this letter because you are indicated for art therapy for the treatment of traumatic experiences. This research takes place at various institutions.

Before you decide whether you want to participate in this study, you will receive an explanation of what the study entails. Please read this information carefully and ask the researcher/ your therapist for an explanation if you have any questions. You can also talk about it with your partner, friends or family. The principal researcher for this research is Suzanne Haeyen, of the specialised research group for art therapy and personality disorders at HAN University of Applied Sciences.

1. Research aim

Art therapy is used in trauma treatment, but it has not been researched enough. In this study we want to investigate the effect of trauma-focused art therapy in adults.

A module of 10 sessions has been developed that will be performed in several institutions, so that we can better help people with trauma-related complaints to recover.

The individual sessions of art therapy are 1 hour at a time.

For the study, we ask participants:

- To complete a set of questionnaires prior to the module, between sessions and after the module. The questions are about symptoms, self-esteem, well-being and art therapy
- To participate in an individual interview after the module. The interview consists of a number of questions and topics, but at the same time offers sufficient space for free input. Your own experience with the art therapy module is central to this interview.

2. What participating means

Participating in this study means that you will attend ten individual sessions of art therapy specifically focused on trauma. The treatment consists of an introduction/acquaintance phase, a phase focused on memories (negative and positive) and concluding sessions.

Before, during and after these sessions you will be asked to complete a number of questionnaires each week. These questionnaires are used to investigate the effect of the treatment. The data from the questionnaires are stored anonymously so that they cannot be traced back to you personally. Completing the questionnaires takes about 15 minutes per week.

You will start filling out questionnaires at some point. The time between filling out the questionnaires for the first time and starting the ten sessions of art therapy differs per person (between 3-5 weeks). This period is determined by chance.

Participating in this survey also means that you will be interviewed once after the 10-session process. This takes a maximum of 45 minutes and is done individually by one of the researchers.

The interview is audio recorded so that the interview can be fully transcribed and analysed. The interview is also processed anonymously, so that it cannot be traced back to you personally.

The results of the research will be processed in a research article in a professional journal and in a research presentation. As already described, your data and statements are processed anonymously. Also, any used quotes will not be traceable back to you.

3. What is expected of you

To ensure that the investigation runs smoothly, it is important that you keep to the agreements. It is also important that you contact the researcher if you no longer wish to participate in the study or if you wish to change your contact details.

4. Possible pros and cons

The risks of participating in this study are very small. It is important that you carefully consider the possible advantages and disadvantages before you decide to participate.

Disadvantages:

- A disadvantage is that you spend time filling out questionnaires and being interviewed.
- A personal difficulty could be that traumatic experiences are dealt with in the therapy. After all, this is the aim of the therapy. This can be emotionally difficult. However, the therapy is tailored to your ongoing treatment and to your own process. You can indicate the limits of what you can tolerate at any time, which will be respected.

Advantages:

- You will receive individual treatment that is specifically aimed at trauma-related symptoms.
- You can view the results of the questionnaires and see how your symptoms have changed during the therapy. This can provide insight into your process.
- The final interview provides extra time to evaluate your experience with art therapy in conversation with the interviewer

- With this research you contribute to the knowledge about art therapy for trauma-related complaints, which can be important for future patients so that they receive a high-quality treatment for their symptoms.

5. If you do not want to participate or want to discontinue your participation in the study

You decide whether you want to participate in the study. Participation is voluntary. If you decide not to participate, you do not need to do anything: you do not have to sign anything. You also do not have to say why you do not want to participate. If you are a patient, your treatment will continue as usual. You are entitled to the same treatment.

If you do participate, you can always change your mind and quit anyway, even during the study. You do not have to say why you are quitting. If this would be the case, please report this as soon as possible to your therapist. Your therapist can then inform the researcher about your decision.

6. End of the investigation

Your participation in the study will end if:

- you have contributed to the research as described above
- you choose to stop participation
- the researcher thinks it is better for you to stop
- the institution (Board of Directors), the government or an assessing Medical-Ethical Review Committee decides to stop the research

After the survey, you can receive the main results of your own data from the survey.

7. Use and storage of your data

For this research, your anonymised personal data will be collected, used and stored. This means that your data is stored under a number and not under your name. This way data cannot be traced back to you.

This concerns the following personal data: age (no date of birth, just a number), gender, diagnosis, cultural and religious background and the number of professional therapy sessions followed.

The collection, use and retention of your data is necessary to:

- be able to answer the questions posed in this research, and
- to publish the results.

We want to be able to answer what effects the patients experience. For this we need a broad group of patients consisting of both men and women, of various age groups and with different diagnoses. Cultural and religious background can play an important role in trauma. Consider, for example, the refugee problem. Culture can also provide insight into how someone views or thinks about a traumatic event. We ask for your permission for the use of this data.

Confidentiality of your data

To protect your privacy, your data is assigned a number. Your name and other information that can directly identify you are omitted.

Your completed consent form (this form) will be kept at the institution where you are being treated.

Access your data for control

Persons who have access to your transcribed interview are only the interviewer involved with you and the principal investigator directly involved. They keep your details confidential. We ask you to give permission for this.

Storage and use of data

Audio recordings of the interviews will be nullified immediately after they are transcribed.

With regard to data retention: the transcribed interviews and data (gender, age, cultural and religious background and diagnosis) are retained for further analysis. At the end of this study, they may still be important for future research into occupational therapy. That is why this data will be stored for 10 years on the secure Research Drive at the Hogeschool van Arnhem en Nijmegen (HAN). You can indicate on the consent form whether or not you agree to this. If you do not agree with this, you can simply participate in the current study.

Withdraw permission

You can always withdraw your consent to use your data. This applies to this research as well as to storage and use for future research. The research data collected up to the moment you withdraw your consent will then be destroyed.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the website of the Dutch Data Protection Authority. If you have any questions or complaints about the processing of your personal data, please contact the principal investigator. You can also contact the data protection officer of the institution concerned, see Appendix A for contact details.

8. No fee for participating

You will not receive any compensation for participating in this study, nor will there be any costs involved.

9. Do you have questions or a complaint?

If you have any questions or complaints about the use or processing of your data, or about your rights, please contact the principal investigator concerned: Dr. Suzanne Haeyen (Suzanne.Haeyen@han.nl).

Contact details can be found in Appendix 1.

10. Aftercare

Your other treatments will not be stopped during the study. The examination therefore runs alongside your usual treatment.

After the research, the interview will take place, in which the opportunity is offered to discuss how the research has been for you. If at any time it is clear that more (after) care is required, this will be indicated to the main practitioner by the performing therapist. If necessary, the interviewer can also provide feedback to the performing therapist in consultation with you.

11. Signing Informed Consent form

When you have had sufficient reflection time, you will be asked to decide whether to participate in this study. If you give permission, we will ask you to confirm this in writing on the accompanying statement of consent. By your written consent, you indicate that you have understood the information and agree to participate in the study. Both you and the researcher will receive a signed version of this consent form.

Thank you for your attention.

