

IRB USE ONLY

Study Number: 2015-09-0100

Approval Date: 02/22/2016

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Consent to Participate in Internet Research

Identification of Investigator and Purpose of Study

You are invited to participate in a research study, entitled “Augmenting Internet-Based Cognitive Behavioral Therapy for Major Depressive Disorder with Low-Level Light Therapy.” The study is being conducted by Francisco Gonzalez-Lima of The University of Texas at Austin, SEA 3.236, 108 E. Dean Keeton Stop A8000, Austin, TX 78712-1043; (512) 471-5895; gonzalezlima@utexas.edu; and Christopher Beevers of The University of Texas at Austin, CLA 4.528, 305 E. 23rd St., Stop E9000, Austin, TX 78712; (512) 232-3706; beevers@utexas.edu.

The purpose of this research study is to examine the enhancing effects of low-level light therapy on the antidepressant effects of an internet-based cognitive behavioral therapy for Major Depressive Disorder. Your participation in the study will contribute to a better understanding of novel treatment methods for depression. You are free to contact the investigators at the above addresses and phone numbers to discuss the study. You must be at least 18 years old to participate.

If you agree to participate:

- You will first complete an online eligibility screening. This screening will take approximately 5 minutes.
- If you are eligible to participate, you will be asked to provide your name, phone number, and email address, and you will complete an additional eligibility screening via phone. This phone screening will last approximately 20 minutes and will be audio recorded.
- If you are still eligible to participate, you will come to the Mood Disorders Laboratory at The University of Texas at Austin to be introduced to the study, complete several more questionnaires, and complete an eye tracking task during which you will view emotional and neutral images. This initial meeting will last approximately one hour.
- Next, you will be given access to Deprexis, an internet-based cognitive behavioral therapy program for depression. You will have access to this online therapy program for 12 weeks. You will be asked to spend approximately 1 hour per week using the program.
- You will complete daily and weekly online questionnaires for up to twelve weeks.
- If you are eligible, you will also come into the Gonzalez-Lima Lab at The University of Texas at Austin to receive low-level light therapy (LLLT) once weekly for four weeks. LLLT sessions will last approximately 20 minutes.

Risks/Benefits/Confidentiality of Data

There are some possible risks involved with participating in this study. Some of the questionnaires and assessments include questions about sensitive topics and could cause emotional discomfort. Also, some of the images in the eye tracking task may be difficult to view. Researchers are trained in detecting and responding to this type of emotional discomfort. Additionally, you may decline to answer any questions that make you feel uncomfortable, and you may discontinue your participation in the study at any time. There will be no costs for participating, nor will you benefit from participating. Your name, phone number, and email address will be kept during the data collection phase for tracking purposes only. A limited number of research team members will have access to the data during data collection. All data will be kept in a secure, password-protected location. Identifying information will be stripped from the final dataset.

If you are eligible to receive LLLT, there may be some additional risks. It is possible that you may experience increased blood flow or a slight sensation of warmth from the light directed at your skin. In addition, improper use of the LLLT apparatus could cause damage to the eyes. All researchers operating the laser have been thoroughly trained in its use, and safety measures will be taken to ensure proper use of the laser.

Participation or Withdrawal

Your participation in this study is voluntary. You may decline to answer any question and you have the right to withdraw from participation at any time. Withdrawal will not affect your relationship with The University of Texas in anyway. If you do not want to participate either simply stop participating or close the browser window.

If you do not want to receive any more reminders, you may email us at mdl@utexas.edu.

Contacts

If you have any questions about the study or need to update your email address contact the researcher Francisco Gonzalez-Lima at (512) 471-5895 or send an email to gonzalezlima@utexas.edu, or contact Christopher Beevers at (512) 232-3706 or send an email to beevers@utexas.edu. This study has been reviewed by The University of Texas at Austin Institutional Review Board and the study number is 2015-09-0100.

Questions about your rights as a research participant.

If you have questions about your rights or are dissatisfied at any time with any part of this study, you can contact, anonymously if you wish, the Institutional Review Board by phone at (512) 471-8871 or email at orsc@uts.cc.utexas.edu.

If you agree to participate, please click “Yes” below.

Thank you.

This consent form is attached as a document below. Please print a copy of this document for your records.