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Effect of heartfulness meditation on mental health and gene expression

Submission date
30/03/2022

Recruitment status
No longer recruiting

Registration date
06/04/2022

Overall study status
Completed

Last Edited
17/12/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Stress is described by the National Institute of Mental Health as the brain's response to any demand. The current COVID-19 pandemic has heightened the anxiety and stress of many people. Medical students, paramedical students, allied health care students, and pharmacy students have a high degree of stress and burnout, and training physicians appear to be especially prone due to the number of hours spent at work each week, the large body of clinical knowledge to master, and the challenges of balancing work and home life. In addition, changes in stress levels correspond to changes in gene expression and even changes within the brain. Despite the potentially serious consequences of stress and burnout, there are few interventions designed to combat this problem in the medical student population.
This study will investigate whether a 12-week Heartfulness meditation program is associated with improvements in stress, anxiety levels, and depression symptoms in participants. The intervention chosen for this study is meditation with the guidance of a Heartfulness Meditation certified trainer who facilitates meditation with yogic energy, pranahuti. Heartfulness meditation is a simple heart-based meditation system aimed at attaining a balanced state of existence that has been shown to improve burnout, stress, and anxiety.

Who can participate?
Medical students, paramedical students, allied health care students, and pharmacy students aged over 18 years

What does the study involve?
Participants will be randomly allocated into the meditation group or the control group. Electronic copies of the assessment tools will be distributed and collected by the investigators. An education and consent session will be set up before the study. Willing participants will attend a talk on Heartfulness meditation and the study detailing the aspects of Heartfulness meditation and what to expect throughout the study and the opportunity to ask any questions. Anyone who agrees to participate in the study, and who signs the consent form, will be asked to fill out the demographics form. They will also be given a practice information sheet to take home.
The control group will receive no specific intervention. For the meditation group the Heartfulness meditation sessions will be available daily for 12 weeks. Participants are asked to

attend daily Heartfulness meditation sessions conducted by Heartfulness trainers. The participants will be given guided relaxation, the instructions of which would involve progressively relaxing the body from the toes to the top of their head followed by gently resting their attention on the idea of a source of light within their hearts. This is to be done in a gentle and natural way. If their attention drifts, they will be asked to gently redirect their attention toward their hearts. The session duration will be about 30 minutes each day. The participants will also be given an audio link for rejuvenation in the evening and relaxation prior to sleep.
At week 0, participants will fill out the forms and undergo tests. Participants will be given a Heartfulness meditation log sheet to assess their practice every week.
Blood samples will be collected at weeks 0 and 12 respectively in both groups and analyzed.

What are the possible benefits and risks of participating?
Benefits include possible improved mental well-being through learning meditation techniques. Some of the participants may have limited endurance and decreased strength related to their health conditions. Some may also have concurrent medical problems such as joint pains, or other challenges. Participants receive written and verbal instructions to never do anything that they feel is dangerous or painful to them. Medical aid is available in the hospitals affiliated with the medical colleges.
In the practice of Heartfulness meditation, although calmness is induced, there can also be the experience of unwanted emotions and thoughts arising and passing. If the participant is unable to continue meditation due to this, they may open their eyes briefly, take a slow deep breath, and then close their eyes to continue to meditate, or alternatively, they may leave if they desire to. There may also be bodily discomfort through sitting for a prolonged period. To address this, participants may change their posture to continue meditation. The recognition of this is a part of the long-term benefit of the course, but it can be upsetting or uncomfortable in the short term. Participants have their first experience of the technique in the supportive atmosphere of the classroom and are taught what to expect and how to cope with the experience as it unfolds. They also have contact information from the trainer and participants may call or email the trainer with any questions or concerns.

Where is the study run from?
Hospital for Mental Health, Ahmedabad, Gujarat (India)

When is the study starting and how long is it expected to run for?
January 2021 to January 2024

Who is funding the study?
1. Gujarat Industries Power Company Ltd (India)
2. Hirabhai Ashabhai Charitable Trust (India)

Who is the main contact?
1. Dr Ajay Chauhan, drajaypc@yahoo.com
2. Dr Jay Thimmapuram, jthimmapuram@wellspan.org

Contact information

Type(s)
Scientific

Contact name
Dr Jayaram Thimmapuram

Contact details
2780 Meadow Cross Way
York
United States of America
17402
+1 (0)7174956027
jthimmapuram@wellspan.org

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
No.Ethics/Approval/01/2022

Study information

Scientific Title
Effect of heartfulness meditation on stress, anxiety, biomarkers and gene expression profile

Study objectives
Current study hypothesis as of 05/01/2023:
The practice of heartfulness will be associated with a reduction in stress and anxiety along with changes in biomarkers, and gene expression profile.

