Emotional freedom technique versus written exposure therapy versus waiting list for post-traumatic stress disorder: protocol for a randomised clinical MRI study

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ABSTRACT

Introduction The emotional freedom technique (EFT) is an acupuncture-based psychotherapy that combines tapping on acupoints with cognitive reframing. EFT has been previously shown to have potential for treating post-traumatic stress disorder (PTSD). However, further clinical evidence and underlying mechanisms of EFT are yet to be fully explored. This proposed clinical trial aims to examine the effect of EFT on patients with PTSD compared with the waitlist (WL) and active controls.

Methods and analysis This study was designed as a randomised, assessor-blinded, three-arm clinical MRI study. A total of 120 eligible patients with PTSD will be recruited and randomised into EFT, written exposure therapy (WET) or WL groups. EFT and WET will be applied once a week for 5 weeks. For patients in the WL group, EFT will be performed after 12 weeks. PTSD symptoms, depression, anxiety, somatic symptoms and quality of life will be evaluated. Assessments will be conducted at baseline (week 0), post-treatment (week 6) and follow-up (week 12). Structural and functional brain images and recording videos of facial expressions to emotional stimuli will be obtained before and after treatment. Sixty participants without lifetime traumatic experiences will be enrolled as healthy controls. The primary objective of the study is to compare the change from baseline in the Clinician-Administered PTSD Scale after treatment (week 6) between EFT and WL groups and between EFT and WET groups.

Ethics and dissemination Ethical approval was obtained from the Institutional Review Board of the Kyung Hee University Korean Medicine Hospital. The research findings will be shared at national and international conferences and will be published in peer-reviewed journals.


INTRODUCTION

Background and rationale Post-traumatic stress disorder (PTSD) is a disorder that occurs after exposure to traumatic events such as death, serious injury or sexual violence. These symptoms include repetitive and painful memories of the traumatic event, intrusive symptoms such as dreams, persistent avoidance of stimuli associated with the traumatic event, negative changes in cognition and emotion associated with the traumatic event and pronounced arousal and responsiveness associated with the traumatic event.1 According to the 2021 National Mental Health Survey conducted in Korea, the lifetime prevalence of PTSD is 1.5% (1.3% for men, 1.6% for women), and the annual prevalence is 0.3% (0.2% for men, 0.3% for women).2 PTSD often involves depressive, substance use and anxiety disorders simultaneously.3

Trauma-focused psychotherapy is the first-line treatment for PTSD.4,5 Strongly recommended treatments for PTSD include cognitive-behavioural therapy, cognitive processing therapy, cognitive therapy and
prolonged exposure therapy. Among the various psychotherapies for PTSD, exposure therapy is one of the most studied and well-established treatments. However, trauma-focused exposure therapy has a high dropout rate. A meta-analysis reported that 36% of patients who received trauma-specific treatment dropped out in clinical trials, and a dropout rate of 30% in real-world practice in the United States Veterans Health Administration Prolonged Exposure Training Program was similar. Two major reasons why veterans dropped out of trauma-focused psychotherapy were a lack of buy-in to treatment and too stressful course, which were mostly related to uncomfortable exposure to the past. Thus, effective therapy with low drop-out rate is required in patients with PTSD.

The emotional freedom technique (EFT) is a acupuncture-based psychotherapy that combines tapping on acupoints and exposure to cognitive reframing. Recently, a systematic review summarised that EFT treatment is effective for psychological and physiological conditions. In reviews on the effect of EFT on patients who experienced traumatic events and were at a high risk of PTSD, 4–10 EFT sessions were effective for PTSD symptoms and were proven to be safe. Two randomised controlled trials reported that EFT is potentially effective in improving PTSD symptoms in patients who are diagnosed as PTSD. Karatias et al reported that after 8 weeks of EFT treatment, PTSD symptom levels decreased and persisted after a 3-month follow-up, which was not significantly different from those of eye movement desensitisation and reprocessing (EMDR) treatment. In another study, Church et al reported that a 4-week EFT treatment reduced PTSD symptom levels and psychological distress compared with the standard care wait list.

According to the assessment by the Korean Medicine Procedure Expert Assessment Committee on 29 April 2021, EFT using acupuncture point tapping was determined as a safe and non-invasive method for symptom improvement in PTSD compared with palliative treatment. However, it was pointed out that there is limited evidence and follow-up data of EFT in PTSD when compared with cognitive-behavioural therapy and EMDR, which are currently recommended as psychotherapies for the treatment of PTSD in textbooks and guidelines. The aforementioned randomised controlled trials have limitations, in which both included a small number of participants (46 and 59, respectively) and used symptom-related parameters to assess efficacy. Therefore, further studies with a sufficient number of participants are necessary to examine the effectiveness of EFT in PTSD.

Before planning this trial, we conducted a feasibility trial of a five-session EFT in 30 patients diagnosed with PTSD. In this before-and-after study, PTSD symptoms of participants generally improved after the EFT intervention, compliance with attending EFT sessions was high, and the dropout rate was low. In this trial, we selected WET as an active control, as it is a short-term therapy, that is adequate for comparison with five-session of EFT. In addition, the waiting list (WL) was included as another control group, and this trial will be planned with a three-arm parallel design.

A critical limitation is that there are no well-established biomarkers related to either the diagnosis or prognosis of PTSD. Exploring the underlying mechanisms and seeking predictive factors for the response to PTSD treatments are also important, in addition to simply evaluating the efficacy of the treatment. To meet such demands, attempts have been made to identify biomarkers for PTSD using various methodologies. In comparison with non-trauma controls, patients with PTSD showed left amygdala hyperactivation, and in comparison with non-trauma controls and trauma-exposed controls, patients with PTSD exhibited diminished activation in the medial prefrontal cortex. In a longitudinal functional MRI study, higher dorsal anterior cingulate cortex, insula and amygdala activations in response to negative pictures were predictors of poor response to PTSD treatment. In the present study, structural and functional brain images will be obtained before and after the intervention to explore the underlying mechanisms.