Appendices to this information

1. Contact details

2. Informed Consent Form

Appendix 1: contact details

Principal researcher
HAN Special Research Group Art Therapy for Personality Disorders

Name: Dr. Suzanne Haeyen

Position: Principal investigator/lecturer/art therapist

Contact details: suzanne.haeyen@han.nl

Accessibility: by e-mail

Data Protection Officer (DPO) of GGNet Scelta

Do you have questions about the processing and protection of your personal data and your rights in this regard? Please contact the Data Protection Officer of the institution concerned:

Name:

Phone:

Accessibility:

Link to the website of the concerned institution on privacy:

Appendix 2: participant consent form

Research: Trauma-Focused Art Therapy

- I have read the information letter and was able to ask questions. My questions have been sufficiently answered. I had sufficient time to decide whether to participate.
- I know that participating is voluntary. I also know that I can decide at any time not to participate or to stop the study. I do not have to give a reason in that case.
- My telephone number/address may be used for the interview appointment, or I will make an appointment directly with the researcher for a date, place and time.
- I consent to the collection and use of my **anonymous** data (only age, gender, cultural/religious background and diagnosis) to answer the research question in this study.
- I know that for the purpose of reviewing the study, the principal investigator may have access to my data. I give permission for access by this person.
- I ☐ **give** ☐ **do not give** permission to keep my anonymous data (transcribed interview, age, gender, cultural/religious background and diagnosis) for longer and to use it for follow-up research into professional therapy. The aim of follow-up research would then be to look at the effects of this treatment at a transcending level, in other target groups or in all professional therapies. This only concerns anonymised research results.
- I give permission to take pictures of visual works for training and publication purposes (e.g., workshops, presentations, article in professional journal).
- I want to participate in this research.

Name participant:

Signature: Date : __ / __ / __

I declare that I have been fully informed about the study.

Name principal investigator:

Signature: Date: __ / __ / __

- I declare that I have fully informed the participant about the study.
- If information becomes known during the study that could influence the consent of the participant, I will inform him/her in a timely manner.

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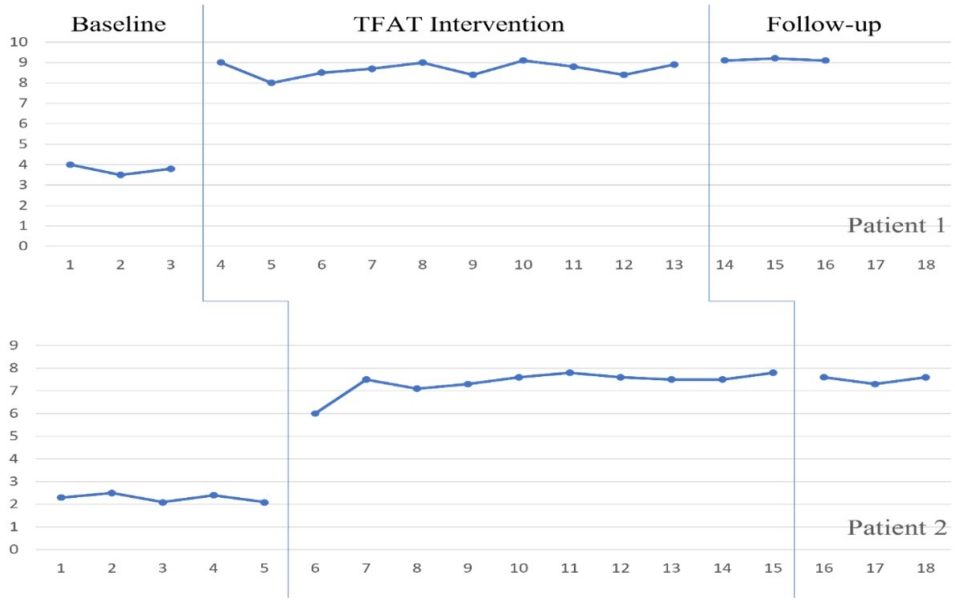

Figure 1: Visualisation of study design

Note. Visualisation of the MBSCED design with patient 1 having a 3-week baseline and patient 2 having a 5-week baseline. This graph represents fictious examples with the ideal improvements in mental health outcomes increase in the intervention period which stay relatively the same in the follow-up period.

143x86mm (220 x 220 DPI)

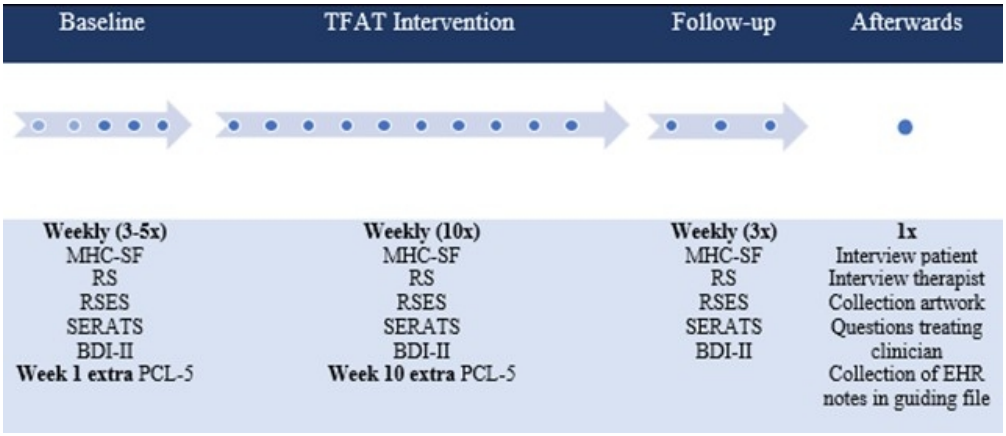

Figure 2: Visualisation of the study procedure

169x72mm (96 x 96 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	19
Protocol version	3	Date and version identifier	18
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	18
	5b	Name and contact information for the trial sponsor	22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	23/24

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4/5/6
	6b	Explanation for choice of comparators	8
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7/8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8/9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	16/17
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9/16/17
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9/17
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7/8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n.a.
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n.a.
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14/15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14/15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14/15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n.a.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n.a.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n.a.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n.a.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n.a.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	1
	31b	Authorship eligibility guidelines and any intended use of professional writers	18
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	25-31
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n.a.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

Effectiveness of Trauma-Focused Art Therapy (TFAT) for psychological trauma: Study protocol of a multiple baseline single case experimental design

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Effectiveness of trauma-focused art therapy (TFAT) for psychological trauma: Study protocol of a multiple-baseline single-case experimental design

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Abstract

Introduction. Treatments such as eye movement desensitisation and reprocessing (EMDR) and (narrative) exposure therapies are commonly used in psychological trauma. In everyday practice, art therapy is also often used, although rigorous research on its efficacy is lacking. Patients seem to benefit from the indirect, nonverbal experiential approach of art therapy. This protocol paper describes a study to examine the effectiveness of a 10-week individual trauma-focused art therapy (TFAT) intervention.

