

Effect of heartfulness meditation on loneliness and sleep in physicians and advance practice providers

Submission date 05/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/03/2021	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Loneliness poses a significant health problem for a sizeable part of the population with increased risks in terms of depression, anxiety, suicidal ideation, health behavior and health care utilization. The medical profession is reported to be one of the loneliest professions of all. Perception of loneliness can also be influenced by the relationship to one's own self and sleep. Wellness events and meditation practices may have a positive impact on burnout. Heartfulness meditation practice has been shown to improve wellbeing and sleep. Heartfulness meditation is a simple heart-based meditation system aimed at attaining a balanced state of mind by asking the participants to focus on the source of light within the heart. This study will investigate whether using this novel approach of a heart-based meditation program leads to measurable changes in improvement of sleep and perception of loneliness in physicians and advance practice clinicians.

Who can participate?

All physicians and advance practice providers of Wellspan

What does the study involve?

A survey monkey questionnaire with baseline characteristics and PSQI questionnaire and UCLA loneliness scale will be sent to all physicians and APCs of Wellspan from the research department. Those who respond to the survey will be included in the study. Those willing to participate in meditation program to improve sleep will be randomized into two groups. One group receives instructions whereas the other group does not. A repeat UCLA loneliness and PSQI questionnaires will be sent to the initial respondents and divided into meditation group and the control group and the no interest group. Data from participants who complete survey questions will be collected at the baseline and intervention weeks respectively.

What are the possible benefits and risks of participating?

Participants who complete the meditation session may be able to have an improvement of sleep and/or perception of loneliness. Stress and burnout along with sleep and loneliness scores may be improved as the subjects become less reactive to worrisome thoughts.

Some of the participants may have no benefit from meditation. As this is voluntary participation, it may take around 15 minutes of the participant's time per day during the intervention period.

Where is the study run from?
Wellspan Health (USA)

When is the study starting and how long is it expected to run for?
February 2020 to October 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Jayaram Thimmapuram, drthimmapuram@yahoo.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
IRB number 1568071-3

Study information

Scientific Title

Effect of heartfulness meditation on loneliness and sleep in physicians and advance practice providers during COVID-19

Study objectives

1. There is a high burden of loneliness in physicians and advance practice clinicians
2. PSQI scores will correlate with scores of loneliness (poor sleep with higher loneliness)
3. Heartfulness meditation practice will be associated with subjects' improved sleep and loneliness scores

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/07/2020, Wellspan IRB (1001, S George St, York, Pennsylvania - 17403, USA; +1 717 8512223; irb@wellspan.org), ref: 1568071-3

Study design

Single institutional randomized controlled prospective study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Loneliness and sleep in physicians and advance practice providers

Interventions

After the enrollment of the participants through email surveys, computerized randomization was performed.

Heartfulness Meditation Audio links were provided to the Heartfulness meditation group to perform meditation for 15 minutes per day for 4 weeks.

The control group continued with their usual routine.

Assessments were made at baseline and 4 weeks.

Intervention Type

Behavioural

Primary outcome measure

1. Loneliness measured using UCLA Loneliness score at baseline and 4 weeks
2. Sleep was assessed using the Pittsburgh Sleep Quality Index at baseline and 4 weeks

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

20/02/2020

Completion date

12/10/2020

Eligibility**Key inclusion criteria**

Any employee who is a physician or an advance practice provider willing to participate

Participant type(s)

Health professional

Age group

Adult

Sex

Both

Target number of participants

100 in each group

Total final enrolment

155

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

21/07/2020

Date of final enrolment

10/08/2020

Locations**Countries of recruitment**

United States of America

Study participating centre

Wellspan Health
1001, S George St
York
United States of America
17403

Sponsor information

Organisation
WellSpan Health

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/01nkne14>

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
30/09/2021

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be 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	results	17/03/2021	09/03/2021	Yes	No