University of California, Los Angeles

RESEARCH INFORMATION SHEET

Effects of Biofeedback on Somatic Symptoms,
Psychological Adjustment and Health Status

INTRODUCTION

Natacha D. Emerson, PhD, from the Psychiatry Department at the University of California, Los Angeles is conducting a research study. This study is being self-funded. You were selected as a possible participant in this study because you (and your parent for minors) at least 15-years-old, speak English, and have a somatic or psychological complaint. Your participation in this research study is voluntary.

Parents or legal guardians, who are giving permission for a child, please note that in this consent form, the word adult refers to your child.

WHAT SHOULD I KNOW ABOUT A RESEARCH STUDY?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

WHY IS THIS RESEARCH BEING DONE?

This study aims to determine whether completing six sessions of biofeedback is associated with improvements in physical and/or psychological symptoms experienced by patients with chronic medical conditions. Biofeedback has already been shown to improve a variety of conditions such as chronic pain, incontinence, and hypertension. We would like to know if biofeedback works similarly in patients with a variety of chronic medical ailments and/or psychological stress.

HOW LONG WILL THE RESEARCH LAST AND WHAT WILL I NEED TO DO?

Participation will take a total up to 120 minutes. You will be asked to complete an online survey before and after six sessions of biofeedback, as well as three months later. If scheduling prohibits immediate scheduling on the first biofeedback session, you will be asked to complete the survey now and again just before starting the biofeedback protocol. Each survey will take about 30 minutes to complete. You can complete the survey from anywhere with internet access.

If you volunteer to participate in this study, the researcher will ask you to do the following:

- Answer questions about your mental health and quality of life
- Answer questions about your recent health care use
- Answer questions about your health status and current symptoms

BIOFEEDBACK TREATMENT

Each biofeedback session will take 1 hour each and will be scheduled once a week for six weeks. The six sessions will cover the following:

1. Session 1 of biofeedback will present the rationale and evidence for the treatment, teach breathing techniques, and introduce the biofeedback sensors for respiration, heart rate and temperature using the Biotrace software. The session will focus on breathing rate practice.
2. Session 2 will introduce heart rate variability (HRV), cover breathing rhythm, and focus on the completion *Resonance Frequency Assessment,* an exercise to identify a participant's ideal breath rate for sustaining HRV. HRV is a biofeedback technique used to align your heart rhythm and breathing so as to help your body naturally recover from anxiety-provoking situations that traditionally exacerbate stress responses.
3. Session 3 will continue HRV practice using a separate software with video games, Alive.
4. Session 4 will repeat session 3 but with more challenging practice of HRV video games.
5. Session 5 will continue HRV practice in the first software (Biotrace) then will introduce participants to temperature control.
6. Session 6 will repeat Session 5 but with more challenging practice for temperature control.

Total time for participation will be approximately seven hours across three to six months.

ARE THERE ANY RISKS IF I PARTICIPATE?

- The only potential risk is a potential breach of confidentiality.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

You will not directly benefit from your participation in the research. The results of the research may benefit other patients like you who also experience physical or psychological symptoms related to their medical conditions.

What other choices do I have if I choose not to participate?

Your alternative to participating in this research study is to not participate.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

The research team may not be able to keep confidential any disclosure or endorsement of thoughts to harm yourself. In the event that you tell the research staff that you are thinking about killing yourself or you answer yes to a question about having thoughts about suicide, the research staff will ask you more questions about the thoughts. Depending on how intense your thoughts are or how much you feel like hurting yourself, the research staff may provide you with referrals for treatment, work with you to contact your personal physician, trusted family member, or therapist to discuss your thoughts of harming yourself; or work with you on a plan that may include getting you to a hospital for safety.

Use of personal information that can identify you:
Your data will be labeled with a code that the research team can link to personal identifying information.

How information about you will be stored:
Data will be stored electronically using encrypted, password-protected software on a secure UCLA network.

People and agencies that will have access to your information:
The research team and authorized UCLA personnel may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

Employees of the University may have access to identifiable information as part of routine processing of your information, such as lab work or processing payment. However, University employees are bound by strict rules of confidentiality.

How long information from the study will be kept:
Records will be kept for the duration of the study, approximately five years.

USE OF DATA FOR FUTURE RESEARCH

Your data including de-identified data may be kept for use in future research.

WILL I BE PAID FOR MY PARTICIPATION?

No.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The research team:
If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact: Natacha Emerson, PhD at 310-794-8416 or ndemerson@mednet.ucla.edu.

UCLA Office of the Human Research Protection Program (OHRPP):

If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: Box 951406, Los Angeles, CA 90095-1406.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

You will be given a copy of this information to keep for your records.