Methods and analysis. A mixed-methods multiple-baseline singe-case experimental design (MBSCED) will be conducted with 25 to 30 participants with psychological trauma. Participants will be randomly assigned to a baseline period lasting 3 to 5 weeks, followed by the TFAT intervention (10 weeks) and follow-up (3 weeks). Quantitative measures will be completed weekly: the Beck Depression Inventory (BDI-II), the Mental Health Continuum Short Form (MHC-SF), the Resilience Scale (RS), the Rosenberg Self-Esteem Scale (RSES) and the Self-expression and Emotion Regulation in Art Therapy Scale (SERATS). The PTSD Checklist (PCL-5) will be completed at week 1 and week 10. Qualitative instruments comprise a semi-structured interview with each individual patient and therapist, and a short evaluation for the referrer. Artwork will be used to illustrate the narrative findings. Quantitative outcomes will be analysed with linear mixed models using the MultiSCED web application. Qualitative analyses will be performed using thematic analysis with ATLAS.ti.

Ethics and dissemination. This study has been approved by the ethics committee of the HAN University of Applied Sciences (ECO 394.0922). All participants will sign an informed consent form and data will be treated confidentially. Findings will be published open access in peer-reviewed journals.

Trial registration. This study is registered at www.ClinicalTrials.gov, trial registration number NCT05593302.

Strengths and limitations

+ The study uses both quantitative and qualitative outcomes
+ The aim is to enhance mental health in addition to decreasing trauma-related symptoms
+ A multiple-baseline singe-case experimental design requires fewer participants than a randomised controlled trial
– Participants cannot be blinded for the intervention as this may cause bias when completing the questionnaires
– As with any therapy, art therapy has to be geared to each patient's needs. The exact implementation of the protocol may therefore vary slightly from its description

INTRODUCTION

Approximately eighty percent of people worldwide experience one or more shocking event in their lives. Ten percent of these subsequently develop post-traumatic stress disorder (PTSD) (1). PTSD is characterised by severe symptoms, including re-experiencing the traumatic event, avoidance and hyperarousal, and is diagnosed if symptoms last longer than one month. The disorder causes significant distress and impairment in patients' social and working lives as well as other areas (2).

According to the Clinical Practice Guideline for the Treatment of PTSD (3) and the National Institute for Health and Care Excellence Guidelines (4), cognitive behavioural therapy (CBT), narrative exposure therapy (NET) and eye movement desensitisation and reprocessing (EMDR) are the treatments of choice for PTSD. Yet, more than a third of patients do not benefit from these interventions (5). This includes individuals with severe trauma, a poor verbal memory and/or difficulties with talking about traumatic experiences.

For these patients, visual art therapy (AT) may offer a promising treatment. The visual, tangible and experiential character of AT reflects the often wordless, visual and sensory nature of traumatic memories (6). AT is one of the creative art therapies (CATs), a group of treatments developed over the last century that includes art, drama, dance and music therapy. In AT, various artistic materials, therapeutic methods and techniques are used to give meaning to past events and gain a better grasp on one's life. AT distinguishes itself from other treatments through its experiential approach and the visible, tangible nature of the process and the resulting artistic product. Acting, doing and experiencing in AT can counter feelings of powerlessness and increase the patient's sense of control and self-esteem. The use of artistic materials triggers emotions, enabling access to traumatic memories (7; 8) and helping patients to explore them in a safe, step-by-step way (9; 7). The resulting artwork is visible, tangible and has a lasting character. This helps

patients to distance themselves from the associated emotions, share the product with the art therapist, and give it meaning (10; 8). Externalising their emotions and memories in the form of artwork can also help patients put them into words. Ultimately, all this enables patients to process and integrate traumatic experiences.

Both patients and professionals report promising results. 'Experience experts', for example, report that trauma-focused AT offers an essential alternative to the usual verbal, cognitive approaches (11). The Post-traumatic Stress Disorder Improvement Report recommends that more people with PTSD should receive trauma-oriented treatment (12). It could also be offered prior to other trauma-focused treatments (e.g. EMDR, CBT or NET). However, scientific evidence is still required to demonstrate the efficacy of AT.

A trauma-focused art therapy (TFAT) protocol has been developed (13) and tested in a pilot study with patients with PTSD caused by multiple, long-term traumas. The protocol has been found to be acceptable, feasible and applicable (14). Preliminary results show decreased severity of PTSD symptoms in some patients, as well as treatment adherence and satisfaction. Further research is needed on the effects and practical implementation of this TFAT intervention, but it would seem to offer opportunities to improve the accessibility, quality and efficiency of trauma treatment, in part because it may be effective in patients who would otherwise not be treated or would receive long-term treatment without results (14).

The intervention involves a short-term, individual and ambulatory trauma-focused AT consisting of 10 one-hour sessions in three phases. The first phase focuses on stabilisation and symptom reduction, and includes getting acquainted, creating a safe environment, and drawing up a list of memories. The second phase, trauma processing, focuses on expressing and exploring positive and negative memories and associated feelings and thoughts. The third phase, integration

and meaning-making, involves arranging the artwork made and bringing the AT to a close (see Intervention).

Problem

According to treatment guidelines for psychotrauma and stress-related disorders in the Netherlands (15), "A survey among 'experience experts' shows that people are unanimously positive about AT and regard it as valuable, especially if patients still find it difficult to talk about their traumas." The difficulty of expressing trauma-related memories and emotions was confirmed by a meta-analysis of dropout during PTSD treatment (16), which found that patients have low tolerance for recounting traumatic memories in detail during exposure-based talk therapies.

Research question

The main research question is as follows: *Does the trauma-focused art therapy (TFAT) intervention increase patients' self-expression and emotion regulation during art therapy, and reduce trauma-related symptoms (including direct trauma symptoms, depressive symptoms, and decreased wellbeing, self-esteem and resilience)?*

The secondary research question is: *How do patients, therapists and treating clinicians perceive their experiences of the TFAT intervention?*

Goals

The aim of this study is to gain insight into the effectiveness and functioning of trauma-focused AT. Ultimately, the goal is to increase the quality and availability of trauma treatment for patients who do not respond well to the usual talk therapy. If trauma-focused AT is found to be effective, the intervention will be further disseminated and implemented with a view to offering appropriate

treatment for patients who would otherwise go untreated or receive long-term treatment without results.

Hypotheses

We hypothesise that the TFAT intervention is effective in the treatment of trauma-related symptoms:

1. TFAT enhances self-expression and emotion regulation in AT
2. TFAT reduces trauma symptoms
3. TFAT reduces depressive symptoms
4. TFAT enhances self-confidence/self-esteem
5. TFAT enhances mental resilience.
6. In an effort to avoid confirmation bias in the thematic analysis of the interviews, we have not formulated hypotheses regarding the patients', therapists' and treating clinicians' perceptions of TFAT.

METHODS AND ANALYSIS

Design

This is a prospective, mixed-methods study combining quantitative and qualitative methods (Figure 1). The quantitative part of the study comprises a multiple-baseline single-case experimental design (MBSCED), which will allow us to evaluate the effectiveness of the TFAT intervention. Participating patients will be randomised for the time at which they start the TFAT intervention, resulting in baseline periods that vary from 3 to 5 weeks. All patients will then start the intervention, which lasts 10 weeks, with a follow-up period of 3 weeks. In an MBSCED, participants are monitored over time and repeated measurements are conducted, in our case

weekly. The randomisation of the baseline period means that each participant functions as his/her own control, enabling us to isolate treatment effects (17). The MBSCED accounts adequately for threats to internal validity (e.g. maturation, history and regression to the mean—instead of the TFAT intervention—as explanations for improvement). Measurements in the intervention period will be compared to measurements at baseline and follow-up. The TFAT intervention will conclude with in-depth, qualitative interviews exploring the perceived effects by therapists and patients.

