

Informed Consent for Basic Research

Study Title: Impact of Heartfulness meditation practices on burden of stress and sleep disturbances during the time of COVID-19 pandemic

Primary Investigator Contact:

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We are asking you to be in a research study. Your involvement in the research study is optional.

If you say yes, you may withdraw from the study at any time. Please take as much time as you need to make your choice.

It will not have an impact on you in any way if you say no.

Why do I need to sign this document?

To be part of this study, you need to sign and return this document.

What is the purpose of this research study?

We want to learn more about helping all adult individuals in the community to cope better with stress especially during the time of COVID-19 pandemic. This study will help us learn more about using meditation to help. This study will also be assessing the effect of meditation on level of stress and quality of sleep.

What happens if I say yes, I want to be in the study?

- We will ask you to provide information before you begin the meditation classes. We will ask you identifying information including name, gender, age, profession. We will ask you to tell us if anything that might hinder your participation in the study.
- Before the Meditation classes, we will ask you to fill out a Perceived Stress Scale (PSS) and Pittsburgh Sleep Quality Index (PSQI). There will be 4 simple questions in regards to impact of current COVID-19 pandemic in addition to these survey questions. Each of these surveys will take less than 15 minutes to complete. There are no right or wrong answers on any of these forms.
- These surveys will need be completed via online survey tool (surveymonkey.com) and appropriate instructions will be sent to the email address you provide. It may take 15-20 minutes to complete the surveys.

- If you need any help completing the surveys, you can contact Dr Kunal Desai through Email communication. He may answer the questions by email or can call you if needed on phone number you would provide.
- You may complete the surveys at the first class or a few days before that. We will answer any questions you have and help you complete the surveys if necessary.
- Dr Kunal Desai is a physician and also a certified Heartfulness Trainer. He will provide information about the details of meditation practice with introductory package prior to the study. There will also be an introductory talk on meditation and we will go over the details of the practice and the study. It includes a simple individual practice which you can do at home and virtual group meditation practice sessions with a certified Heartfulness trainer (Dr Kunal Desai).
- Virtual group meditation sessions are conducted 7 days a week with an expectation for you to attend a minimum of 2 session per week to a maximum of 7 sessions a week.
- You will attend classes to the best of your ability and do the home assignments to the best of your ability.
- You will log in your study journal meditation sessions you attended and the duration. The investigator will provide you the study journal.
- You will complete the both the surveys [Perceived Stress Scale (PSS) and Pittsburgh Sleep Quality Index (PSQI)] and 4 simple questions in regards to impact of current COVID-19 pandemic at 4 weeks, and at the end of 8 weeks after the last session. This will help us know if the meditation program was helpful.
- There is an optional interview at the end of the study that will help us learn about how helpful the program was. This interview will be done via phone call or virtual audiovisual meeting which would take 15-20 minutes of your time.
- You will be provided introductory educational booklet (PDF) through your email which is about 50 pages to review during the study period.

How long will the study take?

- Completing the surveys at the beginning will take about 15-20 minutes of your time.
- The entire study will last 8 weeks.
- Each guided relaxation & meditation session will take about 45 minutes. There will be one virtual meditation session per day at different times (for example: Monday and Wednesday at 7 AM EST, Tuesday and Thursday 7:30 PM EST, Friday at 12:00 noon EST, Saturday & Sunday 10 AM EST). You will be required to attend at least 2 sessions per week.
- There will be 2 introductory sessions per each week for first 3 weeks to provide education regarding Heartfulness practice which will be combined with guided meditation sessions. These sessions will take about 1 hour 15 minutes.

What happens if I say no, I do not want to be in the study?

No one will treat you differently. You will not be penalized. There will be no negative impact on you in any way.

What happens if I say yes, but change my mind later?

You may withdraw from the study at any time. There will be no negative impact on you in any way.

Who will see my answers? How your confidentiality will be protected in this study?

All of the participants are given a survey identification number to protect your identity and answers. All the surveys are conducted through online survey tool.

The only people allowed to see your answers will be the people who work on the study and the people who make sure we run our study the right way.

Your survey answers, demographic information, and a copy of this document will be locked in a cabinet or on a password protected secured file on secured iCloud account. We will share the results of the study with with doctors and other healthcare providers, and at some conferences about healthcare. The results that will be shared with hospital leadership, public, etc. will be in aggregate and de-identified. We may construct a poster about the study or publish an article. When we share the results of the study, we will not include your name. We will do our best to make sure no one outside the study will know you are a part of the study.

