

CONSENT TO PARTICIPATE IN BIOMEDICAL RESEARCH

Study of the Efficacy of Wellbeing Interventions and their Effect on Speech and Affect

SUMMARY

You are invited to participate in a research study conducted by Satrajit Ghosh, Ph.D., from the McGovern Institute for Brain Research at the Massachusetts Institute of Technology (MIT). This study is open to persons over 18 years only. Your participation in this study is entirely voluntary.

To be in a research study, you must give your informed consent. The purpose of this form is to help you decide if you want to participate in this study. Please read the information carefully. If you decide to take part in this research study, a copy of the consent form will be available on voicesurvey.mit.edu and the form you signed will be available to download after signing. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time.

The information below provides a summary of the research:

- **Purpose**
To understand the effect of two wellbeing interventions (meditation or introspective journaling) on speech, affect and mental health.
- **Study Procedures**
You will participate in a “wellbeing challenge” and will be randomly assigned to either the meditation or the introspective journaling activities for the duration of one month. We expect you to complete a short wellbeing activity every day during this month, though you are free to skip any days. We will also ask you to complete three longer questionnaires: one a month before, one immediately before and one after the month-long challenge. You will become eligible for prizes based on how much you participate. All questions, prompts, and audio recordings are optional.
- **Risks & Potential Discomfort**
This is not a medical intervention and we do not expect any medical side effects. However, sometimes questions that relate to mental health can feel discomforting, and you are free to skip anything that you do not wish to answer. Further, while we take utmost care to protect your data, there remains a small risk of data breach.

You should read the information below, and ask questions (by emailing voice_survey@mit.edu) about anything you do not understand, before deciding whether or not to participate.

PARTICIPATION AND WITHDRAWAL

Your participation in this research is completely VOLUNTARY. If you choose to participate, you may subsequently withdraw from the study at any time without penalty or consequences of any kind. If you choose not to participate, that will not affect your relationship with MIT or your right to healthcare or other services to which you are otherwise entitled. If you are an employee of MIT, your participation or non-participation in the research will have no effect on your employment or yearly reviews. If you are a student or lab member of the Senseable Intelligence Group, your decision to participate or not to participate in this study will not in any way influence your grade, funding, or other relationship with Satrajit Ghosh or any other member of the lab.

PURPOSE OF THE STUDY

Science of Wellbeing: Wellbeing is an important aspect of day-to-day life, and many people are interested in finding ways to improve their wellbeing. While there are a number of resources available today, in this study we are particularly interested in evaluating the efficacy of two low-cost, easily scalable solutions: introspective journaling and meditation. Beyond that, we would like to understand how changes in your wellbeing may generate variations in speech and language, and whether those variations can help monitor wellbeing over time.

Web-based participation: New technologies allow people to participate in wellbeing interventions online while also recording how they are feeling at that moment in real time. This study will monitor an individual's wellbeing throughout a month of daily activities (meditation or introspective journaling) using questionnaires and voice recordings via web-based surveys accessible on mobile phones, tablets and computers.

Data sharing: Your study data will include your responses to surveys and your voice recordings. Your data will be added to the data of other study participants and analyzed by the study team. Also, if you choose to, your study data (without your contact information) can be made available to other qualified researchers or publicly for this and future research. You will be able to export and save your own data as well.

PROCEDURES

Brief overview: If you volunteer to participate in this study, you must first sign and date the consent form online. You will then receive an email with a personalized link to our web-based study portal, which you can access via your computer, tablet or phone. You will be asked to fill

out three long assessments over the course of the study (a month before the start, at the start, and at the end of the study). In addition, you will participate in a daily wellbeing activity and answer a few questions for four weeks.

Register to the study: You will follow the prompts on the website to register for an account and confirm your agreement to participate in this study. There will be an electronic consent process explaining the risks and benefits of participating in this study. Registration will include entering your email address and confirming your age and ability to read, write and speak English to verify your eligibility. You can cancel the registration process at any time. Within 24 hours, you will receive a personalized link to our web-based study portal and can begin the study.