Figure 1. Visualisation of study design and procedure.

[Insert Figure 1]

Note. In this MBSCED design, patient 1 has a 3-week baseline and patient 2 a 5-week baseline. This graph represents fictitious examples with idealised improvements in mental-health outcomes in the intervention period, which are roughly maintained in the follow-up period.

Study setting

The study will last 24 months, with preparation from September 2022 to publication of findings in September 2024. It will be conducted in at least four mental-health facilities in the Netherlands in a minimum of three different settings, including psychiatric hospitals, psychiatric forensic facilities, a refugee psychiatric facility, and/or general psychiatric departments. At least four art therapists will be involved, to ensure that the results cannot be ascribed to factors pertaining to one specific therapist. To account for a range of trauma-related issues, art therapists focused on different populations (refugees, veterans, (sexual) abuse survivors, etc.) will be selected, although each therapist will be able to contribute multiple patient cases. To achieve adequate participant enrolment, only clinics with eligible participants will be selected.

Eligibility criteria

Patients will be enrolled through art therapists and clinicians. The eligibility criteria are as follows: 1) aged between 18 and 65, 2) dealing with trauma-related symptoms (nightmares, flashbacks, persistent fatigue or depression, anxiety in regard to specific triggers, sleep disorders), 3) being suitable for individual AT and/or benefiting insufficiently from regular therapy, and 4) being motivated to work on traumatic memories. The patient's multidisciplinary treatment panel (psychiatrist, psychologists, sociotherapists and art therapists) will, in consultation with the patient, determine whether the criteria are met. Exclusion criteria include acute psychosis or crisis, as well as intellectual disabilities (participants need to be able to understand and complete all questionnaires). Treatment as usual will be continued, with the AT as an add-on component. The nature of any other ongoing psychological treatments will be recorded.

Procedure

Participating art therapists are required to be certified in AT and work in mental healthcare clinics or private practices. They will be recruited by snowball effect through the researchers' networks. They will be given a presentation on the study, explaining the content of the TFAT intervention, the data collection methods and our instructions, after which they will be invited to participate. Participating art therapists will be provided with the TFAT intervention, questionnaires and a week-by-week file with guidelines. In this file they will also record notes on the patients' sessions from their Electronic Health Record (EHR). To discuss any insights or problems that arise, they will be asked to join online supervision sessions. On completion of a TFAT intervention with a patient, the art therapist will be interviewed about his/her experiences with the intervention and perceptions of its effects on the patient.

Patient participants will be recruited by their treating clinician on an indication for trauma treatment. The associated art therapist will explain the study. Screening and treatment will start only after patients sign an informed consent form, which explains the data collection and management procedures and other ethical aspects (Supplementary File A). At the start of the intervention, patients will receive a patient number and a computer-generated, randomised baseline period lasting 3 to 5 weeks, followed by the TFAT intervention (10 weeks) and follow-up (3 weeks). The allocation sequence will be designed by a researcher who is not involved in the data collection or communication surrounding the intervention. A different researcher will assign the generated starting dates. Each week, patients will complete the relevant questionnaires. The PTSD Checklist (PCL-5) will also be completed at the start of the intervention and after the final therapy session. The art therapist will not be present when the questionnaires are being completed. After follow-up, each patient will be interviewed by a researcher, focusing on perceived effects of the TFAT. Finally, the treating clinician will be asked to give their opinion on the perceived effects by answering three brief questions by email. Figure 2 provides an overview of the study procedure.

Figure 2. Visualisation of the study procedure.

[Insert Figure 2]

Intervention

The TFAT intervention is a short-term individual therapy comprising 10 one-hour sessions held in person, once a week. These sessions are specifically aimed at processing trauma through AT. Each session includes an introduction, the creation of an artwork using a specific art-therapeutic method, and a verbal reflection. The intervention consists of three phases.

Phase I: Stabilisation and symptom reduction

Four sessions focused on getting acquainted with one another, stabilising the patient, and exploring both traumatic and positive memories. Art-therapeutic methods focus on depicting a lifeline and/or a safe place. During the fourth session, the patient makes a list of negative and positive memories.

Phase II: Expressing and exploring memories

Five sessions in which the chosen memories are depicted with pencil, chalk, paint, clay, or another material of choice. This can be done with sensory, kinaesthetic, affective or symbolic artwork using imagery exercises, or with photos or objects related to the memory in question. If necessary, the patient is guided to return to the safe place or to revisit a positive memory. The therapist tailors the activities to the patient's needs and capabilities.

Phase III: Integration and meaning-making

One final session in which the completed artworks are arranged together (e.g. in a book or collage). The focus is on reflecting on the recent experience of the TFAT and on the here and now: how does the patient view the memories from today's perspective?

Measures

Quantitative measures

Primary outcome

Participants' capacity for self-expression and emotion regulation through AT will be measured using the Self-expression and Emotion Regulation in Art Therapy Scale (SERATS) (18). This one-factor questionnaire consists of 9 items (e.g. *In art therapy I can express my feelings*) measured on a 5-point Likert scale from *(almost) never* to *(almost) always*. A single total score is

calculated. SERATS has been found to show high internal consistency (Cronbach's α = .94) and high convergent validity (18).

Secondary outcomes

Trauma-related symptoms will be measured twice (T0 and T10) using the PCL-5 (19). This questionnaire measures symptoms of PTSD according to the DSM-5 using 20 items, such as: *In the past month, how much were you bothered by repeated, disturbing and unwanted memories of the stressful experience?* Items are scored on a 5-point Likert scale (from *not at all* to *extremely*). The PCL-5 shows excellent internal consistency (Cronbach's α = .95) and strong convergent and divergent validity (20). The PCL-5 will be implemented twice, rather than weekly, to avoid exacerbating the attention paid to trauma-related stress.

Mental health will be measured using the Mental Health Continuum Short Form (MHC-SF) (21), a questionnaire consisting of 14 items aimed at positive mental health. The MHC-SF measures three dimensions of wellbeing: emotional, psychological and social. Items are phrased as follows: *In the past week, how often did you feel …* (e.g. *happy*), with responses given on a 6-point Likert scale (from *never* to *every day*). The total score of the MHC-SF has sufficient to high internal consistency. Cronbach's α ranges from .76 to .91 across studies (22). Confirmatory factor analysis (CFA) confirms the three-factor structure of emotional, psychological and social wellbeing, with convergent validity among these three dimensions (23).

Depressive symptoms will be measured with the Beck Depression Inventory (BDI-II) (24). This questionnaire gives a total score for the severity of depressive symptoms and a score for three sub-scales of depression: affective, cognitive and somatic. The questionnaire consists of 21 items, such as *gloom/sadness*, scored on a 4-point scale (from *I don't feel down* to *I feel so down*

or unhappy I can't bear it). The cutoff scores for interpretation of the severity of depressive symptoms are as follows: 0-13 represents minimal, 14-19 mild, 20-28 moderate and 29-63 severe depressive symptoms (25). Osman et al. (26) report high internal consistency (Cronbach's α = .90) for the total BDI-II score, indicating high reliability. Content validity, convergent validity and divergent validity are all rated as positive.

