RESEARCH PROPOSAL

Gene Expression Correlates of PTSD Symptom Change After EFT (Emotional Freedom Techniques): A Randomized Controlled Trial

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Institutional Review Board
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1. DATE OF AAABEM, IRB APPROVAL:

2. Purpose. The purpose of the study is to measure the change in psychological symptoms and gene expression in war veterans after a series of 10 EFT coaching sessions. Outcome studies have shown statistically significant reductions in depression, anxiety, and PTSD in veterans after EFT, and this study extends earlier research using biological sampling. EFT is a form of Energy Psychology (EP) that is sometimes referred to as “emotional acupuncture.” It involves self-stimulation of 14 acupuncture points at the end of meridians with the fingertips, while recalling an emotional event such as a combat trauma. It is typically effective in 6 to 15 coaching sessions, making it an efficient clinical technique for reducing affect.

3. Results of Previous Related Research. There is peer-reviewed published experimental evidence showing that (a) acupuncture reduces the fear response in the brain, especially the limbic system, and most particularly the amygdala; that (b) tapping or rubbing acupuncture points (acupressure) can be as effective as needling them; that (c) EFTs use of such acupressure is efficacious in reducing anxiety, PTSD and other mood disorders; that (d) EFT reliably reduces emotional intensity associated with traumatic memories, is safe and low-risk; that (e) all EP studies that included a long-term follow-up show that patient gains are maintained over time; that (f) the psychological questionnaires used in this study are validated and safe; and that for all these reasons (g) EP is a treatment of choice among therapists when dealing with the traumatic memories of clients. The key studies for each of these propositions are listed below:

(a) ACUPUNCTURE REDUCES ANXIETY AND FEAR IN THE LIMBIC SYSTEM:

(b) PRESSURE ON ACUPOINTS (ACUPRESSURE) IS EFFICACIOUS:


(c) EFT IS EFFICACIOUS IN REDUCING ANXIETY AND PTSD:


(d) EFT IS SAFE & REDUCES PATIENT DISTRESS


(e) EFT IS A THERAPIST TREATMENT OF CHOICE FOR ANXIETY DISORDERS:


(f) ALL EFT STUDIES WITH LONG-TERM FOLLOW UP SHOW PATIENT GAINS ARE MAINTAINED:


(g) VALIDATION STUDIES FOR THE QUESTIONNAIRES USED IN THE PROPOSED STUDY:


4. **Subject Selection and Exclusion Criteria.**

**Inclusion Criteria:**
- Military Service
- The ability to follow instructions, complete written forms, understand English, and provide informed consent. Subjects are required to be literate and understand English.
- Remaining under the care of a primary care provider such as a VA hospital throughout the entire period of the study
- Between 18 and 80 years old. No children will be research subjects in this study.

**Exclusion Criteria:**
- A current or past physical or psychiatric disorder that would preclude their being able to respond to the psychosocial measures adequately, or to give blood safely (i.e. cognitive dysfunction, psychosis, or any blood or bleeding disorder)
- Regularly work a night or graveyard shift (to avoid effects of alterations in circadian rhythm)
- Inability to come into the San Francisco laboratory for an afternoon for testing
- Immunomodulatory disorders (e.g. AIDS, rheumatoid arthritis, multiple sclerosis, lupus) or cancer history
- Aggressive chronic periodontitis
- Antibiotics within the last 3 months prior to the recruitment date
- A score of more than 4 on questions 34 and 35 of the SA-45:
  - Having urges to beat, injure, or harm someone
  - Having urges to break or smash things

5. **Provisions for Managing Adverse Reactions.** The proposed study has a robust suite of subject protections in place, as follows:

**FOR SUBJECTS**
(a) Subjects are REQUIRED to be under the care of a licensed primary health care provider, for the entire duration of the study, as an inclusion criterion on the study. No subject not under primary care is admitted.
(b) Subjects are encouraged in the consent form to notify their primary care provider in the case of an adverse response (though because of confidentiality rules they cannot be required to do so).
(c) Subjects are given the phone numbers of the investigators to call if there is an adverse reaction.
(d) Subjects can phone the IRB chairperson if no other help is available.
(e) Subjects are advised in the consent form to call 911 if they have a medical emergency.
(f) Subjects are required to carefully read and sign a consent form.
(g) Subject data is processed anonymously, to preserve client confidentiality. Names are removed and codes substituted. All records are destroyed one year after publication of study results.
(h) EFT is delivered under a standardized protocol (attached). No reports of adverse reactions resulting from EFT have been reported in the many EFT studies performed to date.
FOR INVESTIGATORS

(a) Subjects give the EFT provider the name of their primary care provider (usually a Veterans Administration VA hospital), so that EFT providers can contact the primary caregiver in the event of an adverse reaction.
(b) All personnel in the study have completed the CITI human subjects protection class, and passed the exam. Certificates of completion are available on request.
(c) EFT is provided solely as peer-to-peer, client-centered coaching, and at no time is diagnosis or treatment of psychological or medical symptoms considered or permitted by providers.
(d) The coaching provided in the study is supplemental to, and supportive of, the therapeutic alliance between the client, and their primary care provider (usually a VA hospital).
(e) The investigators will report adverse events to the IRB, using the Adverse Event Form already supplied by AABEM IRB, and if an adverse event occurs, terminate that subject’s participation in the study.

