

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

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

**Clinical Trials Information System (CTIS)**  
Nil Known

**ClinicalTrials.gov (NCT)**  
Nil Known

**Protocol serial number**  
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

**Study type(s)**

Quality of life

**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(s)**

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

**Key secondary outcome(s)**

There are no secondary outcome measures

**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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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

ROR

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

## Funder(s)

### Funder type

Other

### Funder Name

Investigator initiated and funded

## Results and Publications

### 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?
<a href="#">Results article</a>	results	17/03/2021	09/03/2021	Yes	No