Project Title: Evaluating the impact of Transcendental Meditation (TM) on reducing PTSD symptoms and stress related conditions amongst ambulance staff: A single arm three-month study

Sponsor: The study will be conducted as a collaboration of David Lynch Foundation UK and the Center for Social-Emotional Health, Maharishi International University (MIU), Fairfield, USA.

Investigators:
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BACKGROUND

In March 2020, the World Health Organisation (WHO) declared the coronavirus pandemic (COVID-19), catching every sector unprepared. This crisis became a significant source of stress for mental health workers, including the ambulance service workforce (Sahebi et al., 2021, whose workload surged due to increased patient numbers and reduced personnel availability from infections and quarantine.

A survey conducted among nearly 4,000 staff and volunteers across police, fire, and ambulance services in the UK (MIND Survey, March 2021) highlighted that ambulance staff were notably affected, with 77% reporting worsened mental health since the pandemic's onset, compared to 66% for police and 65% for fire services.

Moreover, a significant prevalence of moderate depression, anxiety, and PTSD among healthcare workers was identified (Sahebi et al., 2021). A systematic review and meta-analysis during the pandemic revealed anxiety and depression rates of 24.94% and 24.83%, respectively, among healthcare workers, emphasising the urgent need for appropriate support and further research on intervention strategies (Sahebi et al., 2021).

Sickness and Absenteeism

Surveys conducted by the National Health Service (NHS) in England during the COVID-19 pandemic revealed that ambulance staff had the highest average sickness absence rate at 6.2% compared to other healthcare workers (NHS, Five Year Forward View, 2014; NHS Sickness Absence Rates, April 2021).

Further findings during the pandemic suggested that among seventy-eight ambulance service staff members, thirty-eight (48.7%) experienced personal burnout, forty-two (53.8%) experienced work-related burnout, and twenty-nine (37.1%) experienced patient-related burnout (Miller, E. 2021).

Before the emergence of COVID-19, the UK's underfunded and overstretched NHS ambulance service was already in crisis (Wankhade P, 2017). At that time, there was interest in scrutinising stress to understand its links to sickness absence. Results showed an association between work and daily (non-work-related) stress, coping styles, demographic variables (such as health conditions, overtime hours, length of service, shift pattern, age, and sex), and sickness absence. Data showed sickness absence rates ranging from 0 to 83.3% (M=8.92, SD=14.99). Work and daily stress, coping styles, overtime hours, and the presence of a health condition accounted for 17.5% of the variance in sickness absence.

Occupational Stressors and PTSD
The demanding nature of work in emergency medical services not only contributes to increased sickness absence and stress-related conditions among paramedics but also correlates with elevated rates of burnout, divorce, suicide, and substance abuse (Wagner et al., 2002; van der Ploeg and Kleber). Paramedics, as highlighted by Wankhede (2016), face acute and chronic stressors that predispose them to health issues such as cardiovascular diseases, post-traumatic disorders, sleep disturbances, and obesity.

Lawn et al. (2020) acknowledged the significant strain placed on ambulance service personnel due to the demanding nature of emergency medical response. Despite recognising the detrimental effects on mental and physical well-being, there remains limited understanding of how the specific nature of ambulance work contributes to these challenges. The authors review emphasised the critical role of organisational management in addressing the day-to-day concerns of ambulance staff, which may influence the development of conditions like PTSD, depression, and anxiety.

Research published in the British Medical Journal indicates a high prevalence of PTSD among emergency service workers, with 22% of ambulance personnel affected. Factors such as demanding work environments, lack of perceived control, and insufficient support contribute to stress levels (Holmes & Jones, 2017). Furthermore, the need for rapid decision-making in unpredictable situations exacerbates stress, with PTSD symptoms being more severe in cases of particularly distressing events (Clohessy & Ehlers, 1999). The isolated working conditions, long hours, and shift work common among paramedics compound these stressors, highlighting the significant toll on both individual well-being and organisational costs.