Surveys: We will ask you to answer questions about your wellbeing at the time of your daily wellbeing activities in addition to three long surveys (a month before the start, at the start, and at the end of the study). You may skip and leave questions that you do not wish to answer blank. You will be able to export your responses from our study website if you wish to do so.

Activities: Over the course of four weeks, we will ask you to perform brief wellbeing activities daily while using your mobile phone, tablet or computer and record audio data directly from your phone or computer. You will be assigned to one of two interventions, introspective journaling or meditation. You can conduct these activities at any time of the day, based on your convenience. We will ask you to answer a brief set of audio questions before and after the activity.

Examples of audio data:

We will ask you how you are feeling on a given day.

We will ask you how you liked your wellbeing activity on a given day.

We will ask you what went well on a given day.

Our expectation is that you will participate in a wellbeing intervention and the accompanying survey daily, which will require about fifteen minutes of your time per day. We will send notices to your email asking you to complete these activities and surveys. You may choose to act at your convenience (either completing the activities/surveys then or later in the day) and you may choose to participate in all or only in some parts of the study. You may skip days or you may skip individual prompts on a given day, which includes skipping the audio recordings.

Occasionally, we may re-contact you for your feedback about using the study website, about the kind of questions included in the study and to see if you would like to participate in future studies. You may opt out of these emails at any time by emailing voice_survey@mit.edu and asking to not be contacted anymore about feedback and/or future studies. This will not impact your participation in this ongoing study or your eligibility for prizes. If you opt out of future communications, we will delete your contact information as soon as this study is completed or as

soon as you withdraw from the study, whichever is earlier. Otherwise, we will retain your contact information, which will be kept separate from any of your study data.

PRIZES

There will be three prize raffles that require increasing levels of study participation in order for you to be entered into the respective raffle. Depending on your involvement in the study, it is possible that you become eligible for none, one, two or all three prize raffles.

Raffle 1: You will be entered into the first raffle for completion of Assessments 1 and 2. Prizes consist of \$15 Amazon gift cards.

Raffle 2: You will be entered into the second raffle for completion of Assessments 1, 2 and 3, and at least ten days of wellbeing activities. Prizes consist of \$20 Amazon gift cards, noise cancelling headphones and instant cameras.

Raffle 3: You will be entered into the third raffle for completion of Assessments 1, 2 and 3, and at least twenty days of wellbeing activities. Prizes consist of \$30 Amazon gift cards, a writing course by Nadia Colburn, and meditation cushions (zafu) with the MIT Meditation Lab logo.

To be eligible for prizes you have to submit the consent form by the date listed on the consent form signature page and complete Assessments 1, 2 and 3 within one week of receiving each via email (submission of Assessment 3 is only applicable to Raffle 2 and 3). Note that you are only eligible for prizes if you reside in the United States.

POTENTIAL RISKS AND DISCOMFORTS

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought.

- This is not a treatment study and we do not expect any medical side effects from participating.
- The investigators are researchers and not clinicians, and data collected in this study is for research and not clinical purposes.
- Some survey questions may make you feel uncomfortable. Know that the information you provide is entirely up to you and you are free to skip questions that you do not want to answer.

- Other people may glimpse the study notifications and/or reminders on your phone or computer and realize you are enrolled in this study. This can make some people feel self-conscious.
- Be safe – just as you would not text while driving, do not fulfill study tasks activities while driving. Wait until you are in a safe place to perform study-related activities!
- We take great care to protect your information and identity. Any personal data that can be used to directly identify you (such as name, email, address etc), is separated from the research data (voice samples and survey answers) during collection itself. However please note, that there is always a low risk that someone may attempt to re-identify an individual by referencing other sources of information (e.g., your social media). While the risk is low, we need to acknowledge that it is present.
- Accidental public disclosure may occur due to unintended data breaches including hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.
- Data collected in this study will count against your existing data plan if you participate on a mobile phone or tablet with access to data. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan.
- The experiment may involve risks that are currently unforeseeable. Participation in this study may involve risks that are not known at this time. You will be told about any new information that might change your decision to be in this study.