Resilience will be measured using the Resilience Scale (RS) (27), a questionnaire that measures how well one deals with setbacks, challenges and difficulties. A total score is calculated, as well as sub-scores for the sub-scales Personal Competence & Acceptance of Self and Life. The questionnaire consists of 25 statements (e.g. *I can deal with unexpected problems*) answered on a 4-point scale (*strongly agree* to *strongly disagree*). The RS has sufficient to high internal consistency (Cronbach's α ranges from .72 to .94 in different studies), indicating sufficient to high reliability (28). The Dutch RS (RS-nl) has been found to have acceptable construct validity (27).

Self-esteem will be measured with the Rosenberg Self-Esteem Scale (RSES) (29), a questionnaire consisting of 10 items that measure self-confidence (e.g. *On the whole I am satisfied with myself*). Responses are given on a 4-point scale (*strongly agree* to *strongly disagree*). A single total score is calculated. The RSES shows sufficient to high internal consistency (Cronbach's α from 0.77 – 0.90) and good internal and predictive validity (30).

Qualitative measures

Patients and art therapists will take part in semi-structured interviews based on the *change interview*, focusing on identifying change processes in therapy (31). An interview guide with a topic list will be used to prevent important topics from being neglected (Supplementary File B). The aim of the interviews is to enhance the interpretation of individual effects by tapping into the

patient's and therapist's perspectives. Questions include 'Did you notice any positive or negative changes in your mental health during the therapy?', 'Did you see any changes in the patient during the therapy?', 'In your opinion, what caused these changes?' and 'How did you experience the art therapy?' At the beginning of the interview, the artwork will be presented, both as a prompt and to help the conversation to remain patient-specific. Each interview will last approximately one hour.

Data management

Researchers from the Research Group for Arts and Psychomotor Therapies in Health Care at the HAN University of Applied Sciences will manage the data in accordance with the 'FAIR Guiding Principles for scientific data management and stewardship'. A data management plan has been assessed and approved by the ethics committee (ECO 394.0922) of the HAN University of Applied Sciences. Data will be stored on a secured research drive and entered twice to ensure accuracy. Informed consent forms will be stored securely at the patients' treatment facility. The research team will be able to access participant data based on participant number only. Only the research team will have access to the final data set.

Data analysis

Demographic and clinical characteristics

Participants' demographic and clinical traits will be summarised with descriptive statistics (means and standard deviations for interval variables, median and interquartile range for ordinal variables, numbers and percentages for nominal variables). The following demographics will be reported: age, gender, type of trauma (acute/complex/chronic), general nature of trauma (war/violence/(sexual) abuse/bullying/neglect/other) and diagnosis (PTSD/personality

disorder/anxiety disorder/depressive disorder/bipolar disorder/eating disorder/pervasive developmental disorder/other). Based on a power analysis for an MBSCED, assuming a medium effect size (Cohen's d = .6) and an alpha of 5%, inclusion of 10 participants yields 80% power (32).

Quantitative data

Quantitative data will be analysed using MultiSCED. This is an application built with Shiny (33), a framework to create interactive web apps that provide an interface for R functionalities (34). The application offers a point-and-click user interface, allowing practitioners unfamiliar with R syntax to use the freely available R software environment. MultiSCED has been described in detail elsewhere (35). The application will allow for the analysis of repeatedly measured data collected at 16 to 18 time points. The outcomes as measured by the SERATS, MHC-sf, BDI-II, RS and RSES form the dependent variables. Multiple outcomes were chosen as PTSS is a complex disorder with various symptoms. Time, phase (control vs treatment period) and the interaction between them (time * phase) will be included as the independent variables.

Two analyses will be performed in MultiSCED. First, analysis at the level of aggregated data involves a linear mixed model. A random intercept and slope will be included to account for the dependence of observations within participants at different time points. Mean differences in outcomes between the baseline period, intervention period and follow-up period will be calculated. Hypothesis testing for the fixed effects of multilevel models in MultiSCED will be performed using a t-test with the Kenward–Roger approximation for degrees of freedom (36). Linear mixed models are well-equipped to handle missing data under the assumption of 'missing at random' (MAR). In the primary analysis, we will adopt an intention-to-treat approach that includes all participants, regardless of treatment fidelity, therapy compliance and being lost-to-follow-up. The

secondary analysis will only include those participants with adequate treatment fidelity and compliance. In a sensitivity analysis, the robustness of the findings will be analysed by repeating the analysis with only those participants without missing data (complete-case analysis) and without multivariate outliers (Mahalanobis distance).

Second, an analysis will be performed at the level of the individual participants. This analysis will involve ordinary least squares (OLS) regression with the outcomes of the SERATS, MHC-sf, BDI-II, RS and RSES included as the dependent variables. Time, phase (control vs treatment period) and the interaction between time * phase will be included as the independent variables. MultiSCED provides participant-specific regression coefficients, together with their standard errors, t values and p values. Lastly, the individual trajectories and overall outcomes will be visualised in graphs.

Since the PCL will only be administered twice (T0 and T10), the mean within-subject difference over time for this measure will be tested using a paired sample t-test. In all analyses, an alpha of 5% will be adopted.

Qualitative data

The interviews will be audio-recorded, transcribed verbatim and analysed in ATLAS.ti for Windows (Version 23.0). Consistent with the principles of thematic analysis (37), we will apply three coding steps (open, axial and selective coding). All codes will be summed up in a code tree (i.e. a list of codes), then compared and renamed to develop core and sub-categories of themes.

Integration of quantitative and qualitative results

Individual MBSCED trajectories will be analysed through the lens of the interview outcomes. Inter- and intrapersonal similarities and differences in outcomes will be explored. Based on these

findings, the effectiveness of the TFAT intervention will be assessed and recommendations made regarding its use in clinical practice.

Monitoring

This study has an external advisory board consisting of the protocol developer (KS), a health insurance policymaker (JC), two patient representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies (JZ and PU) (11) and a psychology professor from the University of Twente (GW) who advises on the research design and statistics. The external advisory board meets with the principal researcher (SH) every four months during the project period.

One executive researcher (JH) from the research team serves as a monitor. This researcher has an overview of the status of each patient's trajectory, maintains contact with the art therapists and manages the data on the research drive. This researcher also instructs the therapists on how to monitor questionnaires during baseline, intervention and follow-up. Adverse events and difficulties in therapy will be addressed in supervision sessions held once every three months. In these sessions, the art therapists can share their experiences and any issues that arise. The art therapists will monitor the patients' wellbeing, including a weekly check of BDI question 9, on suicidality. If a patient scores this item with a 2 or 3 (indicating moderate to severe suicidality), art therapists will be asked to contact the treating clinician and the research team to discuss whether these suicidal thoughts are new, whether the TFAT intervention should be continued and whether other measures should be taken. The intervention will be discontinued if either the treating clinician or the patient is of the opinion that it would be best to do so. If the intervention is subsequently restarted, the process will again be monitored weekly. Finally, the art therapists' adherence to the intervention will be monitored through the week-by-week guidelines file, in

which they explain what they did in each session. They will also record any important events in the patient's life and changes in the patient's treatment in this file.