Prevention against Stress
Preventative measures can protect against the negative effects of stress (Ogińska-Bulik & Michalska, 2019) and have a significant impact on post-traumatic reactions in paramedics (Ogińska-Bulik & Kobylarczyk, 2015). Simmons et al. (2019) emphasised preventative methods to improve staff well-being and health status, identifying four key areas where provision for ambulance workers is needed: organisational support; informal support; use of humor; and individual coping mechanisms (Lawn et al., 2020; Clompus, S.R & Albarran J.W., 2016). The need to address this issue was further highlighted by findings showing that student paramedics should prepare for mental health challenges (Holmes & Jones, 2017).

Transcendental Meditation as an intervention
A large body of evidence suggests that TM is effective in various settings specifically in reducing stress and stress related illnesses such as symptoms of PTSD, anxiety, anger, depression, and fatigue as well as helping with sleep quality.

TM is a simple mental technique for reducing stress and is recommended to be practiced twice daily for approximately 20 minutes. The technique was first introduced in the West by Maharishi Mahesh Yogi more than 60 years ago. TM provides a meditation technique that sustains scientific assessment due to the standardised course of instruction. In addition, TM is taught by certified instructors. TM can be taught to individuals from all walks of life does not require change in belief, lifestyle, or religion. It is easily practiced while sitting in a comfortable position, the mental technique allows the mind to experience finer levels of the thinking process and to achieve a state of deep relaxation.

Research on the TM technique has shown significant reductions in psychological distress, (Nidich S., et al 2009) including significant decreased anxiety (Eppley, K. R., 1989) and depression (Sheppard, W. D., 1997) As well as an improvement in general psychological

health (Aron, A.,1981), psychological well-being and copying amongst chronically ill patients (Jayadevappa, R.,2007).

TM differs from other meditation programmes in terms of the effortlessness of the practice and how the brain functions during the practice (Travis, F., & Shear, J., 2010). When compared to focused-attention meditation, which is characterised by beta/gamma activity, open monitoring, or mindfulness, techniques that produce theta EEG waves, TM as an automatic self-transcending technique increases alpha EEG waves (Travis, F., & Shear, J. , 2010). As such, TM through the effortless use of a sound without meaning (mantra), allows the mind to settle to quieter levels of thought. TM increases alpha EEG coherence and synchrony, which provides long-range integration of distal cortical-neural groups necessary for sensory, motor, and cognitive behaviour (Elder, C., et al, 2014). In addition, meta-analyses have found that the TM technique was more effective than other meditation and relaxation techniques for reducing trait anxiety (Eppley, K. R.,1989; Sedlmeier P., 2012; Elder, C., 2014)

In a randomised controlled study, 74 military personnel were assigned to either the Transcendental Meditation (TM) treatment group or the control group to investigate the effectiveness of TM in reducing PTSD symptoms. At 1 month, 83.7% of the TM group stabilised, decreased, or ceased medications and 10.8% increased medication dosage; compared with 59.4% of controls that showed stabilisations, decreases, or cessations; and 40.5% that increased medications ($p < 0.03$). A similar pattern was observed after 2 ($p < 0.27$), 3 ($p < 0.002$), and 6 months ($p < 0.34$). Notably, there was a 20.5% difference between groups in severity of psychological symptoms after 6 months, that is, the control group experienced an increase in symptom severity compared with the group practicing TM (Barnes, V. et al 2016).

To illustrate that TM was effective in reducing employee stress, depression, and burnout. A RCT was conducted with 40 secondary schoolteachers and support staff at a therapeutic school for children with behavioural problems. The participants were randomly assigned to either practice of the Transcendental Meditation programme or a wait-list control group. Outcome measures were assessed at baseline and at four months, and included perceived stress, depression, and burnout. Analysis of the 4-month intervention data indicated a significant improvement in the main outcomes of the study resulting from practice of the Transcendental Meditation programme compared with controls (Wilks Λ [3,28] = 0.695; p = 0.019). Results of univariate F tests indicated a significant reduction of all main outcome measures: perceived stress (F[1,32] = 13.42; p = < 0.001); depression (F[1,32] = 6.92; p = 0.013); and overall teacher burnout (F[1,32] = 6.18; p = 0.018). Effect sizes ranged from 0.40 to 0.94 (Elder, C. et al 2014).

Rational

This study will be the first to assess the effectiveness of Transcendental Meditation (TM) for ambulance service workers in the UK. Historically, occupational stress and PTSD symptoms have been significant concerns for emergency service workers. However, the demanding pressures of work, lack of resources, and the need for effective coping strategies during the Covid-19 pandemic have exacerbated these issues, creating a more pressing problem for ambulance service trusts to ensure the well-being of their staff.

