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Assessing the impact of transcendental meditation on the mental health and well-being of UK ambulance service personnel: A single-arm study

Submission date
31/01/2024

Recruitment status
No longer recruiting

Registration date
15/02/2024

Overall study status
Completed

Last Edited
15/02/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The COVID-19 pandemic has significantly impacted the mental health of ambulance service workers, exacerbating existing stressors and leading to increased rates of depression, anxiety, and PTSD among healthcare professionals. Even before the pandemic, the UK's ambulance service faced challenges such as high sickness absence rates and burnout among staff, highlighting the need for effective interventions. Despite existing stress coping methods provided by ambulance service trusts, stress levels among ambulance staff post-pandemic continue to rise, emphasising the necessity for additional solutions.

Transcendental Meditation (TM) has emerged as a promising intervention, showing efficacy in reducing stress and improving psychological well-being across diverse populations. This study aims to assess the effectiveness of TM specifically for ambulance service workers in the UK, recognising the urgent need for interventions to support their well-being amidst ongoing challenges. Through the assessment of PTSD symptoms, perceived stress, and other mental health indicators, this research seeks to offer valuable insights into TM's potential as a practical and effective tool to address a critical gap in current support strategies for ambulance service personnel.

Who can participate?
Individuals working in various roles in the Ambulance Service were eligible to participate in the study.

What does the study involve?
Participants received instruction in Transcendental Meditation (TM) and were recommended to practice the technique twice daily, for 20 minutes each session, in the morning and evening. The TM course included a 60-minute introductory presentation, followed by 4 consecutive days of instruction lasting 90-120 minutes per session, which could be attended either in person for all sessions or as blended learning, with the first session one-to-one in person and subsequent

sessions held in small groups remotely. Remote sessions utilised a specially designed app for course materials, with participants connecting to their TM instructor via video conference for daily meditation sessions. Both in-person and remote courses provided identical content. Additionally, participants were offered individual and group follow-up sessions, available both in person and online. Participants signed a consent form and completed a baseline survey before learning TM, followed by surveys post-TM instruction at 3 weeks and 3 months. Standard self-reporting measures were used to assess post-traumatic stress disorder (PTSD) symptoms, perceived stress, anxiety, depression, insomnia, professional fulfilment including burnout and general mental health and wellbeing,

What are the possible benefits and risks of participating?
Participating in the study and learning TM offered potential benefits to reduce stress and related conditions, enhancing general health and wellbeing, and fostering daily resilience. No anticipated risks were associated with learning TM, and participants were given the option to withdraw from the practice and study at any time.

Where is the study run from?
TM instruction took place in the East of England area. The TM instruction was arranged by the David Lynch Foundation UK and the study was conducted in collaboration with the Center for Social-Emotional Health & Consciousness, Maharishi International University, USA.

When is the study starting and how long is it expected to run for?
June 2021 to March 2023. The study commenced recruitment in July 2021 and concluded in March 2023.

Who is funding the study?
Funding was provided by the David Lynch Foundation UK, with a grant from the Postcode Places Trust.

Who is the main contact?
The main contact was Deirdre Parsons the Principal Investigator,
dparsons@davidlynchfoundation.org.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Ms Deirdre Parsons

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UK Ambulance 2021-2023

Study information

Scientific Title
Evaluating the impact of transcendental meditation (TM) on reducing PTSD Symptoms and stress-related conditions among ambulance staff: A three-month intervention study

Study objectives
The hypothesis is that individuals employed in the ambulance service who regularly practise transcendental meditation (TM) for three months will show improvements in reducing stress levels and related conditions.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 02/07/2021, Maharishi International University (Maharishi University of Management Research Institute) (1000 N 4th Street, Fairfield, Iowa, 52557, United States of America; +1 3196140357; ftravis@miu.edu), ref: DLFUK2021

Study design
Single-arm multi-centre interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Charity/Voluntary sector

Study type(s)
Prevention, Quality of life, Treatment, Efficacy

Participant information sheet
https://form.jotform.com/211894520663357

Health condition(s) or problem(s) studied
Reduction in post-traumatic stress disorder (PTSD) symptoms and stress-related conditions in ambulance staff.

Interventions
This is a single-arm, multi-centre interventional study involving 60 participants from the UK ambulance service, conducted in collaboration with the David Lynch Foundation UK and the Center for Social-Emotional Health, Maharishi International University (MIU) in the USA, where participants voluntarily learned transcendental meditation (TM) and practised it twice daily for three months.

The participants, employed in various roles within the ambulance service, will learn TM and be instructed to practice it twice daily. Standard self-reporting measures will be administered online at baseline, post-TM course, three weeks, and three months. Additionally, semi-structured one-to-one interviews will be conducted via a video call with 11 participants after the three months following TM instruction. Participants receive instruction from a specialised TM instructor in small groups in four sessions over consecutive days, with options for in-person or blended learning, where the initial session is conducted in person, followed by subsequent sessions conducted remotely online using a video conference platform.

Intervention Type
Behavioural

Primary outcome measure
Post-traumatic stress disorder (PTSD) symptoms measured using a self-reporting PTSD Checklist (PCL-5) at baseline, 3 weeks and 3 months

Secondary outcome measures
The following secondary outcome measures are assessed at baseline, 3 weeks and 3 months:
1. Perceived stress using the self-reporting Perceived Stress Scale (PPS-10)
2. Depression using the self-reporting Patient Health Questionnaire (PHQ-9)
3. Anxiety using the self-reporting General Anxiety Disorder 7 scale (GAD-7)
4. The severity, and impact of insomnia using the self-reporting Insomnia Severity Index (ISI-7)
5. Mental well-being covering subjective well-being and psychological functioning using the self-reporting Warwick-Edinburgh Mental Wellbeing Scales (WEMWBS)
6. Professional Fulfilment using the self-reporting Professional Fulfilment Index (PFI-16)
7. Burnout using the self-reporting Professional Fulfilment Index i(PFI-16)

Overall study start date
01/06/2021

Completion date
27/03/2023

Eligibility

Key inclusion criteria
1. Working within the UK ambulance service
2. Adults aged over 18 years

Participant type(s)
Healthy volunteer, Health professional

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Self-reported or diagnosed unstable psychotic symptoms
2. Any prior involvement in TM instruction
3 Signed off or retired from the ambulance service

Date of first enrolment
05/07/2021

Date of final enrolment
10/10/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Missenden Abbey Adult Education College
School Grounds
Great Missenden
United Kingdom
HP16 0BD

Study participating centre

Premier Inn
Prince of Wales Road
Norwich
United Kingdom
NR1 1DX

Study participating centre
Writtle College
Lordship Road, Writtle
Chelmsford
United Kingdom
CM1 3RR

Study participating centre
Regus
8 Duncannon street
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United Kingdom
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Sponsor information

Organisation
David Lynch Foundation UK

Sponsor details
9 Garden Square
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None provided
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Sponsor type
Charity

Website
https://www.davidlynchfoundation.org.uk

Funder(s)

Funder type
Charity

Funder Name
Postcode Places Trust

Funder Name
David Lynch Foundation UK

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/05/2024

Individual participant data (IPD) sharing plan
The data sets generated during and/or analyse during the current study will be available upon request from Deirdre Parsons, Principal Investigator: dparsons@davidlynchfoundation.org.uk beginning at 9 months and ending 36 months following article publication

Documents available: Study Protocol, Informed consent form
Data will be available individual participant data meta-analysis for Investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose..
Data will be available from Investigator's proposals that have been submitted up to 36 months following article publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			15/02/2024	No	No