

Effect of heartfulness meditation on stress and satisfaction with life of students

Submission date 30/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/12/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/12/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The COVID-19 pandemic has had a particular impact on stress and satisfaction with life in women as they are subject to more demands and pressure in society. Since time immemorial, meditation has been accepted as a tool to help deal reduce stress and improve wellbeing. The motto of the Satyam Group of Institutions is 'empowering women through education' which resonates by developing preparedness through professional education, life skills and instilling the values of personal improvement. This study seeks to investigate whether Heartfulness meditation has an impact on satisfaction with life and perceived stress on the students of Satyam Group of Institutions. The intervention chosen for this project is a 12-week online Science of Meditation (SOM) program, with guidance from a Heartfulness meditation trainer coupled with structured education modules. Heartfulness is a simple heart-based meditation system aimed at attaining a balanced state of existence. The uniqueness of the Heartfulness system of meditation is an aspect called transmission which enhances the experience and effects of meditation. This will be explained during the sessions and the participants will be encouraged to experience the effects of transmission. Satisfaction with life is an important factor that can be adversely affected by stress. The aim of this study is to assess the effectiveness of Heartfulness meditation on alleviating stress and improving satisfaction with life among female students.

Who can participate?

Female students aged 18 years and over at the Satyam Group of Institutions

What does the study involve?

The online intervention based on the Heartfulness meditation system is composed of three main components. The live online meditation session is organized on a weekly basis for 12 weeks. The sessions are composed of 4 minutes of micro-meditation practice, a 15-minute presentation on the science of meditation, 24 minutes of guided meditation practice, 2 minutes of journaling and 15 minutes for questions and answers to help participants better understand the practice of meditation. The participants are requested to follow a 12-week self-paced online course. One module will be accessible each week. Participants will follow the pre-recorded content to review, integrate and go deeper into the understanding of the content and practice Heartfulness micro and core practices. The composition of each module is about 15 minutes of content, 24 minutes of one Heartfulness core practice, 2 to 6 minutes of micro-practice and

journaling, and 15 minutes of homework. Participants are requested to practice daily the Heartfulness core practices (meditation, rejuvenation and inner connection) in the following schedule for 12 weeks: 15-20 minutes of Heartfulness meditation in the morning, 15-20 minutes of Heartfulness cleaning in the evening, and 5-10 minutes of Heartfulness inner connection before sleeping.

What are the possible benefits and risks of participating?

Participants may have a decrease in stress levels and increased 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. 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 that is their desire. 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 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 session and are taught what to expect and how to cope with experience as it unfolds. They also have contact information from the trainer and participants may call or e-mail the trainer with any questions or concerns. If any experience in class reveals intent to self-harm, the investigators will follow up promptly. Participants often share their experiences in the group setting; therefore, the issue of confidentiality applies not just to trainers, but to group members as well. Participants will need to hold class events confidentially and will not give each other advice.

Where is the study run from?

Satyam Group of Institutions (India)

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

October 2021 to April 2022

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Jayaram Thimmapuram

jthimmapuram@wellspan.org

Contact information

Type(s)

Scientific

Contact name

Dr Jayaram Thimmapuram

ORCID ID

<https://orcid.org/0000-0002-3189-3863>

Contact details

2780 Meadow Cross Way

York

United States of America
17402
+1 (0)7174956027
jthimmapuram@wellspan.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

0508/Research/SGI-HFN

Study information

Scientific Title

Effect of mindfulness meditation on perceived stress and satisfaction with life of students: a randomized waitlist controlled study

Study objectives

1. Mindfulness meditation practice will be associated with a reduction in perceived stress in students after the meditation program.
2. Mindfulness meditation practice will be associated with improved satisfaction with life after the meditation program.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 13/12/2021, Sathyam Ethics Committee (C-56 /14 &15, Sector 62 Noida-201309, (U.P.), India; +91 (0)9891081110; vandana.jaglan@satyamfashion.ac.in), ref: 0508/Research/SGI-HFN

Study design

Single-centre prospective randomized waitlist controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

School

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Stress and satisfaction with life in students

Interventions

Computer randomization is performed.

The interventional group undergoes 12 weeks of Heartfulness meditation practice with measurement of Perceived Stress Scale scores and Satisfaction with Life Scale scores at week 0, 6, 12 and 18, respectively.

The control group undergoes 12 weeks of Heartfulness meditation practice starting at week 6 of the study with measurement of Perceived Stress Scale scores and Satisfaction with Life Scale scores at week 0, 6, 12 and 18, respectively.

Intervention Type

Behavioural

Primary outcome measure

Stress measured using the Perceived Stress Scale (PSS) at baseline, week 6, week 12 and week 18

Secondary outcome measures

Satisfaction with life measured using the Satisfaction with Life Scale (SWLS) at baseline, week 6, week 12 and week 18

Overall study start date

01/10/2021

Completion date

25/04/2022

Eligibility

Key inclusion criteria

1. Aged 18 years and above
2. Willing to participate in the study
3. Female students of Satyam Group Institutions

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

240

Total final enrolment

212

Key exclusion criteria

1. Inability to sit for 30-45 minutes
2. Unwilling to participate

Date of first enrolment

13/12/2021

Date of final enrolment

19/12/2021

Locations

Countries of recruitment

India

Study participating centre

Satyam Group of Institutions

C-56 A/14 & 15, Sector 62

Noida

India

201309

Sponsor information

Organisation

Satyam Group of Institutions

Sponsor details

c-56 A/14 & 15, Sector 62

Noida

India

201309

+91 (0)9891081110, +91 (0)120 4242805, +91 (0)120 4540130

vandana.jaglan@satyamfashion.ac.in

Sponsor type

University/education

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/01/2023

Individual participant data (IPD) sharing plan

De-identified data may be available with the research board. An Excel sheet with information about the collected scores of the participant will be with the research board. Informed consent was obtained from participants for the study.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/11/2023	01/12/2023	Yes	No