Objectives
The primary objectives are to evaluate the effect of EFT on PTSD symptoms compared with the WL and to evaluate the non-inferiority of EFT on PTSD symptoms compared with WET. The change from baseline in the Clinician-Administered PTSD Scale (CAPS-5) after the intervention will be compared between the EFT and WL groups and between the EFT and WET groups.

The secondary objectives are to evaluate the effect of EFT compared with WL and WET based on the proportion of participants achieving criteria-based remission of PTSD and symptom-based remission of PTSD after the intervention. Additionally, self-reported PTSD symptoms will be evaluated using the PTSD Checklist-5 (PCL-5), and depression and anxiety will be assessed using the Beck Depression Inventory (BDI-II) and Beck Anxiety Inventory (BAI). Somatic symptoms and insomnia will be assessed using the Patient Health Questionnaire (PHQ)-15 and Insomnia Severity Index (ISI). Quality of life will also be evaluated using the EuroQol-5 Dimension-5 Levels (EQ-SD-5L) and WHO quality of life assessment instrument abbreviated version (WHOQOL-BREF). Additionally, the compliance and drop-out rate of each group will be measured. The safety will be assessed through the incidence of adverse events and assessment of suicide risk.

The exploratory objectives are to investigate the biomarkers and other predictors of PTSD diagnosis and prognosis, including (1) the detection of biomarkers for the diagnosis of PTSD at baseline compared with healthy controls, (2) the identification of biomarkers and other predictors for individuals with a better prognosis among patients and (3) understanding the underlying mechanisms of successful treatment. To achieve these objectives, potential biomarkers and other predictors, including...
structural and functional MRI, recordings of facial expressions to emotional stimuli, and blood samples, will be collected longitudinally.

**Trial design**

This study is designed as a randomised, assessor-blinded, three-arm, parallel-group clinical MRI study. The 120 eligible patients with PTSD will be randomly allocated to the EFT, WET or WL groups in a 1:1:1 ratio (figure 1).

**METHODS AND ANALYSIS**

**Study setting**

This study will be conducted at a university hospital in Seoul, Korea.

**Eligibility criteria**

**Patients with PTSD**

The inclusion criteria will be adults aged between 19 and 65 years; diagnosis of PTSD by Structured Clinical Interview for DSM-5; LEC-5, Life Event Checklist for DSM-5; PCL-5, PTSD Checklist-5; PHQ-15, Patient Health Questionnaire-15; SCID-5, Structured Clinical Interview for DSM-5; WET, Written Exposure Therapy; WHOQOL-BREF, WHO QoL assessment instrument abbreviated version; WL, waiting list.
Interview for DSM-5 (SCID-5); symptoms of PTSD for ≥3 months, willing to attend weekly visits for 6 weeks and patients who voluntarily agree to participate.

Exclusion criteria will be risk of suicide as assessed by Columbia-Suicide Severity Rating Scale (C-SSRS)24; current or past history of schizophrenia or bipolar disorder; alcohol or other substance use disorders within 8 weeks; history of cerebrovascular diseases, brain tumour or traumatic brain injury (participants with mild traumatic brain injury will not be excluded); history of neurological or systemic diseases that may affect the central nervous system; history of acute infectious disease within 2 weeks; history of taking the following medications within 4 weeks; use of systemic steroids, antipsychotics, antidepressants, benzodiazepines, sleep medications (participants taking the medications in stable doses for ≥2 weeks will not be excluded); history of taking antibiotics within 2 weeks; vaccination within 4 weeks or plans for vaccination during the study period; moderate or higher cognitive impairment; medical conditions requiring inpatient treatment; receipt of medication or other interventions in other clinical trials within 1 month; current active psychotherapy (based on early observation that a significant number of participants with PTSD had recently undergone psychotherapy, making it challenging to enrol participants with the original exclusion criteria of psychotherapy within 6 months, it was modified starting from protocol V.1.7. The characteristics of previously received psychotherapy will be carefully recorded and summarised as part of the baseline characteristics of enrolled participants); pregnant or lactating women; women who do not use medically acceptable contraception (barrier methods, combined oral contraceptives, contraceptive implant, contraceptive injection, intrauterine devices and personal or partner’s sterilisation) during the study period; and those determined as unsuitable by the investigators.

**Healthy controls**

The inclusion criteria for healthy controls will be adults aged between 19 and 65 years, those without traumatic experiences, those who do not meet the diagnostic criteria of PTSD according to the SCID-5, those who do not have functional/organic disorders and clinically meaningful findings in the history taking and physical examination, PHQ-9 score ≤4, Generalised Anxiety Disorder Screener-7 score ≤4, PHQ-15 score ≤5 and those who voluntarily agree to participate.

The exclusion criteria for healthy controls will include a history of major mental disorders. The other exclusion criteria are shown the clinical study registration. The baseline characteristics between PTSD patients and healthy controls will be compared, to explore the biomarkers of PTSD diagnosis. Healthy controls will be recruited in the same site, after the enrolment of patients with PTSD, with balanced sex and age.

**MRI-specific exclusion criteria**

These exclusion criteria will be applied to patients with PTSD and the healthy controls: ferrous-containing metal substance within the body and difficulty tolerating enclosed, small spaces because of claustrophobia.

**Interventions**

**Emotional freedom techniques**

EFT consists of five, 40 min, weekly sessions that include tapping on acupoints and exposure to cognitive reframing.11 The EFT protocol for patients with PTSD was developed on the basis of previous studies.13 15 25 In the previous feasibility trial, a developed EFT protocol was applied to 30 patients with PTSD in Korea, and the mean PCL-5 score was decreased to −14.33 (95% CI (CI) −19.79 to −8.86) points after the five sessions of EFT. In the first session, the therapist will provide an introduction to EFT. In every session of EFT, therapists will follow the instructions from the EFT Manual (fourth edition).26 At the beginning of each session, the patient and therapist will define the problem and evaluate the level of emotional distress. They will then create a ‘set-up statement’, acknowledging the problem and accepting oneself while tapping the SI3 acupoint on the side of the hand. This is one of the essential parts of EFT and includes exposure to trauma with cognitive reframing, where the patient is encouraged to reframe their negative thoughts about the problem in a more positive light. The therapist will then conduct the first sequence of EFT tapping, tapping on various acupoints while repeating a brief phrase of the problem seven times. After this, the 9 Gamut Procedure will be conducted, and the second sequence of EFT tapping will be repeated. The change in emotional distress will be re-evaluated after the sequences.

