Protocol No.: KIOM_21_ PTSD_EFT
ICF Version No.: 1.3 (2023.03.14)

S1. Informed Consent Form (Translated English version)

Informed Consent Form

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

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

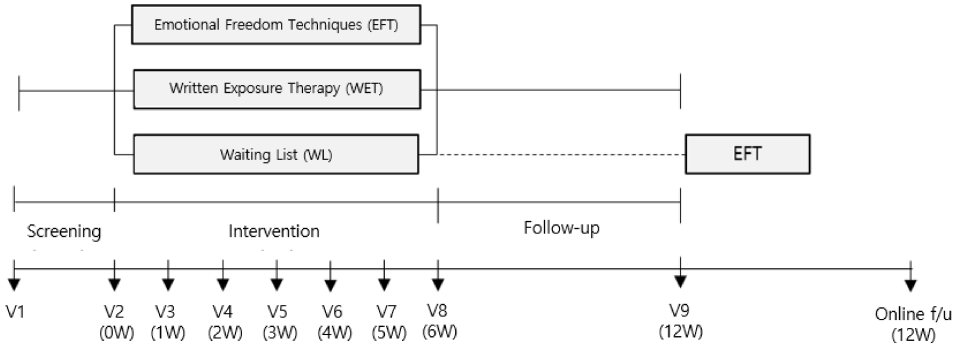
- For the PTSD patient group:

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.

Group	Emotional Freedom Techniques Group	Written Exposure Therapy Group	Waiting List Group
Number of	40	40	40

Participants			

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.



<Study flow>

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>

Time point		Week 0	Week 1~ Week 5	Week 6	Week 12	차
Visit Number	V1	V2	V3 ~ V7	V8	V9	Online f/u
Written consent	O					
Demographics	O					
Medical history taking	O	O				
Physical examination	O					
Vital signs	O	O	O	O	O	
Height/weight	O			O	O	
Laboratory tests	O					
Pregnancy test	O					
Psychiatric interview and assessment	O					
Suicide risk assessment	O			O	O	

Borderline personality assessment	O					
Inclusion/exclusion criteria	O					
Random allocation	O					
PTSD symptoms evaluation		O		O	O	O
MRI scan		O		O		
Emotional tasks		O		O		
Blood sample collection		O		O		
Other questionnaires		O		O		
EFT or WET			O			
Monitoring of concomitant medications			O	O	O	O
Monitoring of adverse events			O	O	O	O
Visit schedule	O	O	O	O		
Completion of the study					O	

<Clinical Study Schedule - PTSD Patient Group, Assigned to WL Group>

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

MRI scan		O	O			
Emotional tasks		O	O			
Blood sample collection		O	O			
Other questionnaires		O	O			
EFT or WET						
Monitoring of concomitant medications			O	O		O
Monitoring of adverse events			O	O		O
Visit schedule	O	O	O			
Completion of the study				O		

- 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.

Group	Healthy control group
Number of participants	60

Here is the specific visit schedule and content:

<Clinical Study Schedule – Healthy control Group>

Time point		Week 0
Visit Number	V1	V2
Written consent	O	
Demographics	O	
Medical history taking	O	
Physical examination	O	
Vital signs	O	O
Height/weight	O	
Depression, Anxiety, Somatic symptoms questionnaire	O	
Laboratory tests	O	

Pregnancy test	O	
Psychiatric interview and assessment	O	
Suicide risk assessment	O	
Borderline personality assessment	O	
Inclusion/exclusion criteria	O	
PTSD symptoms evaluation		O
MRI scan		O
Emotional tasks		O
Blood sample collection		O
Other questionnaires		O
Monitoring of concomitant medications		O
Monitoring of adverse events		O
Visit schedule	O	
Completion of the study		O

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, Ijeongbyeon-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.

⑧ 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.

Name	Affiliation and Position	Contact Information
	KyungHee University Korean Medicine Hospital /Principal investigator	☎
	KyungHee University Korean Medicine Hospital /Sub-investigator	☎
	KyungHee University Korean Medicine Hospital /Clinical Research Coordinator	☎
	Kyung Hee University Korean Medicine Hospital Institutional Review Board	☎

Protocol No.: KIOM_21_ PTSD_EFT
ICF Version No.: 1.3 (2023.03.14)

Consent to Participate

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

*** 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>

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

※ 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>

Sensitive information items	Purpose of collection	Retention period
A. Health (current and past medical history, medication history, etc.) 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)	Evaluation of the effectiveness and safety of Emotional Freedom Technique for patients with PTSD	3 years after the completion of the study

※ You have the right to refuse to provide sensitive information.

☞ Do you agree to the processing of sensitive information as stated above? (☐ Yes, ☐ No)

<Disclosure and Outsourcing of Personal Information to Third Parties>

Recipient of Disclosure	Personal Information Disclosed	Purpose of collection	Retention period
Korea Institute of Oriental Medicine	A. Sex, Date of Birth B. Education, Employment Status, Marital Status	Evaluation of the effectiveness and safety of Emotional Freedom Technique	3 years after the completion of the study

	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)	for patients with PTSD	

※ 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)

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Participant	Name:	Signature:	Date: / /
Legal Guardian (if necessary)	Name:	Signature:	Date: / /
	*Relationship with the participant: (Parent · Spouse · Legal guardian)		
	*Reason:		
Observer (If necessary)	Name:	Signature:	Date: / /
Doctor (Investigator)	Name:	Signature:	Date: / /