Research has demonstrated that ambulance service staff experienced heightened levels of stress, PTSD symptoms, increased sickness and absenteeism, anxiety, depression, and sleep disturbances during the Covid-19 pandemic. Yet, even before the pandemic, there was a recognised need to improve staff mental health and well-being and reduce instances of work-related burnout, indicating that excessive stress levels will persist beyond the pandemic recovery.

While ambulance service trusts currently provide stress coping methods to their employees, it is evident that stress among ambulance staff continues to rise, highlighting the need for further solutions. Consequently, this study aims to investigate TM as a potential technique to enhance ambulance service staff well-being and build resilience to prevent burnout.

Research aim and objectives
The study hypothesises that ambulance service staff who regularly practice TM for at least 12 weeks will demonstrate an improvement in reducing both stress and stress-related conditions.

The primary objective of this study is to assess the effectiveness of TM in demonstrating significant reductions in PTSD symptoms. Additionally, it aims to evaluate whether TM has decreased stress-related symptoms such as depression, burnout, and anxiety, while also examining its impact on professional fulfilment, sleep quality, and general mental health and wellbeing.

Semi-structured interviews will offer additional insights into key stressors, aiming to ascertain participants' experience of practising TM, the practicality of daily TM practice, and benefits of the technique for their personal and professional lives. Also, whether it has contributed to better stress management and alleviation of stress-related conditions. Furthermore, to find out more about other techniques that they are using for managing and coping with stress.

STUDY DESIGN
The single arm study will recruit 60 ambulance service staff in England to trial Transcendental Meditation (TM). The participants will receive instruction in the TM technique in small groups at times convenient for both themselves and their TM instructor. After the first session of the TM instruction the participants will be recommended to practice TM twice a day at home. Participants will complete a battery of online surveys prior to TM instruction and post TM instruction at three weeks and three months.

Duration of the study
The end of study is the point at which all the study data has been collected. The study is expected to be completed in 18 months when all participants will have learned TM and have had three months practice and completed all their surveys. On completion of the study a small sample of participants will be invited to be interviewed about their experience of TM practice.

Participants
A total of 60 participants will be recruited for the study. Participants in this study will be employees from a group of ambulance stations providing a service to approximately 6,2 million people. The participants have volunteered to be part of the evaluation and are learning in their own time outside of work. Funding has been granted by the Postcode and Places Trust, UK to finance 60 participants to learn Transcendental Meditation. Participants will be taught TM on a first-come, first-served basis in their local area. Their participation in the study will last for three months.

Eligible participants will be offered an Amazon Gift voucher as an incentive to attend the online semi-structure interviews for the qualitative aspect of the study upon its completion.

Inclusion criteria: All participants will be adult ambulance service staff, both male and female, engaged in both emergency and non-emergency roles. This includes staff who have been 'signed off' due to sickness from frontline medical duties but continue working in supportive roles within the ambulance service.

Exclusion criteria: Self-reporting unstable psychotic symptoms; and any previous participation in learning TM. Those who have been signed off work due to sickness and are not working in any capacity for the ambulance service.

Prior to learning TM, the purpose of the evaluation and participant's contribution to the study will be explained. All participants will complete written informed consent prior to baseline testing. If at any stage a participant requests to be withdrawn from the study, they will be encouraged to continue with their TM practice and to remain in contact with their local TM teacher and attend any TM meetings.

Recruitment:
Men and women, employed by the ambulance service will be recruited from all service areas within the East of England area. The study and the opportunity to learn TM will be promoted internally through the internal newsletter, social media, and posters at ambulance stations. A member of the ambulance station, who had previously learned TM, has offered to be instrumental in promoting the study to her colleagues and encourage the management team for further recommendations.

