BMJ Open Effectiveness of trauma-focused art therapy (TFAT) for psychological trauma: study protocol of a multiplebaseline single-case experimental design

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ABSTRACT

Introduction Treatments such as eye movement desensitisation and reprocessing 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, non-verbal 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 multiplebaseline single-case experimental design will be conducted with 25-30 participants with psychological trauma. Participants will be randomly assigned to a baseline period lasting 3-5 weeks, followed by the TFAT intervention (10 weeks) and follow-up (3 weeks). Quantitative measures will be completed weekly: the Beck Depression Inventory-II, the Mental Health Continuum Short Form, the Resilience Scale, the Rosenberg Self-Esteem Scale and the Self-expression and Emotion Regulation in Art Therapy Scale. The Post-Traumatic Stress Disorder Checklist-5 will be completed at week 1 and week 10. Qualitative instruments comprise a semistructured 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 number NCT05593302.

INTRODUCTION

Approximately 80% of people worldwide experience one or more shocking events in their lives. Ten per cent 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

STRENGTHS AND LIMITATIONS OF THIS STUDY

- \Rightarrow 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 single-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.

1 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 PTSD³ 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 one-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, 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

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Correspondence to Jackie Heijman; jackie.heijman@han.nl 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.⁷⁹ 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.^{8 10} 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 PTSD 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 (eg, EMDR, CBT or NET). However, scientific evidence is still required to demonstrate the efficacy of AT.

A trauma-focused AT (TFAT) protocol has been developed¹³ 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 TFAT consisting of 10 1-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 the Intervention section).

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 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 well-being, 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 TFAT. 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 TFAT 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 (eg, maturation, history and regression to the mean-instead of the TFAT intervention-as

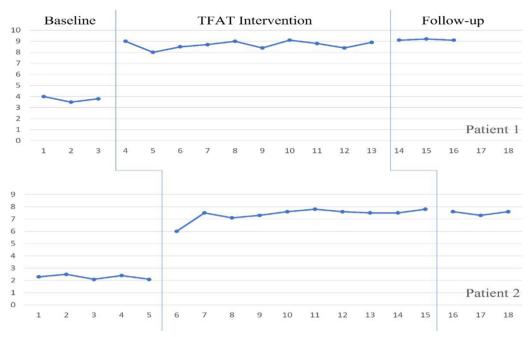


Figure 1 Visualisation of study design and procedure. In this MBSCED design, patient 1 has a 3-week baseline and patient 2 a 5-week baseline. This graph represents fictitious examples with idealised improvements in mental health outcomes in the intervention period, which are roughly maintained in the follow-up period. MBSCED, multiple-baseline single-case experimental design; TFAT, trauma-focused art therapy.

explanations for improvement). Measurements in the intervention period will be compared with measurements at baseline and follow-up. The TFAT intervention will conclude with in-depth, qualitative interviews exploring the perceived effects by therapists and patients.

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 years, (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. 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

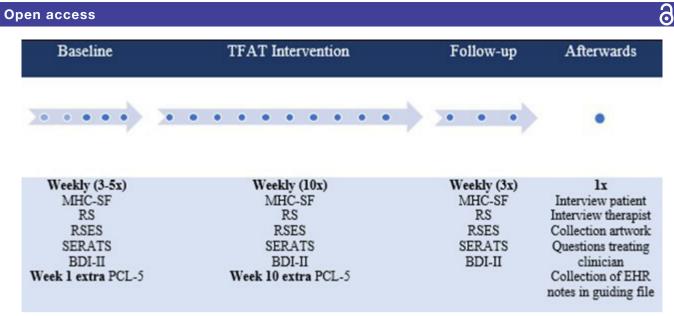


Figure 2 Visualisation of the study procedure. BDI-II, Beck Depression Inventory; EHR, electronic health record; MHC-SF, Mental Health Continuum Short Form; PCL-5, Post-Traumatic Stress Disorder Checklist; RS, Resilience Scale; RSES, Rosenberg Self-Esteem Scale; SERATS, Self-expression and Emotion Regulation in Art Therapy Scale; TFAT, trauma-focused art therapy.

(online supplemental file A). At the start of the intervention, patients will receive a patient number and a computer-generated, randomised baseline period lasting 3–5 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.

Intervention

The TFAT intervention is a short-term individual therapy comprising 10 1-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 (eg, 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 nine items (eg, *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 =0.94) 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 Diagnostic and Statistical Manual of Mental Disorders Fifth Edition 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 =0.95) 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 well-being: emotional, psychological and social. Items are phrased as follows: *In the past week, how often did you feel...* (eg, *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 0.76 to 0.91 across studies.²² Confirmatory factor analysis confirms the three-factor structure of emotional, psychological and social well-being, 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 subscales 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 =0.90) 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 subscores for the subscales Personal Competence & Acceptance of Self and Life. The questionnaire consists of 25 statements (eg, *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 0.72 to 0.94 in different studies), indicating sufficient to high reliability.²⁸ The Dutch RS 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 (eg, *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 to 0.90) and good internal and predictive validity.³⁰

Qualitative measures

Patients and art therapists will take part in semistructured 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 (online supplemental 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 1 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 SDs for interval variables, median and IQR 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=0.6) and an α 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 16–18 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 PTSD 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 df.³⁶ Linear mixed models are well equipped to handle missing data under the assumption of 'missing at random'. 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 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 SEs, 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 α of 5% will be adopted.

Qualitative data

The interviews will be audio-recorded, transcribed verbatim and analysed in ATLAS.ti for Windows (V.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 (ie, a list of codes), then compared and renamed to develop core and subcategories of themes.

Integration of quantitative and qualitative results

Individual MBSCED trajectories will be analysed through the lens of the interview outcomes. Interpersonal 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 (KAS), 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 4 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 3 months. In these sessions, the art therapists can share their experiences and any issues that arise. The art therapists will monitor the patients' well-being, 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.

Patient and public involvement

Patients' representatives of the Client Advisory Board of the Dutch Federation of Arts Therapies¹¹ 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 2 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 (online supplemental file C). Study findings will be published open access in peer-reviewed journals. Metadata will be made publicly accessible on request.

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Contributors SH and KAS 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. KAS commented on the final draft of the paper. All four authors contributed to the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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