**Written exposure therapy**

WET consists of five, 40 min, weekly sessions that focus on expressive writing about a traumatic event. We will follow the WET protocol developed by Sloan et al.18 19 This WET protocol was applied to patients with PTSD in Korea, and the severity of PTSD symptoms was alleviated with large effect size (partial $r^2$: 0.524 for PCL-5) after five sessions of WET.27 In the first session, therapists will introduce WET and select the trauma experience to be covered in this WET session. Before writing, the subjective units of distress (between 0 and 100) will be checked. Instructions for writing will be provided using the WET script developed by Sloan and Marx,28 which ensure the standard delivery of WET protocol, and participants will write about their trauma in detail for 30 min. From the second to the fifth sessions, specific writing instructions will be provided using the WET script, and 30 min of the writing session will be completed. EFT and WET will be applied by qualified therapists working at the Department of Neuropsychiatry in Korean medicine, who have completed exposure-based treatment and Clinical EFT or WET protocol training. The treatment fidelity will be monitored by the perusal of the therapist written notes.
by investigators to ensure that all Clinical EFT and WET standards are met. In addition, to improve adherence to the intervention, participants will be encouraged to visit at predetermined times through regular phone and text messages.

Waiting list
The participants assigned to WL will not receive any intervention until completion of the follow-up visit. After 12 weeks, the follow-up visit and evaluation will be completed, and EFT will be applied to participants in the WL group. For all participants in the three groups, the use of systemic steroids, antipsychotics, antidepressants, benzodiazepines and sleep medications that were not used at the time of enrolment will be prohibited. If any of these medications are newly administered after enrolment, the participant will be excluded from the per-protocol set. However, other medications that were administered 4 weeks before study enrolment, as well as transient medications for other diseases or symptoms, may be allowed at the clinical discretion of the investigators, provided that those medications are not expected to significantly affect the study results.

Criteria for discontinuing or modifying allocated interventions
Participants will be considered for treatment cessation and elimination from the study if they meet the following criteria: participants who are found to have not met the inclusion and exclusion criteria at the screening period due to an error, participants who experience serious adverse events (death, life threatening or hospitalisation due to adverse events), participants with adverse events warranting discontinuation of the study intervention, participants whose symptoms worsen and require another treatment, participants who withdraw their consent, participants who are lost to follow-up and participants who are unsuitable for continuing administration by the investigators.

Outcomes
Primary outcome
The primary outcome is the mean change from the baseline CAPS-5 score at week 6 (post-treatment). CAPS-5 is a representative clinician rating scale for PTSD. The CAPS-5 score will be measured at baseline, week 6 (post-treatment) and week 12 (follow-up). The mean change in CAPS-5 scores between baseline and week 6 will be the primary outcome.

Secondary outcomes
The mean change from the baseline CAPS-5 score at week 12 (follow-up) as well as the proportions of participants achieving criteria-based and symptom-based remissions of PTSD at week 6 (post-treatment) and week 12 (follow-up) will be secondary outcomes used to assess the severity of PTSD symptoms. Criteria-based and symptom-based remissions of PTSD will be defined based on the results of CAPS-5. Criteria-based remission of PTSD will be defined as no longer meeting the diagnostic criteria for PTSD, which includes experiencing fewer than the required number of symptoms in each criterion. Meanwhile, a total CAPS-5 score <20 will be defined as the symptom-based remission of PTSD. Additionally, PCL-5 will be used as a self-rating scale to assess the severity of PTSD symptoms. BDI-II, BAI, and WHOQOL-BREF scores will be used as secondary outcomes.

Safety outcomes
The incidence of adverse events will be presented in three groups based on severity and causality assessment. The occurrence of adverse events will be monitored at every visit. Additionally, the suicide risk will be evaluated by the investigators using C-SSRS at screening, week 6 (post-treatment) and week 12 (follow-up).

Sample size
The sample size was computed to detect the mean difference in change from the baseline CAPS-5 score after treatment between the EFT and WL groups. No previous study has compared the CAPS-5 scores between EFT and WL. We estimated that EFT would have an effect size similar to that of EMDR, and in a previous study comparing EMDR with WL, the effect size (Cohen d) of EMDR was 0.65. With a two-sided significance level of 0.05 and a power of 0.8, 38.14 participants are required in each group. Considering a dropout rate of 5%, 40 participants will be recruited per group, and a total of 120 will be investigated. The dropout rate was calculated based on a previous feasibility trial of EFT in patients with PTSD. Additionally, we calculated the required sample size to evaluate the non-inferiority of EFT compared with WET. Under the assumptions of a significance level of 0.05, power of 0.8, SD of 17, mean difference of 0 and a non-inferiority margin of 10, the estimated sample size per group is 36, without accounting for dropout rates.

Recruitment
To achieve adequate participant recruitment, regular advertisements will be conducted through online media, and approved materials will be attached to the bulletin
boards inside and outside of the hospital. In the case of delayed recruitment, local advertisement can be implemented. The first participant of the study was enrolled on 8 December 2022, and the date of the last observation is expected to be completed in December 2025.

**Allocation**
Random assignment will be performed in compliance with group assignments that are not biased and not exposed to participants and researchers. An independent statistician who is not involved in the performance and evaluation of this clinical trial generated a random assignment sequence in a 1:1:1 ratio for each group using blocked randomisation in SAS (V.9.4, SAS Institute, Cary, North Carolina). The generated random sequence table will be kept by the independent statistician and protected from disclosure.

For each random number, the assignment results will be sealed in an opaque envelope and stored in a locked cabinet. Participants’ random numbers will be assigned according to the order in which the participants are enrolled at visit 2 after the screening process. A random number will be given independently of the screening number. The corresponding envelope will be opened according to the random number, and group assignment will be performed. The date and time of opening and the signature of the researcher who opened it will be written on the open envelope and stored separately.

