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Impact of Heartfulness meditation practices compared to the Gratitude practice on compassion fatigue and burnout

Submission date
11/04/2022

Recruitment status
No longer recruiting

Registration date
12/04/2022

Overall study status
Completed

Last Edited
17/06/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
While involved in the noble profession of helping fellow human beings, healthcare workers are exposed to a challenging work environment where they encounter distressed patients and families. Compassion and empathy are expected of all healthcare professionals though this constant demand can become overwhelming depending on the work environment, patient population, and workload. Heartfulness is a simple heart-based meditation practice supported by yogic transmission aimed to achieve an inner state of balance. Research on heartfulness meditation has demonstrated favorable outcomes in improving burnout, emotional wellness, sleep quality, and perception of loneliness. The virtual approach to wellbeing has become popular during the pandemic and has been well utilized. The American Nurses Foundation and the Greater Good Science Center (GGSC) at the University of California, Berkeley, have developed a Gratitude Practice for Nurses Toolkit to support nurses' social and emotional wellbeing. It is unclear if gratitude improves compassion fatigue and burnout and improves mental wellbeing, especially for healthcare workers, including nurses, as limited research data from randomized studies is available in this population. This study will investigate whether heartfulness meditation practice leads to measurable changes in compassion fatigue, compassion satisfaction and burnout among the nurses and allied healthcare providers compared to Gratitude practice.

Who can participate?
Any adult aged 18 years or over who works as a nurse or an allied healthcare worker providing patient care in Premier Health Network clinical sites in Dayton, Ohio.

What does the study involve?
The participants will be randomly assigned to one of the two study groups: group 1: the Heartfulness meditation group OR group 2: the Gratitude practice group. They will be asked to attend virtual trainer guided Heartfulness relaxation and meditation sessions at least four times a week for 6 weeks if they are in Group 1. They will be asked to attend education sessions

regarding the Gratitude practice once a week if they are in Group 2. They will be asked to practice daily the techniques suggested in weekly virtual sessions. They will also be asked to self-report their adherence to the intervention in the same survey at the end of the study period.

What are the possible benefits and risks of participating?
Learning gratitude practice or relaxation and meditation skills that are part of this study may help the participants cope with stress better. It may also help them sleep better. Participants may experience unwanted emotions and thoughts arising and passing during the meditation.

Where is the study run from?
Wright State University (USA)

When is the study starting and how long is it expected to run from?
August 2021 to October 2022

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Kunal Desai, MD
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Contact information

Type(s)
Principal investigator

Contact name
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Additional identifiers

Protocol serial number
IRB 07187

Study information

Scientific Title

Impact of Heartfulness meditation practices compared to the Gratitude practice on compassion fatigue, compassion satisfaction and burnout for nurses and allied healthcare professionals: a randomized trial

Study objectives
A 6-week virtual Heartfulness meditation program will reduce the burden of compassion fatigue and burnout for nurses and allied healthcare professionals when compared with the Gratitude practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/01/2022, Wright State University IRB (3640 Colonel Glenn Hwy, Dayton, OH 45435-0001, USA; +1 (0)937 775 4462; whitney.mcallister@wright.edu), ref: #07187

Primary study design
Interventional

Study design
Prospective randomized control study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Compassion fatigue and burnout among the nurses and allied healthcare providers

Interventions
The participants will be randomly assigned to one of the two study groups:
Group 1: Heartfulness meditation group
Group 2: Gratitude practice group

The researchers will be using an adaptive recruitment strategy with randomization at the end of recruitment with a plan to randomly assign 70% of participants to the Heartfulness meditation practice group (considering the high attrition rate in past meditation studies) and 30% to the self-motivated Gratitude practice arm. The researchers will be using a basic method of simple randomization (flipping a coin).

Participants will be asked to attend virtual trainer guided Heartfulness relaxation and meditation sessions at least four times a week for 6 weeks in Group 1. They will be asked to attend education sessions regarding the Gratitude practice once a week in Group 2. They will be asked to practice daily the techniques suggested in weekly virtual sessions. They will also be asked to self-report their adherence to the intervention in the same survey at the end of the study period.

Intervention Type
Behavioural

Primary outcome(s)

Measured at baseline and post-intervention at the end of 6 weeks, 3 months and 6 months:
1. Compassion fatigue, compassion satisfaction and burnout measured using the Professional Quality of Life Scale-5 (ProQOL-5)
2. The testimonials or descriptive answers to the open-ended qualitative questions

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
31/10/2022

Eligibility

Key inclusion criteria
1. Adults above 18 years of age willing to participate in the study
2. Nurse or an allied healthcare worker actively employed by Premier Health Network
3. Requires basic knowledge of the Internet and the ability to follow instructions regarding email communications as well as accessing video conferences

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
83

Key exclusion criteria
Individuals less than 18 years of age

Disclaimer: Any person under medical care for depression or other mental health conditions is encouraged not to participate or only participate after discussion with his/her healthcare provider so that the study participation does not interfere with current treatment.

Date of first enrolment
11/04/2022

Date of final enrolment
28/04/2022

Locations

Countries of recruitment
United States of America

Study participating centre
Wright State University
3640 Colonel Glenn Hwy
Dayton
United States of America
45435

Sponsor information

Organisation
Wright State University

ROR
https://ror.org/04qk6pt94

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be stored in a non-publicly available repository with Wright State University provided secured Proofpoint Secure Share. When the study is completed and the data have been analyzed, all code lists linking names to study numbers will be destroyed. This is expected to occur no later than 1 year. This informed consent form will be kept for 5 years after the study is complete, and then it will be destroyed. This is approved by the Wright State University IRB/ethics committee.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/06/2024	17/06/2024	Yes	No