

Aims of iSPOT-D

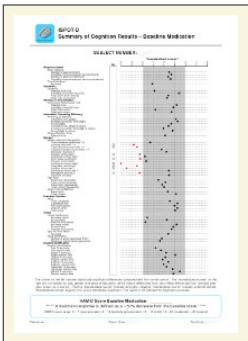
The aim of iSPOT-D is to identify brain and body characteristics that can be used to objectively diagnose depression and to predict how an individual patient diagnosed with major depressive disorder will respond to a range of antidepressants.

The brain and body characteristics that we are interested in include brain structure, certain genes, and performance on cognitive tasks that engage brain and body. Our aim is to develop an evidence-based tool using biological information that can be easily used in a clinical setting.

How can this study benefit the service provided by physicians to their patients?

This study will provide:

- Evidence based reports off and on-medication
- Psychological evaluation of the patient
- EEG assessment of the patient
- Quality care and careful monitoring of progress
- Opportunity to help make a difference



The illustration at the left is an example of a report summarizing the cognitive strengths and weaknesses of a participant. The red circles on the left indicate statistically significant differences compared with the normal controls (grey area).

Yes, I would like to participate!

If you are interested in participating as a Major Depressive Disorder (MDD) participant or if you would like more information about the study,

EITHER CALL 818 - 343 - 1331

OR EMAIL the following information to drbarbara@healingthehumanspirit.com.

- Your name
- City of residence
- Contact phone numbers
- Preferred time to contact you
- Contact email address
- Questions/comments

Dr. Barbara A. Cohen, PhD, MFT
Center for Healing the Human Spirit

International Study to Predict Optimized
Treatment in Depression (iSPOT-D)

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Are you looking for a
different approach to
treatment for
depression?



Clinical Study for
Major Depressive
Disorder
Tarzana, CA

Who will be participating?

A total of 2,016 adult patients meeting DSM-IV criteria for MDD (non-psychotic) and 672 age and sex-matched healthy controls will participate in this international, multi-site study.

You may be able to participate if:

You meet the DSM-IV criteria for a primary diagnosis of Major Depression Disorder (MDD)

You have a depression severity (HAM-D) score of ≥ 16

You are between 18-65 years of age (inclusive)

You are fluent in English (reading and writing)

You are willing to provide written and informed consent

You are NOT able to participate if you have presence of:

Suicidal Ideations (score ≥ 8 in Section C of MINI Plus)

Bipolar Disorder I-III

Psychosis

Post Traumatic Stress Disorder (PTSD)

Obsessive Compulsive Disorder (OCD)

Primary Eating Disorders

ADHD (primary over MDD)

Anxiety (primary over MDD)

Axis II Personality Disorders

Pregnancy, breastfeeding or wish to become pregnant

Any antidepressant drugs which cannot be washed out prior to participation

Any previous negative reaction to Lexapro, Zoloft, or Effexor XR

Any medical condition or neurological disorder that would significantly interfere with assessments

A severe impairment of vision, hearing or hand movements

A brain injury or blow to the head that resulted in lost consciousness for 5 minutes

Recent or current substance dependence on alcohol or drugs (in the past 6 months)

Participation in another Study within the last 4 months

Have you taken antidepressants & wondered if they are really making a difference?

Do you ever feel like a medical record number instead of a person?

Are you depressed? Have you taken antidepressants but wondered if they are really making a difference? Most people suffering from depression will try multiple medications before finding the treatment that is right for them. Many give up frustrated.

By the year 2020, depression will be the second biggest disease burden (after cardiovascular disease). However, the prescription of antidepressant medication can be difficult because there are no evidence-based guidelines to ensure that people receive the type of medication that they will respond best to.

If you are looking for quality, comprehensive treatment for depression, you may be eligible to participate in a clinical research study involving a new technology that uses EEGs to evaluate individual response to medication. The Center for Healing the Human Spirit is seeking volunteers to participate in iSPOT-D, a research study of response to 3 different antidepressants for Major Depression.

iSPOT-D, the largest international study ever undertaken into Major Depressive Disorder (MDD), aims to find objective biological markers to identify depression and treatment outcomes. The goal of iSPOT-D is to develop a tool that can be easily used by physicians and health care professionals to ensure that those suffering from depression receive the right medication first go.

The Center for Healing the Human Spirit is committed to providing the highest level of care to everyone who participates. If you qualify, your progress throughout the study will be closely monitored by Dr. Barbara A. Cohen, who offers a genuine interest in you and the quality of life you are living. Participants will be given a psychological evaluation, EEG assessment, and

study-related laboratory test. This information will provide valuable insight into your depression for both you and your physician. Participation in this study is confidential, and you will be compensated for your time for participating in this study.

What does Participation Involve?

What does the study involve for MDD & Control participants?

Potential participants will first be screened over the phone. If you qualify, you will be asked to visit the Center for Healing the Human Spirit once to begin participation in the study and a second time 8 weeks after your first visit. During these 2 visits, you will participate in Clinical Psychological Assessments, Blood and Urine collection. Electroencephalography (EEG), and Neuropsychological Testing. Throughout the study, participants will be monitored for changes in symptoms, medication, medication side-effects, and quality of life via phone calls and online assessments. Participants will be reimbursed for their time of participation in the study.

For MDD participants ONLY:

After the initial visit to the center, MDD participants will be randomized to one of three commonly prescribed antidepressants: Sertraline (Zoloft), Escitalopram (Lexapro), or Venlafaxine XR (Effexor XR). Participants will be fully aware and informed about the antidepressant treatment they are prescribed. All treatments will be monitored by Dr. Barbara A. Cohen and your own physician.