Patients and public involvement statement

Patients' representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies (11) were involved in the development of the study proposal and research questions. One of these representatives is also monitoring the research process. Patients' experiences and preferences will be investigated through interviews. Their experiences will be incorporated into the TFAT protocol and are of the utmost importance to the research team. The burden posed by the intervention was assessed and approved by patients. The results of the study will be shared with the study participants on request.

ETHICS AND DISSEMINATION

The local medical ethical committee (METC Oost-Nederland) indicated that this study was not subject to the Dutch Medical Research Involving Human Subjects Act (2022-15780). The study was approved by the official Research Ethics Committee of the HAN University of Applied Sciences (ref: ECO 394.09/22). This committee's approval extends to the various sites of the intervention, although coordination is, of course, required with any scientific committee at the clinics involved. Relevant amendments will be communicated with the medical ethical committee and reapproval awaited. The trial registration at clinicaltrials.gov will be amended accordingly. This trial was registered two days after enrolment of the first participant: the first participant was enrolled on a Monday, but the epidemiologist responsible for registering the study works part time and was first present on the Wednesday immediately thereafter (Supplementary File C). Study

findings will be published open access in peer-reviewed journals. Metadata will be made publicly accessible on request.

Authors' contributions

SH and KS conceived of the idea. *SH, JH* and *HW* contributed to the design and the writing of the study protocol. *JH* and *HW* carried out the ethical procedures. *SH* and *JH* will implement the study. *JH* will monitor the therapists' procedures. *HW* verified and will conduct the statistical analysis. *SH* is the principal investigator, supervising the research process and communicating with the advisory board. *KS* commented on the final draft of the paper. All four authors contributed to the final manuscript.

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Competing interests statement

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Date and version identifier

The TFAT protocol was developed by Karin Alice Schouten in 2015 (13).

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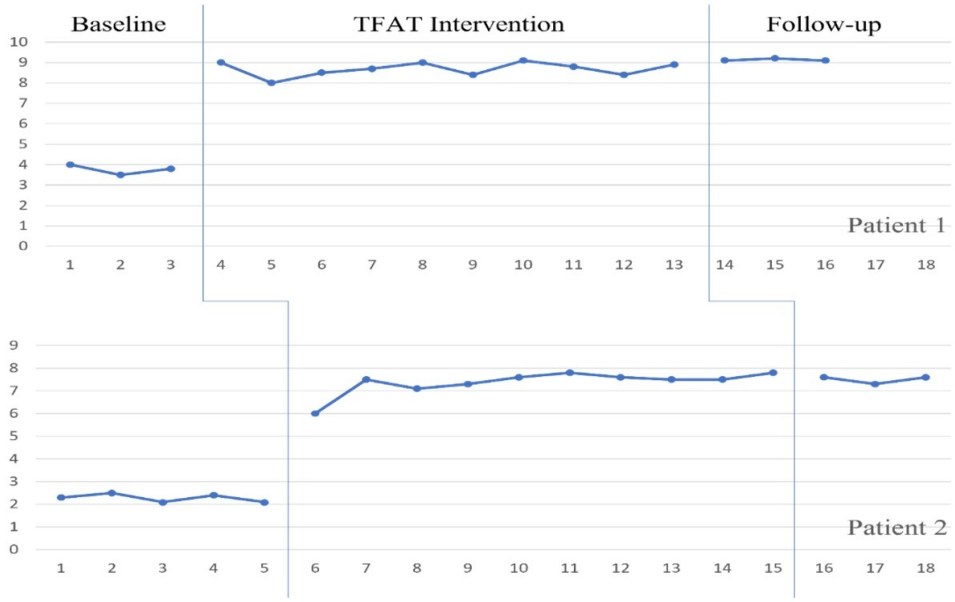

Figure 1: Visualisation of study design

Note. Visualisation of the MBSCED design with patient 1 having a 3-week baseline and patient 2 having a 5-week baseline. This graph represents fictious examples with the ideal improvements in mental health outcomes increase in the intervention period which stay relatively the same in the follow-up period.

143x86mm (220 x 220 DPI)

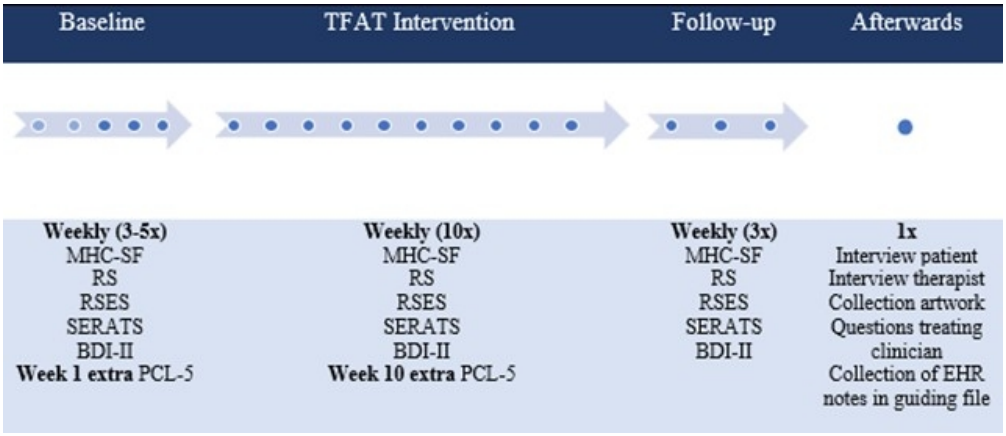

Figure 2: Visualisation of the study procedure

169x72mm (96 x 96 DPI)

Supplementary File A: Participant Information Form

Research: Trauma-focused art therapy

Dear Sir / Madam,

We ask you to participate in a study into the effect of trauma-oriented art therapy. Participation is voluntary. Your written permission is required to participate.

You are receiving this letter because you are indicated for art therapy for the treatment of traumatic experiences. This research takes place at various institutions.

Before you decide whether you want to participate in this study, you will receive an explanation of what the study entails. Please read this information carefully and ask the researcher/ your therapist for an explanation if you have any questions. You can also talk about it with your partner, friends or family. The principal researcher for this research is Suzanne Haeyen, of the specialised research group for art therapy and personality disorders at HAN University of Applied Sciences.

1. Research aim

Art therapy is used in trauma treatment, but it has not been researched enough. In this study we want to investigate the effect of trauma-focused art therapy in adults.

A module of 10 sessions has been developed that will be performed in several institutions, so that we can better help people with trauma-related complaints to recover.

The individual sessions of art therapy are 1 hour at a time.

For the study, we ask participants:

- To complete a set of questionnaires prior to the module, between sessions and after the module. The questions are about symptoms, self-esteem, well-being and art therapy
- To participate in an individual interview after the module. The interview consists of a number of questions and topics, but at the same time offers sufficient space for free input. Your own experience with the art therapy module is central to this interview.

2. What participating means

Participating in this study means that you will attend ten individual sessions of art therapy specifically focused on trauma. The treatment consists of an introduction/acquaintance phase, a phase focused on memories (negative and positive) and concluding sessions.

