

Protocol Registration Receipt  
2007-10-17

Evaluating Physiological Markers of Emotional Trauma: A Randomized Controlled Comparison of Mind-Body Therapies

This study is currently recruiting participants.

Verified by Soul Medicine Institute 2007-10

Sponsors and Collaborators:	Soul Medicine Institute
Information provided by:	Soul Medicine Institute
ClinicalTrials.gov Identifier:	NCT00526266

► Purpose

The purpose of the study is to determine if a physiological marker, joint rotation of the upper body, can be affected by the release of emotional trauma during a brief psychotherapeutic encounter.

Condition	Intervention	Phase
Range of Motion	Behavioral: Emotional Freedom Techniques (EFT) Behavioral: Diaphragmatic Breathing (DB) Behavioral: No Treatment	N/A

Study Type: Interventional

Study Design: Treatment, Randomized, Double Blind (Subject, Investigator, Outcomes Assessor), Placebo Control, Single Group Assignment, Efficacy Study

Number of arms in study: 1

Primary Outcomes:

- Range of Motion (ROM) of joints of the upper body [Time Frame: One Treatment Session]

Secondary Outcomes:

- Score on a standardized psychological test, the SA-45 [Time Frame: Before and immediately after treatment]

Further Study Details:

Expected Total Enrollment: 25

Study Start: 2007-09; Expected Completion: 2008-03

Arms	Assigned Interventions
1: Experimental	Behavioral: Emotional Freedom Techniques (EFT) A half hour treatment with EFT following a standardized protocol. Both Range of Motion (ROM) physical issues are treated with EFT, as well as any possible emotional issues underlying limited ROM.
2: Placebo Comparator	Behavioral: Diaphragmatic Breathing (DB) Diaphragmatic Breathing (DB) instead of EFT tapping, but with all the "Setup Statements" and components of the Experimental Group, with the exception of tapping. DB is substituted for tapping.
3: No Intervention	Behavioral: No Treatment No Treatment. Range of Motion is measured, no treatment is given, and in 30 days Range of Motion is measured again

The effect of emotional trauma on physiological functioning has been documented in a number of studies. The largest of these is the ACE study, (ACE=Adverse Childhood Experiences), which examined the health outcomes of over 17,000 patients at Kaiser Permanente Hospitals.

It was performed by Kaiser in collaboration with the Centers for Disease Control, on a population with a median age of 56. The ACE study found that those patients with a high incidence of Adverse Childhood Experiences or ACEs had higher rates of bone fractures, cancer, heart disease, hypertension, depression, smoking, suicide, diabetes, and other physical and psychological ailments. The authors of the study compared the health care system's focus on treating disease in adults to a fire brigade directing their water at the smoke, rather than at the originating fire. They recommended that health care providers focus on the emotional trauma which they believe contributes to many illnesses.

The current study seeks to determine if the treatment of emotional trauma has an effect on physiological function. As a marker of physiological function, the authors of this study have chosen the range of motion of the joints of the upper body. Shoulder joint stiffness and syndromes such as frozen shoulder typically take months or even years to heal, and rapid resolution is unusual, though most such injuries do indeed heal over time. Range of motion is a convenient marker of physiological change because it can be measured accurately in degrees using a goniometer, a protractor-like device routinely used in occupational therapy and physical therapy. Changes after treatment can be immediately noted.

The emotional trauma treatment modalities being investigated are Emotional Freedom Techniques or EFT, and Diaphragmatic Breathing or DB. They are being compared with a no treatment control group. Studies of EFT have shown this therapy to be effective in removing or reducing emotional traumas, such as phobias, in a single brief treatment session, as well as in reducing anxiety. The effects hold over time. Most prior studies using EFT as a treatment modality study the effects of only one session, and have found that EFT can be effective even with a very brief course of treatment. For the current study, one 30 minute EFT treatment is undertaken. The range of motion of the shoulder joint is recorded before and after treatment by a licensed occupational therapist using a goniometer. The Diaphragmatic Breathing protocol used by the second group has a verbal content identical to the experimental group, but omits the physical touch aspects of EFT. A follow up assessment of subjects is done after 30 days. Range of motion usually does not relapse, but instead becomes greater, following conventional treatments, and this measure has the advantage of requiring a relatively short follow up period, rather than the longer period required for other physiological markers.

The purpose of the study is to discover if a significant change in the range of motion occurs after treatment. Such a finding would reinforce the ACE study's conclusion of a link between physiological functioning and emotional trauma, by determining if the mediation of psychological trauma produces a measurable physiological effect.

## Eligibility

Ages Eligible for Study: 18 Years - 85 Years, Genders Eligible for Study: Both  
Participants: Healthy Volunteers

## Criteria

### Inclusion Criteria:

- Limited Range of Motion (ROM) of a joint in the upper body

### Exclusion Criteria:

- Post-operative recovery
- Receiving rehabilitation treatment
- Under psychiatric care
- Currently using prescription psychotropic medication

## ► Location and Contact Information

Michaela McGivern, BS 707 217 7732 [mcgivern@sonic.net](mailto:mcgivern@sonic.net)

United States, California

Integrative Medical Clinic of Santa Rosa (IMCSR), Santa Rosa, California, 95403,  
United States; Recruiting

Robert Dozor, MD 707-237-6951 [bob@imcsr.com](mailto:bob@imcsr.com)

Study chairs or principal investigators

Dawson Church, PhD, Principal Investigator  
Soul Medicine Institute

## ► More Information

Integrative Medical Clinic of Santa Rosa  
<http://www.imcsr.com>

Adverse Childhood Experiences Study  
<http://www.cestudy.org>

Soul Medicine Institute, sponsoring organization  
<http://www.soulmedicineinstitute.org>

Study ID Numbers ROM-ACEP-SMI-IMCSR-1  
NLM Identifier NCT00526266

