

# 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 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**  
Dr Jayaram Thimmapuram

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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**  
1001, S George St  
York  
United States of America  
17403  
+1 717-851-2223  
irv@wellspan.org

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