**Blinding**
The participants will be allocated to the EFT, WET or WL groups, and it is impossible to blind therapists and participants during the intervention. Nevertheless, this study is designed as an assessor-blinded trial to control for bias as much as possible. Effectiveness and suicide risk will be evaluated by independent assessors who have not performed the intervention procedure or random assignment. Visits for interventions (3–7) and assessment (2, 8 and 9) will be separated.

**Data collection methods**
To assess the severity of PTSD symptoms, the CAPS-5 (clinician-administered tool) and PCL-5 (self-reported instrument) will be used. The CAPS-5 consists of 30 items measuring the severity of PTSD symptoms, and the total score ranges from 0 to 80, with higher scores indicating

<table>
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<th>Time point</th>
<th>Enrolment</th>
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<th>Intervention</th>
<th>Assessment</th>
<th>Follow-up</th>
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<td>Visit 2</td>
<td>Visit 3–7</td>
<td>Visit 8</td>
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**ENROLLMENT:**
- Informed consent
- Eligibility screen
- C-SSRS
- Allocation

**INTERVENTIONS:**
- EFT
- WET
- WL

**ASSESSMENTS:**
- CAPS-5
- CGI-I
- PCL-5, BDI-II
- BAI
- PHQ-15, ISI
- EQ-SD-5L
- WHOQOL-BREF
- MRI
- Emotional task
- EQ, IBS-5SS

**Figure 2** The schedule of enrolment, intervention and assessment. The participants assigned to WL will not receive any intervention until completion of the follow-up visit. After 12 weeks, EFT will be applied to participants in the WL group. The facial expressions will be recorded during the emotional task. BAI, Beck Anxiety Index; BDI-II, Beck Depression Inventory-II; CAPS-5, Clinician-Administered PTSD Scale; CGI-I, Clinical Global Impressions-Improvement scale; EFT, Emotional Freedom Techniques; EQ, empathy quotient; EQ-SD-5L, EuroQol-5 Dimension-5 Levels; IBS-SSS, Irritable Bowel Symptoms Severity Scale; ISI, Insomnia Severity Index; PCL-5, PTSD Checklist-5; PHQ-15, Patient Health Questionnaire-15; WET, written exposure therapy; WHOQOL-BREF, WHO QoL assessment instrument abbreviated version; WL, waiting list.
The second null hypothesis is that the mean change from baseline at week 6 in the WET group will be the same as that in the WL group \((H_0: \mu_1 = \mu_2, H_1: \mu_1 \neq \mu_2)\). MMRM will be used as in the first hypothesis. From the results of the second hypothesis, the non-inferiority margin (M) will be defined. The lower limit of the 95% CI of the mean difference between two groups will be M.

The third null hypothesis is that the mean change from the baseline at week 6 in the WET and EFT group will be greater than M \((H_0: \mu_3 - \mu_1 > M, H_1: \mu_3 - \mu_1 \leq M)\). The third hypothesis assesses the non-inferiority of EFT compared with WET, and M calculated in the second hypothesis will be used. MMRM will be used, similar to the first hypothesis, but the significance level will be set to 2.5% since the non-inferiority test is one sided.

The problem of multiple testing will be solved using the fixed sequence method. If the statistical result for hypothesis 1 is significant, the tests for hypotheses 2 and 3 will be performed. If the first null hypothesis was not rejected, tests for hypotheses 2 and 3 will not be performed. If the first null hypothesis is rejected and the test for hypothesis 2 is performed, in case that the statistical result for hypothesis 2 is significant, the test for hypothesis 3 will be conducted.

Statistical methods for analysing the secondary outcomes
Continuous variables (mean changes in CAPS-5, PCL-5, BDI-II, BAI, PHQ-15, ISI, EQ-5D-5L, WHOQOL-BREF and Clinical Global Impression scores) will be tested using the same method as for the primary outcome. Additionally, to compare the difference between before and after the intervention in each group, the Student paired t test or Wilcoxon signed-rank test will be used. Repeated measures analysis of variance will be performed to test the interaction between group and time.

Binary variables (criterion-based remission of PTSD and symptom-based remission of PTSD) will be tested using logistic regression analysis. ORs (95% CI) for the two groups will be presented. Hypothesis setting and multiple-testing problem-solving methods will be the same as those used for the primary outcome.

Statistical methods used to handle missing data
The primary outcome will be analysed using MMRM. The MMRM considers missing data using the maximum likelihood and does not require the process of replacing the missing data. In the case of an additional analysis of covariance, missing data will be replaced using the multiple imputation method.

Data monitoring
Considering the low risk of interventions and the study purpose, a data monitoring committee is not needed. An interim analysis is not planned. If intervention-related moderate or severe adverse events occur in >25% of all participants, the study will be stopped.
Harms
Adverse events will be carefully recorded at every visit, and the frequency, severity and causality of the adverse events will be assessed in the three groups. Additionally, the suicide risk of the participants will be evaluated using the Columbia Suicide Severity Rating Scale.

Auditing
Monitoring will be conducted to verify that the clinical study data are accurate and complete, and that the clinical study is performed in accordance with the approved protocol and related regulations. Monitoring of clinical studies will be conducted through regular visits to the institute. The scope of monitoring will include compliance with the clinical study protocol, collection of appropriate and accurate data, obtaining informed consent and recording adverse events. The monitor will check the eCRF, source documents and essential documents during regular visits.

ETHICS AND DISSEMINATION

Research ethics approval
This study has been approved by the Institutional Review Board (IRB) of the Kyung Hee University Korean Medicine Hospital (KOMCIRB2021-11-005-001).

Protocol amendments
Protocol modifications will be determined after sufficient discussion by investigators at the hospital and KIOM and will be applied to the study after obtaining approval for the amendment from the IRB. The current version of protocol is V.1.7 (date: 28 March 2023).

