

Protocol Registration Receipt
03/18/2008

The Effect of Psychotherapy on Stress Biochemistry: A Comparison of CBT and EFT

This study is not yet open for participant recruitment.

Verified by Soul Medicine Institute, March 2008

Sponsored by:	Soul Medicine Institute
Information provided by:	Soul Medicine Institute
ClinicalTrials.gov Identifier:	

► Purpose

The purpose of this study is to determine whether there is a change in levels of cortisol, a key stress hormone, during the course of a psychotherapy session. The two forms of psychotherapy compared are Cognitive Behavioral Therapy (CBT) and Emotional Freedom Techniques (EFT). A no treatment control group provides a baseline measure. The change in cortisol level is compared between the start and end of a one hour session.

Condition	Intervention	Phase
Stress Depression Anxiety	Behavioral: Psychotherapy: Emotional Freedom Techniques (EFT) Behavioral: Cognitive Behavioral Therapy (CBT)	N/A

Study Type: Interventional

Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Caregiver, Outcomes Assessor), Randomized, Active Control, Efficacy Study

Official Title: The Effect of Psychotherapy on Stress Biochemistry: A Blind Comparison of Cognitive Behavioral Therapy (CBT) and Emotional Freedom Techniques (EFT)

Further study details as provided by Soul Medicine Institute:

Primary Outcome Measure:

- spot cortisol level [Time Frame: 60 minutes] [Designated as safety issue: No]

Secondary Outcome Measures:

- SA-45 symptom assessment questionnaire, with subscales for depression, anxiety, hostility, interpersonal sensitivity, phobias, and other psychological traits [Time Frame: 60 minutes] [Designated as safety issue: No]

Estimated Enrollment: 30

Study Start Date: April 2008

Estimated Study Completion Date: May 2008

Estimated Primary Completion Date: May 2008

Arms	Assigned Interventions
Experimental: 1 Psychotherapy: Emotional Freedom Techniques (EFT), a psychotherapy intervention with a somatic component	Behavioral: Psychotherapy: Emotional Freedom Techniques (EFT) A form of therapy that includes cognitive reframing with somatic reinforcement through touch or tapping of specified points on the body
Active Comparator: 2 Psychotherapy: Cognitive Behavioral Therapy (CBT), a psychotherapy intervention	Behavioral: Cognitive Behavioral Therapy (CBT) A form of therapy that focuses on negative cognitions of problems, and reframing them in positive terms, but without somatic reinforcement.
No Intervention: 3	

Cortisol is a crucial physiological marker for stress. Stress produces elevated cortisol levels for as long as the body can supply the precursors. Elevated cortisol levels are associated with physical conditions such as impaired immune system function, cardiovascular disease, stroke, and accelerated aging. Elevated cortisol levels are also implicated in many psychological conditions. If the adrenal glands, which produce cortisol, are stimulated by the physical or psychological environment to produce stress hormones, they shunt production away from making DHEA, which is vital for cell regeneration.

The current pilot study examines the change in cortisol levels that result from a one hour psychotherapy session. It measures salivary cortisol, which indicates the levels of cortisol readily available to the body. This measure is relatively stable, and is not susceptible to large swings in the relatively brief period of a one hour psychotherapy session. Excluded are subjects with major depressive disorder, posttraumatic stress syndrome, and chronic diseases which have been shown to affect cortisol levels. Cortisol assessments will also take place in the afternoon or evening, to control for low waking cortisol which may be present in some normal subjects.

It is hypothesized that if psychotherapy is successful at treating trauma, cortisol levels will decline between the beginning of the hour and the end of the hour. The structure of the session is that the client discusses their emotional trauma in the first half of the session, and is treated with either cognitive behavioral therapy (CBT) or emotional freedom techniques (EFT) in the second half of the session. A no treatment control group provides

baseline data. Half an hour is sufficient time for cortisol reuptake, and if therapy is successful at reducing physiological markers of stress, the client might demonstrate lower levels of cortisol at the conclusion of the psychotherapy session. Subjects who spontaneously have recall of a new significant trauma during the treatment portion of the session will also be excluded, since such recall can result in a cortisol spike. The study also evaluates a range of psychological conditions before and after the session using the SA-45. This brief questionnaire has subscales for anxiety, depression, phobias, hostility and other characteristics; these can be compared to cortisol levels to determine any correlations between psychological and physiological change.

Eligibility

Ages Eligible for Study: 18 Years to 75 Years

Genders Eligible for Study: Both

Accepts healthy volunteers.

Inclusion Criteria:

- Good Health History

Exclusion Criteria:

- MDD (Major Depressive Disorder)
- PTSD (Post Traumatic Stress Disorder)
- Psychotropic Prescription Drug Use
- Currently Under Psychiatric Care
- Major disease, cancer, cardiovascular disease
- Autoimmune disease
- CFS (Chronic Fatigue Syndrome)
- Cushing's Syndrome
- Addison's Disease
- Spontaneous Trauma Recall in Final 30 minutes of Session
- History of Psychological Illness

Contacts and Locations

Contacts

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Locations

United States, California

Soul Medicine Institute **Recruiting**

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Sub-Investigator: Dorothy Mandel, PhD

Investigators

Principal Investigator: Dawson Church, PhD

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More Information

Publications:

Gaab J, Blättler N, Menzi T, Pabst B, Stoyer S, Ehlert U. Randomized controlled evaluation of the effects of cognitive-behavioral stress management on cortisol responses to acute stress in healthy subjects. *Psychoneuroendocrinology*. 2003 Aug;28(6):767-79.

Responsible Party: Soul Medicine Institute (Dawson Church, Executive Director)

Study ID Numbers: SMI-CORT-32008

Health Authority: United States: Institutional Review Board