

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: Evaluating the Use of Mindfulness Meditation Utilizing a Consumer-Grade EEG Biofeedback Device for Patients Awaiting Treatment For Obsessive Compulsive Disorder

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INFORMED CONSENT

You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood.

This form explains the purpose of this research study, provides information about the study, the measures and procedures involved, possible risks and benefits, and the rights of participants.

Please read this form carefully and ask any questions you may have. You may have this form and all information concerning the study explained to you. If you wish, someone may be available to verbally translate this form into your preferred language. You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, or your family doctor. Please ask the study staff or one of the investigator(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

INTRODUCTION

You are being asked to consider participating in this study because you have been referred to our Centre for assessment or treatment services for Obsessive Compulsive Disorder (OCD) or OCD Related Disorders.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the benefits of offering guided mindfulness sessions at home, provided by a wireless EEG device, to individuals awaiting consultation or treatment for OCD. It may be that engaging in mindfulness practice can have a positive effect on OCD symptoms, as well as a person's readiness to engage in long term treatment, and can therefore offer early benefits to individuals waiting for services at the Frederick W. Thompson Anxiety Disorders Centre.

WHAT WILL HAPPEN DURING THIS STUDY?

If you decide to participate in this study you will be asked to do the following:

1. All participants will be asked to attend three sessions, over the course of eight weeks, at the Sunnybrook Health Sciences Centre, lasting approximately 1 to 1.5 hours. During the session, you will be completing a brief mindfulness practice while wearing a wireless EEG device that provides data involving how you are attending to your experience. Following this meditation practice, we will ask you several questions about your experience during the practice, and record your verbal responses. The audio recordings will be de-identified, renamed according to your subject id, and kept secure, stored on an encrypted Sunnybrook approved USB device. You will then complete a series of paper-and-pencil based questionnaires. For example, in one questionnaire you will have to answer questions about your symptoms or health.
2. Patients will be randomized to one of the following 2 groups:
 - a. 8 week meditation program involving use of an EEG-based feedback
OR
 - b. Wait list as per usual

For those participants who are randomized to the mindfulness condition – you will be supplied with a wireless headset and software that can be installed on your smartphone or ipad. Over the course of eight weeks, while at home, you will be completing a daily guided mindfulness practice lasting for twenty minutes. We may occasionally call you to check in on your progress, and answer any questions you might have about the meditation practices. Further, if you have any questions regarding your meditation practice, and/or any element of the study, please feel free to contact either Alex Theodorou (Research Assistant) or the principal investigator (Dr. Lance Hawley). Mr. Theodorou's phone number is 416 480 6100 x81229, and his email is alexander.theodorou@sunnybrook.ca Dr. Hawley's phone number is 416 480 6100 x84076, and his email is lance.hawley@sunnybrook.ca

3. At baseline (week 0), mid treatment (session 4), and post intervention (week 8), all participants will complete 8 questionnaires (which will take approximately 30 minutes).
4. Once per week, all participants will complete several questionnaires online, using the "Survey Monkey" portal. Daily practice data from the EEG headsets will be automatically uploaded to an encrypted server, for participants in the mindfulness condition. The surveys will take approximately 5-10 minutes. Please note that the online survey is hosted by "Survey Monkey" which is a web survey company located in the USA. All responses to the survey will be stored and accessed in the USA. This company is subject to U.S. laws, in particular, to the U.S. FREEDOM Act that allows authorities access to the records of internet service providers. If you choose to participate in the survey you understand that your responses to the questions and your IP address will be stored and accessed in the USA. The security and privacy policy for Survey Monkey can be viewed at <http://www.surveymonkey.com/>

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 100 people will participate in this study. The entire study is expected to take approximately two years to complete and the results should be known at the end of the study.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

This study involves collecting self-report questionnaire information as well as EEG information for participants in the mindfulness condition. This information has been included in the End User License Agreement (EULA) which you will be reading over before deciding whether you would like to participate in the study. All EEG data will be de-identified prior to being uploaded to the encrypted Interaxon server and Interaxon will have no access to any personal health information of study participants. Participants are advised to not share with Interaxon's customer support team or anyone else at Interaxon any information other than the email address assigned to them as a participant in the study.

There are no known risks associated with participation in this study and any potential risk will be no greater than that encountered in day-to-day activities. There are no known risks involved with using the EEG headset. You will be asked to answer personal questions as part of the paper-and-pencil questionnaires. Some people may experience some discomfort answering these questionnaires, however, you are free to withdraw your participation at any time.

You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff. This may include new information about the risks and benefits of being a participant in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not benefit directly from participating in this study. However, we hypothesize that the benefits may include an improvement in symptoms and overall functioning.