Consent or assent
Written informed consent will be obtained from all participants prior to screening (online supplemental material S1). The principal investigator and subinvestigators, who are Korean medicine doctors in the hospital and delegated by the principal investigator, will provide information about the clinical study and obtain informed consent from the participants. Informed consent and a description of the study approved by the IRB will be used. Sufficient time and opportunity for the participants to ask questions about the details of the clinical study and to decide whether to participate will be provided. Additional consent will be obtained for the collection and analysis of blood samples.

Confidentiality
The personal information of each participant will not be entered into eCRF, and the data of each participant will be collected under screening and random numbers.

Ancillary and post-trial care
Follow-up observation and online follow-up observation will be conducted at weeks 12 and 24. Compensation criteria and plans will be prepared for those who suffer harm from trial participation. The occurrence of adverse events will be assessed at every visit, and the required treatment and observation will be applied until the symptoms disappear.

Dissemination policy
The clinical study information and results will be registered with the Clinical Research Information Service. This study’s findings will be presented at conferences and published in peer-reviewed journals. The participant-level data set will be uploaded to the Korean Medicine Data Repository (kmdr.kiom.re.kr) after study completion.

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Contributors
HK, S-HC, YC, YK and SC conceived the trial. YEC, O-JK, DK and S-HL helped with study implementation. YC and YK completed the initial draft of the manuscript. O-JK generated the randomisation sequence and provided biostatistical advice and information. All authors designed the study and read, edited and approved the final manuscript and supplementary files.

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Competing interests
None declared.

Patient and public involvement
Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication
Not applicable.

Provenance and peer review
Not commissioned; externally peer reviewed.

Supplemental material
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S1. Informed Consent Form (Translated English version)

**Informed Consent Form**

<table>
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<th>Emotional Freedom Techniques vs Written Exposure Therapy vs Waiting List for Posttraumatic Stress Disorder: A Randomized Clinical Trial</th>
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<tr>
<td>Principal Investigator</td>
<td>Department of Neuropsychiatry, KyungHee University Korean Medicine Hospital, KyungHee University Medical Center 23, Kyungheedae-ro, Dongdaemun-gu, Seoul Prof. Seung-Hun Cho</td>
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<td>Sub-Investigator</td>
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<tr>
<td>Study Site</td>
<td>Department of Neuropsychiatry, KyungHee University Korean Medicine Hospital, KyungHee University Medical Center 23, Kyungheedae-ro, Dongdaemun-gu, Seoul</td>
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<td>Source of Monetary/Material Support</td>
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<td>Institutional Review Board</td>
<td>Kyung Hee University Korean Medicine Hospital Institutional Review Board 23, Kyungheedae-ro, Dongdaemun-gu, Seoul</td>
</tr>
</tbody>
</table>

This information sheet and consent form have been prepared to provide you with an explanation of the content of the clinical study and your role, compensation, and other relevant details. It is important that you fully understand why this clinical study is being conducted and what your involvement will entail before making a voluntary decision to participate. Take sufficient time to read this information sheet, and if desired, consult with your family or other individuals. You have the right to withdraw from the study at any time if you wish. If you have any questions, feel free to ask the principal investigator or research coordinator and take the necessary time to decide whether or not to participate in this clinical study. The research team will be available to answer your questions before, during, and after the study. Once you have thoroughly reviewed and agreed to the contents of this information sheet, please sign the consent form. You will receive one copy each of this information sheet and the signed consent form.

1. **Background and Objectives of the Study**

This clinical study is conducted for research purposes to evaluate the effectiveness and safety of Emotional Freedom Techniques for Posttraumatic Stress Disorder (PTSD). PTSD is a condition that manifests with characteristic symptoms following exposure to traumatic events such as death, severe injury, or sexual assault. These symptoms include intrusive recollections of the traumatic event, distressing dreams, persistent avoidance of stimuli associated with the trauma, negative changes in cognition and mood related to the event, and heightened arousal and reactivity.
associated with the trauma.

2. Study Participants
A total of 120 participants, aged 19 years or older but under 65 years, with symptoms of PTSD, and 60 participants, aged 19 years or older but under 65 years, without a history of trauma, will be enrolled in this clinical study.

3. Information about the Intervention (Applicable to the patient group only)
Emotional Freedom Techniques (EFT) is a combination of traditional east Asian medicine's meridian theory and psychotherapeutic techniques, forming a meridian-based psychotherapy. Previous research has reported the effectiveness of EFT in improving symptoms of PTSD. Clinical studies applying EFT to patients with anxiety disorders and insomnia have been conducted in Korea.

In this clinical study, participants will be divided into three groups: the EFT group, the Written Exposure Therapy (WET) group, and the Waiting List group. If assigned to the EFT group, you will receive EFT sessions once a week for a total of five weeks. If assigned to the WET group, you will receive WET sessions once a week for a total of five weeks. WET is one of the most extensively researched psychotherapeutic methods known to be effective in improving symptoms of PTSD. If assigned to the Waiting List group, after the 12-week assessment period, you will receive EFT sessions once a week for a total of five weeks.

4. Method of Group Assignment (Applicable to the patient group only)
Once you have been determined as eligible for this clinical study through screening evaluations and tests, you will be randomly assigned to one of the three groups in a 1:1:1 ratio according to a predetermined randomization table. The group assignment is purely random and does not involve any intentional decision based on individual characteristics or issues. It follows a random allocation method (similar to flipping a coin), and the probability of being assigned to each group is equal.

5. Procedures You Will Receive During Study Participation
   - For the PTSD patient group:
If you agree to participate in this clinical study and sign the written consent form, you will undergo a medical history interview, vital sign measurements, questionnaires, laboratory tests, and other relevant assessments to determine your eligibility for this clinical study. If you do not meet the inclusion and exclusion criteria based on the screening results, you will not be able to participate in the study. During the screening visit, specific tests and evaluations will be conducted to assess your eligibility according to the predetermined inclusion/exclusion criteria. If you meet the criteria, you will be randomly assigned to one of the three groups in a 1:1:1 ratio according to the predetermined randomization table.