Previous study hypothesis:
The practice of heartfulness will be associated with a reduction in stress and anxiety along with changes in biomarkers, gene expression profile, and brain fMRI corresponding to improved mental wellbeing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2022, Ethics Committee, Hospital for Mental Health Ahmedabad (Ahmedabad, 380004, India; +91 (0)79 25624583; ethicshmha@gmail.com), ref: Ethics/Approval/1/12022

Study design
Prospective randomized single-center controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Stress and anxiety in healthy volunteers

Interventions
Current interventions as of 05/01/2023:
Participants will be computer randomized to a Heartfulness meditation arm or a control arm with no specific intervention. The intervention includes daily guided Heartfulness meditation through a certified trainer for 12 weeks. Depression Anxiety Stress Scale (DASS-21) will be administered prior to the study and at the end of 12 weeks. Gene expression profile, and biomarkers will be done prior to the study and at the end of 12 weeks.

Previous interventions:
Participants will be computer randomized to a Heartfulness meditation arm or a control arm with no specific intervention. The intervention includes daily guided Heartfulness meditation through a certified trainer for 12 weeks. Perceived stress scale (PSS), Depression Anxiety Stress Scale (DASS-21) and impostor phenomenon scales will be administered prior to the study and at the end of 12 weeks. Gene expression profile, biomarkers and an fMRI brain scan will be done prior to the study and at the end of 12 weeks.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 05/01/2023:
1. Depression, anxiety and stress measured with the Depression Anxiety Stress Scale (DASS-21) prior to the study and at the end of 12 weeks
2. Biomarkers measured using serological test prior to the study and at the end of 12 weeks
3. Gene expression profile including transcriptome analysis using mRNA sequencing prior to the study and at the end of 12 weeks

Previous primary outcome measures:
1. Stress measured with the perceived stress scale (PSS) prior to the study and at the end of 12 weeks
2. Anxiety measured with the Depression Anxiety Stress Scale (DASS-21) prior to the study and at the end of 12 weeks
3. Impostor syndrome measured using the Impostor Syndrome Scale prior to the study and at the end of 12 weeks
4. Brain changes measured using functional magnetic resonance imaging (fMRI) prior to the

study and at the end of 12 weeks
5. Biomarkers measured using serological test prior to the study and at the end of 12 weeks
6. Gene expression profile including NFkB (Nuclear Factor kappa B) transcriptome analysis using mRNA sequencing prior to the study and at the end of 12 weeks

Secondary outcome measures
Current secondary outcome measures as of 05/01/2023:
There are no secondary outcome measures

Previous secondary outcome measures:
Qualitative experience gathered using interviews at the end of the study

Overall study start date
01/01/2021

Completion date
01/01/2024

Eligibility

Key inclusion criteria
1. Adults above 18 years of age
2. Those who give consent for the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
80

Total final enrolment
78

Key exclusion criteria
1. Individuals less than 18 years of age
2. Active suicidal ideation, current or past diagnoses of manic-depressive disorders, post-traumatic stress disorder, psychotic disorders or any other psychiatric conditions requiring treatment
3. Individuals with claustrophobia, metal in the body, history of head injury, and current use of psychiatric medications
4. Those who don’t give consent for the study

Date of first enrolment
22/03/2022

Date of final enrolment
24/04/2022

Locations

Countries of recruitment
India

Study participating centre
Hospital for Mental Health - Gujarat Institute of Mental Health
Bhadreshwar Society
Kazipur Dariyapur
Ahmedabad
India
380004

Sponsor information

Organisation
Gujarat Industries Power Company Ltd

Sponsor details
Ranoli
Gujarat
Vadodara
India
391350
+91 (0)265 2232768
genbaroda@gipcl.com

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name

Gujarat Industries Power Company Ltd

Funder Name
Hirabhai Ashabhai Charitable Trust

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/08/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/12/2024	17/12/2024	Yes	No