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Sleep patterns in internal medicine resident physicians and the effect of heartfulness meditation

Submission date	Recruitment status	[_] Prospectively registered
24/02/2021	No longer recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
04/03/2021	Completed	[X] Results
Last Edited	Condition category	[_] Individual participant data
09/06/2022	Other	

Plain English summary of protocol

Background and study aims
Resident physicians have a high level of burnout and stress. Adequate sleep is essential for resident wellbeing. Interventional studies on resident sleep patterns are scant. The current study aims to measure the sleep patterns of resident physicians during 1 week of outpatient rotation using a consensus sleep diary (CSD) and actigraphy watches during baseline week and assess the impact of Heartfulness meditation on these parameters during the intervention week.

Who can participate?
All eligible internal medicine resident physicians at Wellspan York Hospital.

What does the study involve?
The study involves filling a CSD daily and wearing the actigraphy watches during the baseline and intervention weeks. It also involves participating in daily guided meditation during the day time and listening to relaxation audio before sleep during the intervention week

What are the possible benefits and risks of participating?
The benefits include possible improvement of sleep quality and other parameters of sleep. There may be unwanted emotions, thoughts and feelings surfacing up during meditation that may provoke anxiety or stress. If such experiences occur, participants may stop at any time and may only do what they are comfortable with.

Where is the study run from?
Wellspan Apple Hill internal medicine outpatient office (USA)

When is the study starting and how long is it expected to run for?
February 2017 to October 2020

Who is funding the study?
1. Alliance for Academic Internal Medicine (AAIM) (USA)
2. Lake Eerie College of Osteopathic Medicine (LECOM) (USA)

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)717 851 2345
jthimmapuram@wellspan.org

Additional identifiers

Protocol serial number
1040076-6

Study information

Scientific Title
Sleep patterns in internal medicine resident physicians and the effect of heartfulness meditation during outpatient rotation

Study objectives
Participation in daily Heartfulness meditation improves sleep parameters in resident physicians during outpatient rotation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/05/2017, WellSpan Institutional Review Board (1001, S George St., Wellspan Health, York, Pennsylvania, 17402, USA; +1 (0)717 851 2223; irb@wellspan.org), ref: not applicable

Primary study design
Interventional

Study design
Single-center non-randomized prospective pre-post cohort study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Sleep quality in resident physicians

Interventions
A consensus sleep diary (CSD) is completed, and sleep is monitored using actigraphy during a 1-week outpatient rotation. After four intervening weeks, when the residents returned to the same rotation, Heartfulness meditation is practiced and the same parameters are measured. All the participating residents in the study are given instructions on Heartfulness meditation, and daily guided relaxation and meditation sessions are conducted in the office for 20 minutes. In addition, participants are asked to listen to a Heartfulness relaxation audio prior to sleep.

Intervention Type
Behavioural

Primary outcome(s)
Sleep quality measured using Consensus Sleep Diary (CSD) and actigraphy watches measured during baseline outpatient rotation week and repeated during the intervention week with Heartfulness meditation

Key secondary outcome(s)
1. Subjective sleep quality measured using CSD during baseline outpatient rotation week and repeated during the intervention week with Heartfulness meditation
2. Objective sleep parameters measured using actigraphy watches during baseline outpatient rotation week and repeated during the intervention week with Heartfulness meditation

Completion date
01/10/2020

Eligibility

Key inclusion criteria
All resident physicians willing to participate in the study

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
36

Key exclusion criteria
1. Residents unwilling to participate in the study
2. This study is not designed for people who are experiencing psychological distress that may be associated with bipolar disorder, substance abuse (drugs or alcohol abuse in last 6 months), alcohol withdrawal, BMI <18 kg/m², suicidal ideation, active psychotherapy, major depression, anxiety disorder, obstructive sleep apnea requiring CPAP, eating disorder, borderline personality disorder, posttraumatic stress disorder, or psychotic disorder

Date of first enrolment
06/01/2019

Date of final enrolment
03/02/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Wellspan Health
1001, S George St
York
United States of America
17402

Sponsor information

Organisation
WellSpan Health

ROR
https://ror.org/01nknep14

Funder(s)

Funder type
University/education

Funder Name
Lake Eerie College of Osteopathic Medicine

Funder Name
Alliance for Academic Internal Medicine

Results and Publications

Individual participant data (IPD) sharing plan
Participant data is stored with the research department at Wellspan Health.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/09/2021	09/06/2022	Yes	No