<table>
<thead>
<tr>
<th>Group</th>
<th>Emotional Freedom Techniques Group</th>
<th>Written Exposure Therapy Group</th>
<th>Waiting List Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of</td>
<td>40</td>
<td>40</td>
<td>40</td>
</tr>
</tbody>
</table>
Once you participate in the clinical study, you will need to visit again within 14 days for an initial assessment (week 0), including an MRI examination. If you are assigned to the Emotional Freedom Techniques or Writing Exposure Therapy group, you will receive treatment once a week for a total of 5 sessions. After the completion of treatment (6 weeks), you will undergo a post-treatment evaluation, including an MRI examination. At 12 weeks from the initial assessment, you will visit again for follow-up observation. At 24 weeks from the initial assessment, you will be required to complete an additional online survey. If you are assigned to the Waiting List group, you will not start the Emotional Freedom Technique treatment immediately. Instead, after the completion of the 12-week follow-up observation, you will receive Emotional Freedom Techniques treatment once a week for a total of 5 sessions.

The specific visit schedule and contents for the clinical study are as follows:

<Clinical Study Schedule - PTSD Patient Group, Assigned to EFT or WET Group>
### Clinical Study Schedule - PTSD Patient Group, Assigned to WL Group

<table>
<thead>
<tr>
<th>Time point</th>
<th>Week 0</th>
<th>Week 6</th>
<th>Week 12</th>
<th>Week 13-17</th>
<th>Week 24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit Number</td>
<td>V1</td>
<td>V2</td>
<td>V3</td>
<td>V4</td>
<td>V5-V9</td>
</tr>
<tr>
<td>Written consent</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical history taking</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vital signs</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>Height/weight</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Psychiatric interview and assessment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suicide risk assessment</td>
<td>O</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borderline personality assessment</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inclusion/exclusion criteria</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Random allocation</td>
<td>O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTSD symptoms evaluation</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

<Clinical Study Schedule - PTSD Patient Group, Assigned to WL Group>
For the healthy control group:

If you agree to participate in this clinical study and sign the written consent form, you will undergo a medical history interview, vital signs measurement, questionnaire, and laboratory tests to determine your eligibility for the study. If the screening test results do not meet the inclusion and exclusion criteria, you will not be able to participate in the research. During the screening visit, you will undergo the designated tests and evaluations to determine if you meet the inclusion/exclusion criteria for this clinical study. If you meet the criteria, you will be enrolled in the study and the next visit schedule will be determined. Within 14 days, you will return for an evaluation, including an MRI scan.

<table>
<thead>
<tr>
<th>Group</th>
<th>Healthy control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of participants</td>
<td>60</td>
</tr>
</tbody>
</table>

Here is the specific visit schedule and content:

<Clinical Study Schedule – Healthy control Group>

<table>
<thead>
<tr>
<th>Time point</th>
<th>Written consent</th>
<th>Demographics</th>
<th>Medical history taking</th>
<th>Physical examination</th>
<th>Vital signs</th>
<th>Height/weight</th>
<th>Depression, Anxiety, Somatic symptoms questionnaire</th>
<th>Laboratory tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit Number</td>
<td>V1</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Week 0</td>
<td>V2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Protocol No.: KIOM_21_ PTSD_EFT
ICF Version No.: 1.3 (2023.03.14)
6. Expected Duration of Participant

- For the PTSD patient group:

The expected duration of your participation in this clinical study is approximately 24 weeks. During the initial visit for screening, the examination will take about 1-2 hours. If you are enrolled, you will need to visit within 2 weeks for the initial evaluation, which includes an MRI scan, and it will take approximately 3 hours. When receiving the Emotional Freedom Techniques (EFT) or Written Exposure Therapy (WET), you will have weekly visits with each session lasting approximately 1 hour and 30 minutes. At the 6-week visit, another evaluation including an MRI scan will be conducted, taking approximately 3 hours. At the 12-week visit, an assessment of major symptoms related to post-traumatic stress disorder (PTSD) will be performed, and it is expected to take about 1 hour.

7. Potential Discomfort or Risks Associated with Study Participation

In this clinical study, blood collection is required for examinations and blood sample analysis. Throughout the study period, there will be a total of three blood collection procedures (two for the healthy control group), with approximately 10ml of blood collected per procedure, which is a typical amount for blood tests. While the risks associated with blood collection are generally low, it is possible to experience pain during the procedure. Needle puncture may cause local pain, bruising, dizziness, and rarely, fainting or an infection at the puncture site. If you experience any discomfort after the blood collection, please inform the investigators.

8. Expected Benefits of Participation

By participating in this study and receiving either Emotional Freedom Techniques (EFT) or Written Exposure Therapy (WET), it is anticipated that there will be improvements in PTSD symptoms. However, it cannot be guaranteed that...
your condition will necessarily improve as a result of participating in this study. By participating in this clinical research, it is expected that you and other patients involved may benefit from the findings of this study in the future. Additionally, your participation may contribute to the development of new treatment approaches for other patients. It is important to note that participating in this clinical study is not the only option for the treatment of your PTSD symptoms.

9. Alternative Treatment Options
When it comes to treating PTSD, the first consideration is psychotherapy focused on trauma and the use of antidepressant medication. Psychotherapeutic approaches for PTSD include cognitive-behavioral therapy (CBT), cognitive processing therapy, exposure therapy, prolonged exposure therapy, eye movement desensitization and reprocessing (EMDR), narrative exposure therapy, stress inoculation training, and stage-based treatment. Traditional Korean medicine approaches such as Gyeongja Pyeongji therapy, Jieon Goron therapy, ljeongbyeon-gi therapy, and Ojisangseung therapy can also be applied.

10. Participant Responsibilities
The following guidelines are essential for ensuring participant protection and accurate research conduct:
① Adhere strictly to the scheduled visits and examinations.
② Inform the investigator in detail before starting any new medication during the study period, including both current medications and any additional ones.
③ Refrain from seeking symptom-improvement therapies during the study period to exclude the effects of other treatments.
④ Participants who are pregnant or breastfeeding cannot participate in the study for safety reasons. If you are capable of becoming pregnant, please inform us of the contraceptive method you are using, and if your contraceptive method is not reliable, you cannot participate in the study.

