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Effect of virtual heartfulness meditation and yoga program on mental wellbeing

Submission date
07/02/2022

Recruitment status
No longer recruiting

Registration date
09/02/2022

Overall study status
Completed

Last Edited
08/09/2023

Condition category
Other

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

Plain English summary of protocol

Background & study aims
Yoga and meditative practices are known to significantly improve psychological well-being. The practice of yoga produces a physiological state opposite to that of the flight-or-fight stress response and with that interruption in the stress response, a sense of balance and union between the mind and body can be achieved. Heartfulness is a simple heart-based meditation practice supported by yogic transmission aimed to achieve an inner state of balance. Prior literature on heartfulness meditation has demonstrated favorable outcomes in improving burnout, emotional wellness, sleep quality, and perception of loneliness. The virtual approach to wellbeing has become popular during the pandemic and has been well utilized.
The current study aims to assess the effects of a virtual yoga and meditation program on measures of anxiety, loneliness, and satisfaction with life.

Who can participate?
Any adult 18 years of age and above residing in the United States of America can participate in the study.

What does the study involve?
It requires attending a virtual training webinar session conducted by certified yoga and meditation trainers comprising yoga exercises followed by heartfulness relaxation and meditation once a week for six weeks. The participants will be asked to practice daily the techniques suggested in weekly virtual sessions and also to self-report the adherence to the intervention in the same survey at the end of the study period.

What are the possible benefits and risks of participating?
Learning yoga, relaxation, and meditation skills that are part of this study may help an individual cope with stress better. It may also help one sleep better. There may be bodily discomfort through sitting for a prolonged period or doing yogic exercises. One can also have the experience of unwanted emotion and thoughts arising and passing during the meditation.

Where is the study run from?
The study will be run through a virtual platform and email communication from Dayton, Ohio, USA.

Where is the study starting and how long is it expected to run from?
November 2021 to March 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Kunal Desai, MD
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Contact information

Type(s)
Principal investigator

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Dr Kunal Desai

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Additional identifiers

Protocol serial number
IRB 07171

Study information

Scientific Title
Effect of virtual heartfulness meditation and yoga program on anxiety, loneliness, and satisfaction with life in the general US population

Study objectives
Intervention of heartfulness meditation practices and yoga may be associated with reduction in anxiety levels, reduction in perception of loneliness and improvement in satisfaction with life.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 30/11/2021, Wright State University IRB (3640 Colonel Glenn Hwy, Dayton, OH 45435-0001, USA; +1 937-775-4462; whitney.mcallister@wright.edu), ref: #07171

Primary study design
Interventional

Study design
Prospective pre-post intervention single-arm study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Studying impact of meditation and yoga on anxiety, loneliness and satisfaction with life

Interventions
The study participants will be offered education & training of yoga exercises and heartfulness meditation practice by certified yoga and meditation trainers on a virtual platform over 6-week period.

Intervention Type
Behavioural

Primary outcome(s)
Measured at baseline and post intervention at the end of 6 weeks:
1. Generalized anxiety measured by GAD-7 scale
2. Loneliness measured by UCLA Loneliness scale
3. Satisfaction with life measured by Satisfaction with life scale

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
13/03/2022

Eligibility

Key inclusion criteria
1. Adults above 18 years of age with an interest to participate in the study
2. Basic knowledge of the Internet and ability to follow instructions regarding email communications as well as accessing video conferences

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
73

Key exclusion criteria
1. Individuals less than 18 years of age or uncontrolled psychiatric conditions
2. Participants with a history of meditation practice (≥ 100 hours of meditation) will be excluded from the study to avoid participant bias

Disclaimer:
1. 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.
2. Any person with physical limitation to perform yoga exercises are advised to seek guidance from his/her healthcare provider, so that study participation does not interfere with current treatment and does not put oneself at risk of any physical injury.

Date of first enrolment
02/01/2022

Date of final enrolment
04/02/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Wright State University
3640 Colonel Glenn Hwy
Dayton
United States of America
45435

Sponsor information

Organisation

Wright State University

ROR
https://ror.org/04qk6pt94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a non-publicly available repository, will be stored with Wright State University secured resources.

IPD sharing plan summary
Stored in non-publicly available repository