ISRCTN16995269 https://doi.org/10.1186/ISRCTN16995269

Effects of guided Heartfulness meditation on meditation depth and brain waves

Submission date
30/11/2023

Recruitment status
No longer recruiting

Registration date
01/12/2023

Overall study status
Completed

Last Edited
01/12/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Heartfulness meditation is a simple heart-based meditation practice that has been shown to improve sleep and reduce loneliness and stress. The use of transmission is the most distinguishing feature of Heartfulness and sets it apart from all other paths and is said to help practitioners enter a state of meditation more easily. It has been suggested that transmission will help a practitioner reach deeper stages of meditation sooner; this may be reflected in the neural signatures. The aim of this study is to investigate whether using this novel approach of a heart-based meditation program leads to measurable changes in the electroencephalogram (EEG) and whether there is any correlation between the waveforms and the depth of meditation. The subjective depth of the meditation experience will be measured using a questionnaire.

Who can participate?
Adults above 18 years of age with less than 100 hours of meditation experience and long time (> 10 years) Heartfulness meditators

What does the study involve?
Participants with no significant meditation experience will be randomly allocated into two groups.
Group 1: Participants with unguided sessions close their eyes for 5 minutes while EEG recordings are performed. Following 5 minutes, they will be asked to relax with their eyes closed for 30 minutes with continued recording. After finishing the session, they fill out a meditation depth questionnaire and answer questions on subjective experience.
Group 2: Participants with a trainer-guided session close their eyes for 5 minutes while EEG recordings are performed. After 5 minutes, they will do a guided relaxation and meditation session for 30 minutes with a Heartfulness trainer with continued recording. After finishing the session, they also fill out a meditation depth questionnaire.
Any willing participant from Group 1 will be given an opportunity to participate in the Group 2 intervention (trainer-guided session) on a different day or the same day after a 15–20-minute break.
A group of experienced Heartfulness meditators will be recruited with the help of the Heartfulness Institute, Dayton, to undergo a similar trainer-guided session as group 2.
Heartfulness meditation trainers who will be conducting the guided sessions will also be

participating in measuring EEG recordings for themselves.
Each participant will be tested individually. Guided sessions will be conducted one-on-one (participant and trainer) as well.

What are the possible benefits and risks of participating?
The researchers cannot guarantee or promise that participants will receive any benefits from this study. Participants who complete the meditation session may be able to learn how to relax, and this may be a tool in the long run. There are no other major benefits.
There is a chance that participants might feel bodily discomfort during the meditation session due to prolonged sitting. While most research shows meditation benefits, some also suggests potential adverse effects. Potential adverse effects include but are 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 kinesthetic 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. There is no concluding data on the long-term nature of the adverse effects of meditation.
The EEG sensors on the forehead and temple may cause discomfort, but it has no latex, so latex allergy is not prohibitive.

Where is the study run from?
Wright State University (USA)

When is the study starting, and how long is it expected to run for?
July 2023 to July 2024

Who is funding the study?
Heartfulness Institute (USA)

Who is the main contact?
Dr Kunal Desai, kunal.desai@wright.edu (USA)

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Kunal Desai

ORCID ID
https://orcid.org/0000-0002-4959-8061

Contact details
33 West Rahn Road
Dayton
United States of America
45409
+1 (0)9374338990
kunal.desai@wright.edu

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Impact of Heartfulness meditation on color density spectral array (EEG) measured by bispectral index monitor

Study objectives
1. Trainer-guided meditation practice with Heartfulness will be associated with subjects' increased depth of meditation compared to simply closing their eyes for the duration.
2. Trainer-guided meditation practice with Heartfulness will show a brain wave pattern on processed EEG reflected by Color Density Spectral analysis (CDSA) associated with deeper relaxation compared to simply closing their eyes for the same duration.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 27/11/2023, 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-2023-349

Study design
Prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Meditation experience

Interventions
Participants with no significant meditation experience will be randomly allocated into two groups using a computer program
Group 1: Participants with unguided sessions close their eyes for 5 minutes while EEG recordings are performed. Following 5 minutes, they will be asked to relax with their eyes closed for 30

minutes with continued recording. After finishing the session, they fill out a meditation depth questionnaire and answer questions on subjective experience.
Group 2: Participants with a trainer-guided session close their eyes for 5 minutes while EEG recordings are performed. After 5 minutes, they will do a guided relaxation and meditation session for 30 minutes with a Heartfulness trainer with continued recording. After finishing the session, they also fill out a meditation depth questionnaire.
Any willing participant from Group 1 will be given an opportunity to participate in the Group 2 intervention (trainer-guided session) on a different day or the same day after a 15–20-minute break.
A group of experienced Heartfulness meditators will be recruited with the help of the Heartfulness Institute, Dayton, to undergo a similar trainer-guided session as group 2. Heartfulness meditation trainers who will be conducting the guided sessions will also be participating in measuring EEG recordings for themselves.
Each participant will be tested individually. Guided sessions will be conducted one-on-one (participant and trainer) as well.

Intervention Type
Behavioural

Primary outcome(s)
1. Processed EEG in the form of Color Density Spectral Analysis (CDSA) along with Bispectral Index (BIS) measured (0-100) by BIS monitor, assessed for the following:
1.1. Participants with no significant (less than 100 hours) meditation experience while simply closing their eyes for 5 minutes followed by relaxing for 30 minutes.
1.2. Participants with no significant (less than 100 hours) meditation experience while simply closing their eyes for 5 minutes and then with trainer-guided Heartfulness relaxation and meditation for 30 minutes.
1.3. Participants with more than 10 years of experience with Heartfulness meditation while simply closing their eyes for 5 minutes and then with trainer-guided Heartfulness relaxation and meditation for 30 minutes.
2. Participants' subjective experience assessed using a MEDEQ questionnaire and subjective questions regarding the experience that measure the depth of the meditation experience after the session

Key secondary outcome(s))
Processed EEG in the form of Color Density Spectral Analysis (CDSA) along with Bispectral Index (BIS) measured (0-100) by BIS monitor for the Heartfulness trainer conducting guided Heartfulness relaxation and meditation for 30 minutes and assess if there is any resonance reflected by EEG-CDSA; between the trainer and meditator during the last 10 minutes of the session.

Completion date
15/07/2024

Eligibility

Key inclusion criteria
1. Adults 18 years or older with less than 100 hours of meditation experience residing in the Dayton area
2. Experienced Heartfulness meditators and trainers residing in the Dayton area

Participant type(s)
Healthy volunteer, Health professional, Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Those who are unable to sit for 30 minutes due to either physical or mental condition
2. Participants with known brain problems with brain tumors or any seizure history
3. Those on benzodiazepines or psychiatry medications, sleep disorders, or sleeping pills that may potentially interfere with EEG patterns
4. EEG recordings through BIS are safe, non-invasive measurements, but if participants are unable to have the leads on their scalp or skin, they will be excluded

Date of first enrolment
15/12/2023

Date of final enrolment
15/07/2024

Locations

Countries of recruitment
United States of America

Study participating centre
Premier Health Partners
One Wyoming Street
Dayton
United States of America
45409

Sponsor information

Organisation
Heartfulness Institute

Funder(s)

Funder type
Research organisation

Funder Name
Heartfulness Institute

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Kunal Desai, MD (kunal.desai@wright.edu). The type of data that will be shared: Collected data and analysis will be shared after study completion and analysis. Consent from participants was required and obtained.

IPD sharing plan summary
Available on request