Before, during and after these sessions you will be asked to complete a number of questionnaires each week. These questionnaires are used to investigate the effect of the treatment. The data from the questionnaires are stored anonymously so that they cannot be traced back to you personally. Completing the questionnaires takes about 15 minutes per week.

You will start filling out questionnaires at some point. The time between filling out the questionnaires for the first time and starting the ten sessions of art therapy differs per person (between 3-5 weeks). This period is determined by chance.

Participating in this survey also means that you will be interviewed once after the 10-session process. This takes a maximum of 45 minutes and is done individually by one of the researchers.

The interview is audio recorded so that the interview can be fully transcribed and analysed. The interview is also processed anonymously, so that it cannot be traced back to you personally.

The results of the research will be processed in a research article in a professional journal and in a research presentation. As already described, your data and statements are processed anonymously. Also, any used quotes will not be traceable back to you.

3. What is expected of you

To ensure that the investigation runs smoothly, it is important that you keep to the agreements. It is also important that you contact the researcher if you no longer wish to participate in the study or if you wish to change your contact details.

4. Possible pros and cons

The risks of participating in this study are very small. It is important that you carefully consider the possible advantages and disadvantages before you decide to participate.

Disadvantages:

- A disadvantage is that you spend time filling out questionnaires and being interviewed.
- A personal difficulty could be that traumatic experiences are dealt with in the therapy. After all, this is the aim of the therapy. This can be emotionally difficult. However, the therapy is tailored to your ongoing treatment and to your own process. You can indicate the limits of what you can tolerate at any time, which will be respected.

Advantages:

- You will receive individual treatment that is specifically aimed at trauma-related symptoms.
- You can view the results of the questionnaires and see how your symptoms have changed during the therapy. This can provide insight into your process.
- The final interview provides extra time to evaluate your experience with art therapy in conversation with the interviewer

- With this research you contribute to the knowledge about art therapy for trauma-related complaints, which can be important for future patients so that they receive a high-quality treatment for their symptoms.

5. If you do not want to participate or want to discontinue your participation in the study

You decide whether you want to participate in the study. Participation is voluntary. If you decide not to participate, you do not need to do anything: you do not have to sign anything. You also do not have to say why you do not want to participate. If you are a patient, your treatment will continue as usual. You are entitled to the same treatment.

If you do participate, you can always change your mind and quit anyway, even during the study. You do not have to say why you are quitting. If this would be the case, please report this as soon as possible to your therapist. Your therapist can then inform the researcher about your decision.

6. End of the investigation

Your participation in the study will end if:

- you have contributed to the research as described above
- you choose to stop participation
- the researcher thinks it is better for you to stop
- the institution (Board of Directors), the government or an assessing Medical-Ethical Review Committee decides to stop the research

After the survey, you can receive the main results of your own data from the survey.

7. Use and storage of your data

For this research, your anonymised personal data will be collected, used and stored. This means that your data is stored under a number and not under your name. This way data cannot be traced back to you.

This concerns the following personal data: age (no date of birth, just a number), gender, diagnosis, cultural and religious background and the number of professional therapy sessions followed.

The collection, use and retention of your data is necessary to:

- be able to answer the questions posed in this research, and
- to publish the results.

We want to be able to answer what effects the patients experience. For this we need a broad group of patients consisting of both men and women, of various age groups and with different diagnoses. Cultural and religious background can play an important role in trauma. Consider, for example, the refugee problem. Culture can also provide insight into how someone views or thinks about a traumatic event. We ask for your permission for the use of this data.

Confidentiality of your data

To protect your privacy, your data is assigned a number. Your name and other information that can directly identify you are omitted.

Your completed consent form (this form) will be kept at the institution where you are being treated.

Access your data for control

Persons who have access to your transcribed interview are only the interviewer involved with you and the principal investigator directly involved. They keep your details confidential. We ask you to give permission for this.

Storage and use of data

Audio recordings of the interviews will be nullified immediately after they are transcribed.

With regard to data retention: the transcribed interviews and data (gender, age, cultural and religious background and diagnosis) are retained for further analysis. At the end of this study, they may still be important for future research into occupational therapy. That is why this data will be stored for 10 years on the secure Research Drive at the Hogeschool van Arnhem en Nijmegen (HAN). You can indicate on the consent form whether or not you agree to this. If you do not agree with this, you can simply participate in the current study.

Withdraw permission

You can always withdraw your consent to use your data. This applies to this research as well as to storage and use for future research. The research data collected up to the moment you withdraw your consent will then be destroyed.

More information about your rights when processing data

For general information about your rights when processing your personal data, you can consult the website of the Dutch Data Protection Authority. If you have any questions or complaints about the processing of your personal data, please contact the principal investigator. You can also contact the data protection officer of the institution concerned, see Appendix A for contact details.

8. No fee for participating

You will not receive any compensation for participating in this study, nor will there be any costs involved.

9. Do you have questions or a complaint?

If you have any questions or complaints about the use or processing of your data, or about your rights, please contact the principal investigator concerned: Dr. Suzanne Haeyen (Suzanne.Haeyen@han.nl).

Contact details can be found in Appendix 1.

10. Aftercare

Your other treatments will not be stopped during the study. The examination therefore runs alongside your usual treatment.

After the research, the interview will take place, in which the opportunity is offered to discuss how the research has been for you. If at any time it is clear that more (after) care is required, this will be indicated to the main practitioner by the performing therapist. If necessary, the interviewer can also provide feedback to the performing therapist in consultation with you.

11. Signing Informed Consent form

When you have had sufficient reflection time, you will be asked to decide whether to participate in this study. If you give permission, we will ask you to confirm this in writing on the accompanying statement of consent. By your written consent, you indicate that you have understood the information and agree to participate in the study. Both you and the researcher will receive a signed version of this consent form.

Thank you for your attention.

Appendices to this information

1. Contact details

2. Informed Consent Form

Appendix 1: contact details

Principal researcher
HAN Special Research Group Art Therapy for Personality Disorders

Name: Dr. Suzanne Haeyen

Position: Principal investigator/lecturer/art therapist

Contact details: suzanne.haeyen@han.nl

Accessibility: by e-mail

Data Protection Officer (DPO) of GGNet Scelta

Do you have questions about the processing and protection of your personal data and your rights in this regard? Please contact the Data Protection Officer of the institution concerned:

Name:

Phone:

Accessibility:

Link to the website of the concerned institution on privacy:

Appendix 2: participant consent form

Research: Trauma-Focused Art Therapy

- I have read the information letter and was able to ask questions. My questions have been sufficiently answered. I had sufficient time to decide whether to participate.
- I know that participating is voluntary. I also know that I can decide at any time not to participate or to stop the study. I do not have to give a reason in that case.
- My telephone number/address may be used for the interview appointment, or I will make an appointment directly with the researcher for a date, place and time.
- I consent to the collection and use of my **anonymous** data (only age, gender, cultural/religious background and diagnosis) to answer the research question in this study.
- I know that for the purpose of reviewing the study, the principal investigator may have access to my data. I give permission for access by this person.
- ☐☐I **give** **do not give** permission to keep my anonymous data (transcribed interview, age, gender, cultural/religious background and diagnosis) for longer and to use it for follow-up research into professional therapy. The aim of follow-up research would then be to look at the

effects of this treatment at a transcending level, in other target groups or in all professional therapies. This only concerns anonymised research results.