11. Expected Participant Costs
By participating in this study, there are no additional costs incurred for the participants. You will not be responsible for any medical or examination fees associated with the clinical study during your participation. However, any unrelated hospitalization expenses or consultation fees incurred during or after the study period will be your responsibility. Additionally, participants who take part in the clinical study will receive a reimbursement of 50,000 won per visit for transportation expenses and questionnaire completion costs. The reimbursement for transportation expenses will be processed within approximately 20 to 30 days after each visit, considering the necessary administrative procedures. Please take this into account when participating in the study.

13. Compensation and Treatment Measures in Case of Harm
The research team will take the necessary measures according to the clinical study protocol and handle any medical issues directly related to the research. In the event of direct injury or health damage resulting from participation in this clinical research, you will be eligible for compensation through the "Compensation Agreement" and the Clinical
Research Injury Insurance. However, damages not directly caused by participation in the clinical study may be excluded from compensation.

The principles of compensation are as follows: ① Compensation will be provided for physical injuries suffered by participants due to unexpected incidents or side effects during the course of the clinical study. ② Compensation will be provided if the injury is caused by an intervention related to the clinical study. ③ Compensation will be provided for injuries resulting in sustained disabilities, rather than temporary pain or easily treatable injuries. ④ Compensation will be provided for injuries directly caused by the intervention of the clinical study or during the process of managing side effects.

In the event of any injury or adverse event related to the clinical study, you must immediately inform the investigator.

14. Participant’s Decision and Withdrawal from the Clinical Study

The decision to participate in this clinical study is entirely voluntary and up to your free will. You have the right to decide not to participate in the study at any time, and you also have the option to withdraw from the study. If you wish to discontinue your participation, please inform the investigator.

In the event that you withdraw from the study after the initial evaluation, any scheduled tests (vital signs, laboratory tests, etc.) and assessments (questionnaires) within 7 days of the withdrawal will be conducted at the discretion of the investigator.

You will not experience any disadvantages by choosing not to participate in this research, and your decision to refuse or discontinue participation in the clinical study can be made without any loss of benefits that you would normally receive. By signing the form or giving consent to participate in the study, please be aware that you are not waiving your legal rights to protection. If you decide to withdraw from or revoke your consent for the clinical study, your information will no longer be collected thereafter. However, the information collected up to that point may be accessed by relevant investigators within the bounds of confidentiality regarding your personal data protection.

15. Suspension of Participant’s Involvement in the Research and Reasons

Your participation in this study may be suspended under the following circumstances:

① If a participant is found to have not met the inclusion and exclusion criteria at the screening period due to an error.

② If a systemic disorder that was not detected during the screening examination is discovered.

③ If a participant experiences a serious adverse event (death, life-threatening, or hospitalization due to adverse events)

④ If an adverse event is deemed serious enough by the investigator to be inappropriate for continued participation.

⑤ If symptoms worsen, and the investigator determines that another treatment is necessary.

⑥ If a participant withdraws their consent for clinical study participation or requests to discontinue their involvement.

⑦ If a participant’s visits and follow-ups cannot be conducted.
If, in the researcher's judgment, continuing administration of the clinical study is deemed unsuitable for other reasons.

If a participant's involvement in the clinical study is suspended during the study, they will be informed of these circumstances. In the event that the participation is discontinued due to an adverse reaction, necessary tests to assess your health status and receive optimal treatment will be provided to ensure appropriate management. In the case of a serious adverse event, the study will be suspended, and prompt and appropriate measures will be taken.

16. Access to Records and Protection of Personal Information

To ensure the validity of this clinical study and verify the procedural integrity and reliability of the data without compromising the confidentiality of participants, monitors, auditors, and the Institutional Review Board (IRB) of the study site may directly access your medical records within the limits set by relevant regulations. Your signature on the consent form indicates your permission to allow direct access to these records by authorized individuals. All personal information, including your identity and clinical trial data, will be strictly kept confidential and protected. While study results may be shared with relevant researchers for the purpose of the study, your personal information will be safeguarded, with only initials or pseudonyms being disclosed to protect your privacy. In the event of publication of the clinical study findings, your personal information will remain confidential.

The personal information collected from your participation in this study includes your name, contact information, demographic characteristics, personal medical history, and bank account number. This information will be stored and used for research purposes for a period of 3 years after the study's completion. The collected information will be strictly managed in accordance with the "Personal Information Protection Act" and other applicable regulations. Personal information will be stored in secure locations with access controls (such as data management rooms), and electronic documents will be encrypted. Only the principal investigator and authorized investigators will have access to this information. We will make every effort to ensure the confidentiality of all personal information obtained through the study. When personal information obtained from the study is published in journals or conferences, your name and other personal identifiers will not be used.

Personal information-related materials will be stored, managed, and provided for disposal for a maximum of 3 years from the completion of the study, or upon request for information disposal. Personal information that has exceeded the retention period will be destroyed in accordance with Article 16 of the "Personal Information Protection Act" Enforcement Decree. However, research data may be used beyond 3 years for public purposes, related research, or medical purposes, provided that they are anonymized.

Furthermore, collected personal information and sensitive information may be provided to third parties such as the Korea Institute of Oriental Medicine (KIOM) and data processing agencies for the purpose of organizing clinical study data, scientific research, and preservation of public interest records, as stipulated in Article 18 of the Bioethics Act. In such cases, your research information will be anonymized and shared with third parties after deliberation by the Institutional Review Board. Your signature on this consent form will be considered as prior knowledge and acceptance of these provisions.

17. Research Data Sharing Plan
After the completion of the clinical study, anonymized and organized data, including brain imaging data, of the participants may be registered in the Korean Medicine Data Repository (kmdr.kiom.re.kr), which is a publicly accessible or partially accessible database for managing and sharing research data in Korean medicine R&D. This system serves as a platform for registering research data conducted with public resources. Additionally, the anonymized data and brain imaging data may be used for public purposes, such as uploading to public data servers required for submitting scientific papers or for neuroscience-related research.

