Beth Israel Deaconess Medical Center

HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

Investigating Changes in Anxiety, Sleep Quality and Duration after Shoonya Meditation
Study Doctor: Dr. Balachundhar Subramaniam

Thank you for your interest in our study!
Below you will find some additional information about the study. If after reading through this, you are still interested in potentially participating, you will be asked a few questions to see if you are eligible for the study.

Purpose of the Study
The purpose of the study is to determine the effect of the Shoonya Intensive (SHY) program on anxiety, as well as several aspects of sleep-mainly duration and quality. If you decide to participate we will ask you to complete a short 20-25 min questionnaire on the weekends of April 2nd- 4th, April 30th - May 2nd and May 28th - May 30th. We will also ask you to record your sleep start and end times from April 1st – June 3rd.

It is important that you know that this is a research study, and your participation is completely voluntary. You can decide to no longer participate or withdraw at any time. In addition, we cannot guarantee that there will be any benefit to you now or in the future, however it is possible that your participation may help others in the future as a result of knowledge gained from this research.

Benefits and Risks
We do not anticipate any physical risk from the study as it includes only surveys. There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. You will not be paid for participating in the study.

Questions
If you have any questions and would like to talk to a member of the study team, please contact us by calling 949-394-0398, or by emailing me at ajoshi4@bidmc.harvard.edu.

Participation
Are you interested in potentially participating in this study?

- **Yes, I am interested in potentially participating in this study.** Please note the next step would be to ask you some questions to see if you are eligible for the study. If you are, we will provide more information about the study before you agree to participate.

- **No, I do not want to participate in this study.**
  If no, the survey will end with the following message: Thank you for your time.

Preliminary Questions
Please complete the following questions to determine if you are the right fit for our study. If you are unsure about any of the answers, please select 'No'.

Are you 18 years of age or older? ☐ No ☐ Yes

If yes: Please indicate your age: _____

Are you planning to complete the Inner Engineering Program? ☐ No ☐ Yes

Are you able to read and understand English? ☐ No ☐ Yes

Are you currently residing in United States? ☐ No ☐ Yes

If no to any question: Thank you for completing these questions. Based off of your responses, you are not eligible for our study. If you have any questions about this, please do not hesitate to contact the study team at ajoshi4@bidmc.harvard.edu or by calling us at 949-394-0398.

Are you currently diagnosed with any psychological or sleep disorder? ☐ No ☐ Yes

If yes: Thank you for completing these questions. Based off of your responses, you are not eligible for our study. If you have any questions about this, please do not hesitate to contact the study team at ajoshi4@bidmc.harvard.edu, or by calling us at 949-394-0398.

If yes to questions 1-4, no to question 5 and age ≥ 18: Thank you for completing these questions. Based off of your responses, you are eligible to take part in the study. We will now tell you a little more about the study and ask you whether or not you would like to consent to participate. Please click 'Next Page' to continue.

Informed Consent to Take Part in a Research Study

Please read this information carefully. Once you read and understand what your participation in this study will involve, you will be asked to consent if you wish to take part.

Purpose

The purpose of the study is to determine the effect of the Shoonya Intensive program on varied aspects of wellbeing, including anxiety and sleep quality. You have been asked to participate because you have signed up for the April 8th-11th Shoonya Intensive program.

What happens if I decide to participate?

If you decide to participate the following things will happen: You will be asked to complete a brief survey at the beginning of the study. As part of this study we will ask you to complete some demographic information regarding your consumption of caffeine and raw foods, and a survey on how likely you are to fall asleep in certain situations, on any difficulties you may or may not have while falling asleep, and whether you are experiencing stress or anxiety. The survey takes about 20-25 minutes to complete and can be completed through a mobile application we will provide you. You will be asked to complete this survey on any day during the weekend of April 2nd- 4th.

After you learn the shoonya meditation, you will be asked to fill out the survey again on the weekends of April 30th - May 2nd and May 28th - May 30th. During these two weekends, we will also ask you how many days you could not practice the meditation. Lastly, you will be asked to record your sleep start and end times every day during the duration of the study (April 1st – June 3rd). This can be done within the app itself and should not take more than one minute.

Your participation in the study will be complete after 63 days.. The longest time commitment will be at the beginning of the study, which should take less than 30 minutes to complete and can be done electronically.

Who might see my data?

In addition to the members of the study team, your responses may be seen by staff at BIDMC who monitor the conduct of research, or people who work for other agencies that oversee human subject research. Given the nature of the questions we are asking, we will not share your individual responses with other researchers outside the study team. Whenever results are reported, we will never identify you individually.

Risks and Discomforts / Benefits

We do not feel there are any physical risks associated with this study, as it only involves the administration of online interventions and surveys. It is possible that in completing the questionnaires you might think more about how your mind feels than you would if you were not in the study. If this is bothersome to you, the study doctor will talk with you to try to help.

There is the potential for loss of confidentiality by participating in this study. Every effort will be made to protect the confidentiality of your identifiable information. We take your privacy very seriously, and will be following a very careful plan to keep all your information confidential. Electronic data will be kept in confidential on password-protected computers in the research office. All of your data will be assigned a study specific ID in order to minimize any risk that you might be identified.

It is not possible to predict whether you will benefit directly from participation in this study. However, your participation may help others in the future as a result of knowledge gained from the research.

You will not be paid for your participation in this study.

If You Decide Not to Take Part in the Study

Participation in this study is voluntary. You have the right to decide not to take part in this study. If you choose to participate, you have the right to leave the study at any time. Your decision to not participate will not result in any penalties or loss of benefits to you.

You may contact the Human Subjects Protection Office at [617] 975-8500 in the event that you would like to obtain information or to offer input about the research study. This office is independent of the investigator or investigator's research staff and can also assist with questions relating to your rights as a participant in research, which may include questions, concerns or complaints about your participation in the study.

Whom to Contact If You Have Questions
This study is being conducted by Balachundhar Subramaniam, MD, MPH at Beth Israel Deaconess Medical Center. There is no funding agency in this study. If you have any questions, concerns or complaints about this research, you should contact Dr. Subramaniam at [617] 754-2675, or by emailing bsubrama@bidmc.harvard.edu.

Participation
Participating in this study is entirely voluntary. By agreeing to participate you are giving your consent to the researcher to use your responses for the research study. If at any point you decide that you no longer wish to be a part of this study, you may end your participation.

Are you interested in participating in this study?

- **Yes, I am interested in participating in this study.**
  If yes, it advances to the baseline survey: Thank you for your participation. We will now ask you to complete the baseline survey. This can take approximately 15 minutes to complete. We suggest that you complete this survey in a private area to further maintain your confidentially.

- **No, I do not want to participate in this study.**
  If no, the survey will end with the following message: Thank you for your time.

Thank you again for your participation in our study!
Please complete the contact information below so that a member of the study team may contact you for the follow up surveys. Please note we will not share this contact information outside the study team.

Please indicate your name: _____

Please indicate your email address: _____@_____

Questions?
As a reminder, you may contact the study team at any time with questions by calling 949-394-0398, or by emailing ajoshi4@bidmc.harvard.edu.