- I give permission to take pictures of visual works for training and publication purposes (e.g., workshops, presentations, article in professional journal).
- I want to participate in this research.

Name participant:

Signature: Date : __ / __ / __

I declare that I have been fully informed about the study.

Name principal investigator:

Signature: Date: __ / __ / __

- I declare that I have fully informed the participant about the study.
- If information becomes known during the study that could influence the consent of the participant, I will inform him/her in a timely manner.

Supplementary File B: Interview guide

Interview guide 1) patient participants:

Focused on Client Change Interview Schedule

Subject	Main question	Sub-questions	Purpose
Opening	Hello, how nice that we can interview you for the research you participated in.	a) I'm going to turn on the recorder and then, as far as I'm concerned, we can start the interview. b) I am very curious about your experiences with art therapy. It's not a test; So it doesn't matter if you don't know something for a while. Try to answer as honestly as possible. Are you ready?	Open call/ start recording/ reassure participant
General view	How did you experience the art therapy in general?	a) How did you find the structure (per phase) (making an inventory, coming to a choice of memories?) b) How did you feel about working out your memories in images? (both positive and negative) c) Phase 3: How did you come to a conclusion?	Painting a general picture
Visual work	How did you go about the sessions?	a) Can you describe what you did during the therapy? (possibly: artworks included) b) What materials did you use to do this? c) Which assignments did you find particularly helpful/which did you find less so?	Learning how the participant works visually
Changes	What changes have you noticed in your symptoms since you started art therapy?	a) Has anything improved since you started? b) Has anything deteriorated since you started? c) Has something NOT changed that you expected? d) Would these changes have happened even if you hadn't had the therapy?	Mapping changes in complaints
Cause changes	What do you think have caused these changes?	a) What helped during the sessions? Think of materials, instructions or the attitude of your therapist? b) Zoom in on answer	Attribution mapping
Improvements	Are there things you would like to change about art therapy as it has been offered?	a) Are there things you found too difficult or too easy? b) Are there things you missed in the sessions?	Mapping suggestions

		c) What is the quality of these ten sessions?	
The research	What was it like for you to participate in the study?	a) How did you feel about completing the questionnaires on a weekly basis?	Mapping participation in research
Fence	Are there any things we missed in this interview?	a) Do you have any questions/comments? b) We would like to thank you very much for your participation! We hope that the therapy has brought you a little further. After this interview has been transcribed, the recording will be destroyed. c) Processing the outcome of the research takes a long time; Reporting results?	Exiting/ catching missed comments

Interviewguide 2) Art Therapist participants:

Subject	Main question	Sub-questions	Purpose
Opening	Hello, how nice that we can also interview you for the research.	a) I'm going to turn on the recorder and then, as far as I'm concerned, we can start the interview.	Open Call / Start Recording
Patient journey	How did the patient end up with you?	a) Was that done through a referral? b) Who made the referral? c) Do you know what care the patient has received so far?	
General view	How did you experience art therapy in general?	d) How did you find working with this protocol? e) What can the protocol contribute to the overall treatment of PTSD? f) Would you use the protocol more often?	Painting a general picture
Visual work	How did you go about the sessions?	a) What kind of therapeutic attitude have you adopted?	Mapping out the way of giving therapy
Changes	What changes in symptoms have you noticed in the patient since you started art therapy?	a) Has anything improved since you started? b) Has anything deteriorated since you started?	Mapping changes in complaints
Cause changes	What do you think have caused these changes?	a) What helped during the sessions? Think of materials, instructions or your own attitude?	Attribution mapping

Protocol Improvements	Are there things you would change about the treatment you received?	a) Are there things that didn't fit in well with practice? b) Are there things that have been missed in this protocol? c) Are there things that could be improved in the communication about the research?	Mapping suggestions
Fence	Are there any things we missed in this interview?	a) Do you have any questions/comments? b) Would you like to be informed of the outcome of the investigation? c) We would like to thank you very much for your participation!	Exiting/ catching missed comments

Appendix: Questions main practitioner (from 'Fill-in file Therapists')

Pay attention to anonymity!

1. Do you think that the 'trauma-focused art therapy' protocol has been effective for the patient?
2. Do you see a change in the patient and if so, in what way? (this can be a positive or negative change)
3. Do you have any additional comments?

Supplementary File C: Summary of clinical trial registration

Data category	Information[32]
Primary registry and trial identifying number	ClinicalTrials.gov NCT05593302
Date of registration in primary registry	Oktober 12, 2022
Secondary identifying numbers	Unique protocol ID: TFAT SU1424 -101
Source(s) of monetary or material support	Care and Cure by Creativity (CCC) foundation
Primary sponsor	Care and Cure by Creativity (CCC) foundation
Secondary sponsor(s)	-
Contact for public queries	*Dr. Suzanne Haeyen*, [suzanne.haeyen@han.nl]
Public title	The Effectiveness of Trauma Focused Art Therapy (TFAT)
Scientific title	The Effectiveness of Trauma Focused Art Therapy (TFAT): a Multiple Baseline Single Case Experimental Design
Countries of recruitment	The Netherlands
Health condition(s) or problem(s) studied	Psychological Trauma
Intervention(s)	Trauma-Focused Art Therapy (TFAT)
Key inclusion and exclusion criteria	Ages eligible for study: ≥18 years Sexes eligible for study: both Accepts healthy volunteers: no Inclusion criteria: adult patient (≥ 18 years), being eligible for art therapy on discretion of multidisciplinary treatment panel (consisting of a psychiatrist, psychologists, sociotherapists, and art therapists).

	Exclusion criteria: intellectual disability (precluding the filling out of questionnaires).
Study type	Interventional Allocation: patients randomised for the time at which they start the intervention: CONSORT recognises this design as an N=1 Trial, please refer to https://www.consort-statement.org/extensions/overview/n-of-1 Intervention model: Multiple baseline single case experimental design Masking: None (Open Label) Primary purpose: Treatment Phase: N/A
Date of first enrolment	October 10, 2022
Target sample size	12
Recruitment status	Recruiting
Primary outcome(s)	- SERATS
Key secondary outcomes	- PCL-5 - RSES - RS - BDI-II - MHC-SF

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	19
Protocol version	3	Date and version identifier	18
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	18
	5b	Name and contact information for the trial sponsor	22
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	23/24

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4/5/6
	6b	Explanation for choice of comparators	8
Objectives	7	Specific objectives or hypotheses	7
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7/8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8/9
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	9
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	16/17
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9/16/17
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	9/17
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-14
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	9
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7/8
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	10
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	10
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	10
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	n.a.
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n.a.
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	7-15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	16

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	14
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14/15
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14/15
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14/15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	n.a.
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n.a.
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	n.a.
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n.a.
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	17
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	17

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	10
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n.a.
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	10
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	18
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	14
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n.a.
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	1
	31b	Authorship eligibility guidelines and any intended use of professional writers	18
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	17
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	25-31
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n.a.

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.