At the beginning of the longer assessments and daily surveys, the application will remind you to go to a quiet, distraction-free location where you will be able to speak out loud. It is best to complete the surveys in a room without any other people. This will limit any noises or distractions and will also provide you with the most privacy and comfort when responding to survey questions and conducting audio recordings.

Incidental Findings

The tests and analyses performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. However, the investigator *may notice* a finding that seems abnormal, such as vocal tremor, which might be detected during the study or during retrospective review of the data. If this occurs, the investigator will contact you and inform you of the finding. The decision as to whether to proceed with further examination of treatment lies solely with you and your physician.

ANTICIPATED BENEFITS TO SUBJECTS

Participation in the study might lead to an increase in your daily wellbeing as a result of the intervention assigned to you, and you may learn strategies for improving your wellbeing that you

can use after completion of the study. You will also be able to export your data at will to share with your medical doctor and anyone you choose. Further, we will return the insights learned from analysis of the study data through the study website, blogs and/or research publications, but these insights may not be of direct benefit to you. We cannot, and thus we do not, guarantee or promise that you will personally receive any direct benefits from this study.

ANTICIPATED BENEFITS TO SOCIETY

The goal of this study is to create knowledge, which can benefit us as a society. The benefits are primarily insights into the efficacy of two wellbeing interventions (meditation and introspective journaling) and the identifications of new wellbeing biomarkers from speech.

ALTERNATIVES

There are two wellbeing interventions included in this study, and we provide no third alternative as part of this study. The only other alternative is to not participate.

PAYMENT FOR PARTICIPATION

You will receive no payment for participating. Prizes will be randomly distributed to participants depending on the extent of the study that was completed.

FINANCIAL OBLIGATION

There is no financial obligation to you for participating in this research study other than to your data or wifi plans if applicable.

PRIVACY AND CONFIDENTIALITY

The only people who will know that you are a research subject are members of the research team or individuals who can access your phone, tablet or computer, or other devices that you use for study participation. No information about you, or provided by you during the research will be disclosed to others without your written permission, except: if necessary, to protect your rights or welfare, or if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity without your authorization. Further, if you consent to

sharing your responses with other qualified researchers or publicly, your written responses will be de-identified, meaning we will remove any information that may be linked to you, such as your name, email address or other identifying information that you mention in your written responses. Raw audio recordings will only be shared with other qualified researchers or publicly if you specifically consent to this.

We will archive the data for a duration of at least 3 years following the end of data analysis. Beyond that it will depend on the availability of funds and data backup resources.

NEW FINDINGS

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

EMERGENCY CARE AND COMPENSATION FOR INJURY

If you feel you have suffered an injury, which may include emotional trauma, as a result of participating in this study, please contact the person in charge of the study as soon as possible.

In the event you suffer such an injury, MIT may provide itself, or arrange for the provision of, emergency transport or medical treatment, including emergency treatment and follow-up care, as needed, or reimbursement for such medical services. MIT does not provide any other form of compensation for injury. In any case, neither the offer to provide medical assistance, nor the actual provision of medical services shall be considered an admission of fault or acceptance of liability. Questions regarding this policy may be directed to MIT's Insurance Office, (617) 253-2823. Your insurance carrier may be billed for the cost of emergency transport or medical treatment, if such services are determined not to be directly related to your participation in this study.

IDENTIFICATION OF INVESTIGATORS

If you have any questions about the research, please feel free to contact:

Satrajit Ghosh, Ph.D.

617-324-3544

MIT Building 46-4033f, 43 Vassar St., Cambridge, MA 02139

RIGHTS OF RESEARCH SUBJECTS

You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you feel you have been treated unfairly, or you have questions regarding your rights as a research subject, you may contact the Chairman of the Committee on the Use of Humans as Experimental Subjects, MIT, Room E25-143B, 77 Massachusetts Ave, Cambridge, MA 02139, phone 1-617-253 6787.