How long will this permission last?

If you agree, by signing this form, that researchers can use your data, your permission does not expire. . Remember, however, as stated above, you can change your mind and withdraw your permission at any time.

What are my rights regarding access to my personal health information?

You have the right to refuse to sign this consent form

Will it cost me anything to be in the study?

No.

Will being in this study help me in any way?

Learning the meditation skills that are part of this study may help you to cope better with stress but this cannot be guaranteed.

Will I be paid for my time?

No.

Is there any way being in this study could be bad for me?

Yes. There is a chance that:

- You might feel bodily discomfort during the meditation sessions from prolonged sitting on a chair. You may change your posture to continue meditation. If it is too uncomfortable to sit through, you may leave at any time.
- In the practice of meditation, although calmness is induced, persons can also have the experience of unwanted emotion and thoughts arising and passing.

What if I have questions?

Please email Dr Kunal Desai: heartfulness-research@wright.edu if you have any questions about the study. He may call you or answer questions through email depending on the nature of questions.

You can also call the Wright State University IRB Staff (937) 775-4462 to ask questions about participating in a research study or if you have questions about your rights as a research participant. However, the IRB Staff will not be able to answer questions specific to this project.

Do I have to sign this document?

No. You sign this document only if you want to be part of the study.

What should I do if I want to be in the study?

You will be sent this document via email and you will be required to review this document thoroughly and email us back with your contact information. Dr Kunal Desai (Primary investigator) will call you on the number provided to discuss this study, consent document and will answer any questions you may have. Once you decide to participate in the study, it is preferred that you physically sign the form, scan and return via email. If that is not possible, you may choose to sign this form electronically (Enter your name and date) and return to us via email.

By signing the document, you are saying:

- You agree to be in the study.
- We talked with you about the information in this document and answered all your questions.

Do I need Internet service at my home or office in order to participate in this study?

Yes. You will require reliable high-speed Internet service in order to attend secured online video education and virtual meditation sessions.

You will be provided detailed instructions and necessary sensitive information such as meeting identification number and password in advance to join the video sessions.

Statement of Confidentiality

By signing this document, the participant agrees to keep the class room related discussions confidential.

DISCLAIMER

Meditation is generally considered a safe activity, and has been linked to many positive outcomes. Center of disease control and prevention (CDC) has recognized the impact of stress due to the current pandemic. CDC has recommended several ways to cope with stress including eating regularly, good sleep hygiene, exercise as well as relaxation and meditation.

Here is a list of potential benefits:

1. Reduction of stress and burn out
2. Improvement in sleep quality
3. Increase inner contentment and peace
4. There are many health benefits including improvement in cardiovascular health and blood pressure, increase heart-rate variability (which is sign of healthy heart), increase immunity, slowing of cognitive decline etc.
5. Reduces anxiety and increase emotional stability

While a majority of literature shows benefits of meditation, there is also some literature suggesting potential adverse effects.

Here is a list of potential adverse effects reported which include but not limited to:

Relaxation-induced anxiety and panic, paradoxical increases in tension, less motivation in life, boredom, pain, impaired reality testing, confusion and disorientation, feeling 'spaced out', depression, being more judgmental, feeling addicted to meditation, uncomfortable kinaesthetic sensations, mild dissociation, feelings of guilt and via anxiety-provoking phenomena, psychosis-like symptoms, grandiosity, elation, destructive behavior and suicidal feelings, defenselessness, fear, anger, apprehension and despair, sobbing and release of hidden memories and themes from the past.

It is possible to experience no benefit or any harms or adverse effect during limited time of this study.

There is no concluding data on the long term nature of adverse effects.

The Principle Investigator (PI) or any other organizations or anyone associated with the study do not guarantee that any of the information or practices will have any particular outcome for the participants. By signing this consent, the participant agrees that he/she is participating in this study at his/her own volition and any information and techniques of meditation provided will be used entirely at his/her own discretion

Any person under medical care for depression or other mental health conditions are encouraged not to participate or to only participate after discussion with his/her healthcare provider, so that the study participation does not interfere with current treatment.

Responsibility of participant:

Initial _____ I agree NOT to share provided sensitive information such as Virtual/Video meeting identification number and password to anyone.

Initial _____ I agree NOT to share provided sensitive information such as Virtual/Video meeting identification number and password on any social media platform.

I have reviewed and understood all the information provided and I give consent to participate in this study.

Signature: _____

Date: _____

Contact information:

Name: _____

Email: _____

Phone number: _____