6. Description of Procedures. Subjects will be recruited by referral from the San Francisco Veterans Administration hospital, and referrals from other veterans. EFT practitioners will submit case records to the investigators after the records have been made anonymous by substituting codes for names, in order to preserve subject confidentiality. The practitioners are required to be certified in EFT, to have completed CITI human subject protection training and have passed the CITI exam, and be actively coaching veterans. Subjects will be assessed for a variety of psychological conditions. Evaluations will be made using well-validated instruments, the BPI, HADS, Rivermead TBI screen, SF 12 v 2, SA-45, ISI, and the PCL-M.

Subjects will be randomized into two groups. A wait list control group continues to receive Standard of Care (SOC) from their current healthcare provider. The experimental group receives SOC plus 10 one-hour sessions of EFT coaching that is supportive of SOC and supplementary to usual care. A baseline measurement is obtained when subjects apply to participate in the study, and again immediately before the first session. Participants are assessed after 10 sessions. Follow-up assessments occur three months and six months post-coaching. Wait list participants receive the same protocol after a ten week wait period. Participants provide blood and saliva samples in person at the lab before the first EFT session and after the last session.

At the end of the first session, the subject receives a one page EFT reminder sheet, and an Assignment Sheet to remind them of the issues that have come up for them. EFT practitioners will record notes on the Session Notes form. Fidelity to the EFT method will be monitored by review by the investigators of Session Notes. These will occur the second Monday of each month at 6 pm PST / 9 pm EST. The study expects to enroll 24 subjects.

Assessments: The study uses 7 standardized and well-validated questionnaires:
1. HADS (Hospital Anxiety and Depression Screen)
2. Rivermead Post Concussion Symptoms Questionnaire (TBI Screen)
3. BPI Brief Pain Inventory (first 6 items).
4. SF 12 v 2 (overall physical health measure)
5. Symptom Assessment 45 (SA-45)
6. Insomnia Severity Index (ISI)
7. PTSD Checklist - Military Version (PCL-M)

Other documents used in the study:
1. Session Notes
2. EFT Basic Recipe page
Analysis: Biological samples will be collected at the Institute of Noetic Sciences by a trained phlebotomist. Subjects will come into the testing room one at a time and the investigators will guide them through the protocol and administer the acute psychosocial assessments. The investigators will ship blood samples to the laboratory. For subjects also providing saliva samples, a Laboratory Technician (LT) will be present at the testing room to preprocess the saliva samples for immediate transfer to the laboratory and processing. The LT will isolate mRNA, generate cDNA and perform QRT-PCR assays for all samples (blood and saliva) at the laboratory under the direction of Dr. Yount to measure the expression of the genes that code for stress and inflammation hormones such as cortisol. Psychological assessments will be graded anonymously at the Soul Medicine Institute office, and statistical analyses performed.

7. Non-Significant Risk Explanation. EFT presents no significant risk. It is a purely behavioral self-help intervention. The studies cited above show that therapists prefer EP when dealing with troublesome emotional memories, because the degree of client emotional intensity quickly reduces during a session. EFTs affect-reduction effect has been noted in various studies, and not a single adverse event has been reported in thousands of cases.

8. Minimal Risk. (Applies when children are research subjects). Not applicable to this study.

9. Disclosure of Funding and Budgeting of Such Funds. The investigators and providers are volunteers, and do not receive payment. The cash costs of data entry, questionnaires, and data analysis will be paid by Soul Medicine Institute, which is supported by small voluntary contributions from several hundred individual donors. Soul Medicine Institute is registered with the IRS as a 501 (c) (3) research and education nonprofit, with a mission of furthering the acceptance of energy medicine and energy psychology methods.

10. Disclosure of any Financial Interest with the Sponsor. The only funding to AAABEM IRB is the IRB supervision fee. AAABEM has no financial interest in EFT.

LIST OF ATTACHMENTS:
Assessments:
1. PCL-M (PTSD Checklist - Military)
2. HADS (Hospital Anxiety & Depression Screen)
3. Rivermead Post Concussion Symptoms Questionnaire (a TBI screen)
4. ISI (Insomnia Severity Index)
5. BPI Brief Pain Inventory (first 6 items)
6. SF 12 v 2 (measures overall physical health)
7. SA-45 (psychological symptom assessment, 45 items)

Other documents used by providers or clients:
1. Session Notes
2. EFT Basic Recipe page
3. Consent Form
4. Recruitment Announcement
5. EFT Research Protocol

CVs:
12. Investigator Church CV
13. Investigator Yount CV