18. Inquiries Regarding the Study
If you have any questions, concerns, or discomfort related to this study, or if any harm occurs as a result of the clinical study, please consult with our research team. If you need to contact us regarding the study, you or your legal guardian can schedule a telephone consultation at any time. The contact information for the available research team members is provided below. If you wish to discuss questions, concerns, complaints, or the rights of the participants, you may also consult with the Institutional Review Board (IRB) of our institution.

If you have chosen to participate in this study, you will receive a copy of the signed informed consent form.

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation and Position</th>
<th>Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>KyungHee University Korean Medicine Hospital /Principal investigator</td>
<td>☎️</td>
<td></td>
</tr>
<tr>
<td>KyungHee University Korean Medicine Hospital /Sub-investigator</td>
<td>☎️</td>
<td></td>
</tr>
<tr>
<td>KyungHee University Korean Medicine Hospital /Clinical Research Coordinator</td>
<td>☎️</td>
<td></td>
</tr>
<tr>
<td>Kyung Hee University Korean Medicine Hospital Institutional Review Board</td>
<td>☎️</td>
<td></td>
</tr>
</tbody>
</table>
Consent to Participate

<table>
<thead>
<tr>
<th>Study title</th>
<th>Emotional Freedom Techniques vs Written Exposure Therapy vs Waiting List for Posttraumatic Stress Disorder: A Randomized Clinical Trial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Principal Investigator</td>
<td>Department of Neuropsychiatry, KyungHee University Korean Medicine Hospital, KyungHee University Medical Center 23, Kyungheedae-ro, Dongdaemun-gu, Seoul  Prof. Seung-Hun Cho</td>
</tr>
<tr>
<td>Sub-Investigator</td>
<td>Department of Neuropsychiatry, KyungHee University Korean Medicine Hospital, KyungHee University Medical Center 23, Kyungheedae-ro, Dongdaemun-gu, Seoul</td>
</tr>
<tr>
<td>Study Site</td>
<td>Department of Neuropsychiatry, KyungHee University Korean Medicine Hospital, KyungHee University Medical Center 23, Kyungheedae-ro, Dongdaemun-gu, Seoul</td>
</tr>
<tr>
<td>Source of Monetary/Material Support</td>
<td>Korea Institute of Oriental Medicine</td>
</tr>
<tr>
<td>Institutional Review Board</td>
<td>Kyung Hee University Korean Medicine Hospital Institutional Review Board 23, Kyungheedae-ro, Dongdaemun-gu, Seoul</td>
</tr>
</tbody>
</table>

*** Please carefully read the following information and have a thorough discussion with the investigator. If you voluntarily agree, please check the box. 

1. I have read the explanation of this study and have discussed it with the responsible researcher. □

2. I have been informed about the risks and benefits of this study and have received satisfactory answers to my questions. □

3. I have received sufficient explanations from the researcher regarding the benefits and risks associated with this study, and I understand that I can request further explanations from the researcher at any time regarding these matters. □

4. I voluntarily agree to participate in this study. □

5. I understand that I can withdraw from this study at any time and that this decision will not have any negative consequences for me. □
6. I consent to the collection and processing of information about me obtained in this study by the investigators, within the limits allowed by current laws and institutional review board regulations. □

7. I agree that after the completion of the study, collected data that has been processed in an anonymized format may be registered in a publicly accessible database. □

**<Collection and Use of Personal Information>**

<table>
<thead>
<tr>
<th>Personal information items</th>
<th>Purpose of collection</th>
<th>Retention period</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Name, Sex, Birth Date</td>
<td>Evaluation of the effectiveness and safety of Emotional Freedom Technique for patients with PTSD</td>
<td>3 years after the completion of the study</td>
</tr>
<tr>
<td>B. Education, Employment Status, Marital Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C. Resident Registration Number, Phone Number, Address, Bank Account Number</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

※ You have the right to refuse to provide personal information.
☞ Do you agree to the collection and use of personal information as stated above? (□ Yes, □ No)

**<Collection and Use of Sensitive Information>**

<table>
<thead>
<tr>
<th>Sensitive information items</th>
<th>Purpose of collection</th>
<th>Retention period</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Health (current and past medical history, medication history, etc.)</td>
<td>Evaluation of the effectiveness and safety of Emotional Freedom Technique for patients with PTSD</td>
<td>3 years after the completion of the study</td>
</tr>
<tr>
<td>B. Facial images obtained from the Emotional tasks (the images are stored in numerical format, and recorded video data is permanently deleted from the storage device within 1 year of acquisition)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

※ You have the right to refuse to provide sensitive information.
☞ Do you agree to the processing of sensitive information as stated above? (□ Yes, □ No)
C. Health (current and past medical history, medication history, smoking history, alcohol consumption history, etc.)

D. Facial images obtained from the Emotional tasks (the images are stored in numerical format, and recorded video data is permanently deleted from the storage device within 1 year of acquisition)

※ You have the right to refuse third-party disclosure and outsourcing. ※ Do you agree to the processing of personal information as described above? (□ Yes, □ No)

8. I agree that the research team and authorized representatives, including monitoring agents, inspection agents, institutional review boards, the Minister of Health and Welfare, and the Director of the Food and Drug Administration, may have access to my medical records within the scope of protecting the confidentiality of my personal information, in order to verify the implementation procedures and data quality of the research in accordance with relevant laws and regulations. I also understand that the signed consent form allows for the access to such information. □

9. I agree that after the completion of the study, collected data that has been processed in an anonymized format may be registered in a publicly accessible database. □

10. My signature indicates that I have received a copy of this informed consent form and will keep a copy until the end of my participation in the study. □

I have fully understood the contents of the consent form and hereby agree to the above statements by signing below.

If employees of the study site participate:

I voluntarily participated in this study (handwritten)
<table>
<thead>
<tr>
<th>Role</th>
<th>Name:</th>
<th>Signature:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Legal Guardian (if necessary)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observer (If necessary)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor (Investigator)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Relationship with the participant: (Parent • Spouse • Legal guardian)

*Reason: