

Effects of Heartfulness meditation on the wellbeing of Indian physicians and medical students

Submission date 30/06/2023	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/07/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/09/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Healthcare providers, including medical students and physicians, encounter notable challenges regarding burnout and loneliness, posing detrimental effects on their well-being and patient care. Physicians of Indian origin in the United States specifically face higher burnout levels than their counterparts. In India, medical students and physicians also confront substantial challenges concerning burnout and loneliness. Considering the potential benefits of meditation in mitigating stress and burnout among healthcare providers, including physicians and medical students, it is crucial to investigate its impact on these populations. The Heartfulness meditation practice, a specific method of meditation, has been shown to decrease loneliness, improve sleep, and reduce burnout in healthcare workers. This study aims to investigate the impacts of a virtual, heart-based meditation program (Heartfulness practice) on the Indian medical student and physician populations in India and the Indian physician population in the United States.

Who can participate?

Physicians of Indian origin residing in the United States, physicians and medical students residing in India

What does the study involve?

After baseline surveys are completed, physicians are randomly allocated into the intervention group and the control group for a 4-week intervention considered Phase I of the study. The intervention group will participate in the Virtual Heartfulness meditation program, which will include one orientation session, three education and guided relaxation and meditation sessions over three consecutive days, three weekly group education and meditation sessions and daily self-paced meditation practices. In addition, the Heartfulness trainer-guided virtual sessions will be offered which will be conducted daily, 5 days a week for the duration of the study period by Heartfulness trainer and primary investigator Dr Kunal Desai or other Heartfulness trainers only via Webinar mode to maintain the privacy of the participants. Heartfulness trainers will be assigned to participants and will offer individual guided sessions twice a week during the study period.

The control group will not partake in any programming and will continue with regular daily

activities. At the end of the 4 weeks, all participants will be required to complete surveys. At the end of the first 4-week intervention, emails will be sent to all participants asking for voluntary participation in Phase II of the study. The control group will be invited to participate in the same 4-week Heartfulness meditation program mentioned above. The intervention group will be invited to continue to participate in the program, with an opportunity to complete a total 8-week program. At the end of the 8 weeks, all participants will be required to complete surveys. All participants in both groups will be provided with information, including recorded video presentations for Heartfulness meditation practice, at the end of the 8 weeks.

What are the possible benefits and risks of participating?

Participants who complete the Heartfulness meditation program may experience reduced burnout and may have an improved sense of emotional wellness and improvement in satisfaction with life.

In the practice of meditation, although calmness is induced, there can also be the experience of unwanted emotions and thoughts arising and passing. There may also be bodily discomfort through sitting for a prolonged period.

Where is the study run from?

Wright State University (USA)

When is the study starting, and how long is it expected to run for?

January 2023 to April 2025

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Kunal Desai, kunal.desai@wright.edu

Contact information

Type(s)

Principal Investigator

Contact name

Dr Kunal Desai

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Impact of Heartfulness meditation practices on burnout, loneliness, and satisfaction with life among Indian physicians and medical students: a randomized controlled survey study

Study objectives

Heartfulness meditation practice may reduce burnout and loneliness and increase satisfaction with life among Indian physicians and medical students.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 26/06/2023, Wright State University Institutional Review Board (3640 Colonel Glenn Highway, Dayton, 45435, United States of America; +1 (0)937 775 4462; irb-rsp@wright.edu), ref: IRB-2023-309

Study design

Prospective randomized controlled crossover study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Internet/virtual

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Burnout and loneliness

Interventions

The baseline survey will obtain demographic information, detailed in the Participant Detail Form, as well as responses to the UCLA 3-Item Loneliness Scale (ULS-3), the abbreviated Maslach Burnout Inventory (aMBI), and Satisfaction with Life (SWLS).

After baseline surveys are completed, physicians interested in study participation will be separated, through computerized randomization, into the intervention group and the control group for a 4-week intervention considered Phase I of the study. The intervention group will participate in the Virtual Heartfulness meditation program, which will include one orientation session, three education and guided relaxation and meditation sessions over three consecutive days, three weekly group education and meditation sessions and daily self-paced meditation practices. In addition, the Heartfulness trainer-guided virtual sessions will be offered which will be conducted daily, 5 days a week for the duration of the study period by Heartfulness trainer and primary investigator Dr. Kunal Desai or other Heartfulness trainers only via Webinar mode to maintain the privacy of the participants. Heartfulness trainers will be assigned to participants and will offer individual guided sessions twice a week during the study period. This will help reduce the attrition observed in the previous studies.

The control group will not partake in any programming and will continue with regular daily activities. At the end of the 4 weeks, all participants will be required to complete the Phase I Completion survey that includes the ULS-3, aMBI, and SWLS reassessments. Additionally, the intervention group participants will be required to complete the Qualitative Feedback Survey and Practice Frequency Survey.

Upon completion of the first 4-week intervention, email communication will be sent to all participants asking for voluntary participation in Phase II of the study. The control group will be invited to participate in the same 4-week Heartfulness meditation program mentioned above. The intervention group will be invited to continue to participate in the program, with an opportunity to complete a total 8-week program.

At the end of the 8 weeks, all participants will be required to complete the Qualitative Feedback Survey, Practice Frequency Survey, and Phase II Completion Survey that includes ULS-3, aMBI, and SWLS reassessments.

All participants in both groups will be provided with information, including recorded video presentations for Heartfulness meditation practice, at the end of the 8 weeks.

Intervention Type

Behavioural

Primary outcome measure

1. Loneliness measured using the UCLA 3-Item Loneliness Scale (ULS-3) at baseline, week 4 and week 8
2. Burnout measured using the abbreviated Maslach Burnout Inventory (aMBI) at baseline, week 4 and week 8
3. Satisfaction with life measured using the Satisfaction with Life (SWLS) at baseline, week 4 and week 8

Secondary outcome measures

Subjective experience measured using qualitative questions at baseline, week 4 and week 8

Overall study start date

09/01/2023

Completion date

01/04/2025

Eligibility

Key inclusion criteria

1. Adults above 18 years of age are willing to participate in the study
2. Physicians of Indian origin residing in the United States
3. Physicians residing in India and medical students enrolled medical schools in India
4. Requires basic knowledge of the Internet and ability to follow instructions regarding email communications as well as accessing video conferences

Participant type(s)

Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

600

Key exclusion criteria

1. Individuals less than 18 years of age
2. Participants with a history of meditation practice (≥ 100 hours of meditation) will be excluded from the study to avoid participant bias
3. Any person under medical care for depression or other mental health conditions is encouraged not to participate or only participate after discussion with his/her healthcare provider so that the study participation does not interfere with current treatment

Date of first enrolment

01/02/2025

Date of final enrolment

01/03/2025

Locations

Countries of recruitment

India

United States of America

Study participating centre
Not applicable
United States of America
-

Sponsor information

Organisation
Wright State University

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The researchers expect to publish the study results and manuscript in a PubMed-indexed journal.

Intention to publish date

01/09/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date