We hope that the information from this study will help expand treatment options for others suffering from OCD.

WHAT OTHER CHOICES ARE THERE?

If you decide not to participate in this study this will **not** affect your ability to receive treatment here or at any other health care institution.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Participation in this study is voluntary. Your choice of whether to participate will not influence your future relations with Sunnybrook Health Sciences Centre. You may decide not to be in this study, or to be in the study now and change your mind later. You may leave the study at any time without affecting you or your family's care or your employment status.

If you decide to participate, you are free to withdraw your consent and to stop your participation at any time without having to give a reason or to suffer any penalty.

The investigator(s) may decide to remove you from this study without your consent for any of the following reasons:

- You are unable or unwilling to follow the study procedures
- The investigator decides it is not in your best interest to continue

If you are removed from this study, the investigator(s) will discuss the reasons with you. If you decide to withdraw from this study because you find the interview process distressing, you may be referred for support/counselling or you can request a referral.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?

You will not have to pay for any of the procedures involved with this study. Participating in this study may result in added costs to you, such as costs for parking and transportation.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?

You will receive \$40 to participate in this study, paid at the end of the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

This study involves collecting data over the internet. Collecting data over the internet can increase potential risks to confidentiality. Your confidentiality will be kept to the degree permitted by the technology being used; no guarantees can be made regarding the interception of data sent via the Internet. Please read the terms and agreement of the service provider for further information regarding data security and anonymity. You have the right to have any information about you and your health that is collected, used or disclosed for this study to be handled in a confidential manner.

If you decide to participate in this study, the investigator(s) and study staff will look at your personal health information and collect only the information they need for this study. "Personal health information" is health information about you that could identify you because it includes information such as your;

- name,

- address,
- telephone number,
- date of birth,
- new and existing medical records, or
- the types, dates and results of various tests and procedures.

You have the right to access, review and request changes to your personal health information.

The following people may come to the hospital to review your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook

Access to your personal health information will take place under the supervision of the Principal Investigator.

“Study data” is health information about you that is collected for the study, but that does not directly identify you. Any study data about you that is sent outside of the hospital will have a code, your initials and full date of birth and will not contain your name or address, or any information that directly identifies you. Please note that the online survey is hosted by “Survey Monkey” which is a web survey company located in the USA. All responses to the survey will be stored and accessed in the USA.

Study data that is sent outside of the hospital will be used for the research purposes explained in this consent form.

The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The Principal Investigator will keep any personal health information about you in a secure and confidential location for 10 years and then destroy it according to Sunnybrook policy.

When the results of this study are published, your identity will not be disclosed.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact Dr. Lance Hawley, Department of Psychiatry, (416) 480- 6100 X 84076.

DO THE INVESTIGATORS HAVE ANY CONFLICTS OF INTEREST?

There are no conflict of interests to declare related to participation in this study

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to receive all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction, before you make any decision. You also have the right to ask questions and to receive answers throughout this study.

If you have any questions about this study you may contact the person in charge of this study (Principal Investigator) **Dr. Lance Hawley, Department of Psychiatry, 416 480 6100 X 84076.**

If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the **Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.**

DOCUMENTATION OF INFORMED CONSENT

You will be given a copy of this informed consent form after it has been signed and dated by you and the study staff.

Full Study Title: Evaluating the Use of Mindfulness Meditation Utilizing a Consumer-Grade EEG Biofeedback Device for Patients Awaiting Treatment For Obsessive Compulsive Disorder

Name of Participant: _____

Participant/Substitute decision-maker

By signing this form, I confirm that:

- This research study has been fully explained to me and all of my questions answered to my satisfaction
- I understand the requirements of participating in this research study
- I have been informed of the risks and benefits, if any, of participating in this research study
- I have been informed of any alternatives to participating in this research study
- I have been informed of the rights of research participants
- I have read each page of this form
- I authorize access to my personal health information, medical record and research study data as explained in this form
- I have agreed, or agree to allow the person I am responsible for, to participate in this research study

Name of participant/Substitute
decision-maker (print)

Signature

Date

My Signature here indicates that I also agree to being contacted in the future to be informed of other research participation opportunities. Please note that your signature indicates that you would like to be contacted in the future, and you are not agreeing to participate in a future study. You are simply giving us permission to contact you to see if you are agreeable.

Name of participant/Substitute
decision-maker (print)

Signature

Date

Person obtaining consent

By signing this form, I confirm that:

- This study and its purpose has been explained to the participant named above
- All questions asked by the participant have been answered
- I will give a copy of this signed and dated document to the participant

Name of Person obtaining
consent (print)

Signature

Date