Those who are interested in participating will respond to the DLF UK and will be given a further explanation of the study and the TM programme. Following this initial phase of recruitment individuals will be invited to attend a TM presentation to describe the course of instruction, the benefits of the TM technique, previous scientific research, and the proposed research study

METHODOLOGY
Statistical Methods:
A within group analysis will be performed with IBM SPSS (V 28.01) using paired samples t-test, with the independent variable being the treatment TM. The primary outcome will be to determine the reduction of PTSD symptoms using the PTSD Checklist (PCL-5). Secondary outcomes will measure perceived stress, anxiety, depression, insomnia, burnout, general mental health and wellbeing and professional fulfilment. Self-reporting measures to be used for secondary outcomes: Warwick-Edinburgh Mental Wellbeing Scale (14-item); Patient Health Questionnaire (9 items); Perceived Stress Scale (10 items)). General Anxiety Disorder (7 items); Insomnia Severity Index (7 items); Professional Fulfilment Index (16-items)

Qualitative data:
Quantitative data will be drawn from interviews with eligible participants who have completed the TM course of instruction and submitted surveys at all time points will be selected for interviews.

Interviews will be conducted one-to-one over a video conference platform, with interviewees asked semi-structured questions lasting approximately 30-40 minutes. Participants will be encouraged to share their experiences openly to provide further insight into assessing TM as an intervention.

The interviews will be recorded and transcribed after the sessions. Subsequently, the transcripts will undergo analysis to identify major themes related to issues prior to learning TM and the benefits derived from TM practice.

Intervention:
The TM technique will be taught in a standardised course by four or more certified TM instructors with extensive teaching experience. Learning the TM technique will involve seven

steps, beginning with a TM introductory and preparatory presentation (60 minutes), followed by a personal meeting with the TM instructor (5-10 minutes), and four sessions over consecutive days (60-90 minutes per session). Participants will have the option of completing the TM course with either a blended "in person and at home" learning approach or attending all sessions in person with the TM instructor. After the first session, participants will be encouraged to practice TM twice a day for 20 minutes at home or at work.

The in-person course will require attendance at all four sessions. The first session will be one-to-one with the TM instructor and the participant, followed by subsequent sessions held individually or in small groups.

The at-home learning instruction will be an interactive digital course consisting of videos and Q&As, accessible via a custom-designed 'TM app' on their smartphone or tablet. During the days of remote learning, participants will also be required to connect to daily meditation 'check-in' sessions individually or in small groups, conducted online via video conferencing lasting about 20-30 minutes, with their TM instructor.

Due to the shift patterns of ambulance service staff, it is anticipated that most participants will choose the at-home and in-person course of instruction.

Follow-up individual and group sessions will be offered after the TM instruction period via video conference and in person. These sessions provide an opportunity to review and discuss experiences of TM practice.

The first follow-up session will be offered approximately 10 days after TM instruction and thereafter, every month for at least three months, with an option to continue beyond this period.

Participants will also be invited to join a TM Facebook group where they can read comments from other meditators, access further knowledge and Q&As on TM, and receive information on TM events around the country. Additionally, participants will be encouraged to join daily morning and afternoon phone-in meditation sessions.

Compliance with the instruction and follow-up sessions will be encouraged through regular communication with their personal TM instructor.

Study Settings
The in-person sessions will be conducted at multiple centres and held in participants' local TM centres or rented premises. Participants will have the flexibility to choose the most convenient location for them.

Outcome measures:
The following measures will be employed:

Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) - WEMWBS is a 14-item scale of mental well-being covering subjective well-being and psychological functioning. All items are positively worded to cover key aspects of psychological functioning including, optimism, autonomy, agency, curiosity, clarity of thought and positive relationships. In addition, to test the effects on confidence, feeling relaxed, cheerful, and having the energy to spare. The scale is scored by summing responses to each item answered on a 1 to 5 Likert scale.

WEMWBS has shown to be responsive to changes occurring in a wide range of mental health interventions undertaken in different populations to provide a secure base for research and development (Maheswaran H, et al 2012). WEMWBS was validated on a

student and representative population sample and showed a good content validity, assessed by reviewing the frequency of complete responses and the distribution of responses to each item. Confirmatory factor analysis was used to test the hypothesis that the scale measured a single construct. Internal consistency was assessed using Cronbach's alpha to score of 0.89 (student sample) and 0.91 (population sample) which suggests some item redundancy in the scale. However, results showed WEMWBS to have high correlations with other mental health and well-being scales and lower correlations with scales measuring overall health. Test-retest reliability was confirmed to be high (0.83) after one week using intra-class correlation coefficient. Susceptibility to bias was measured using the Balanced Inventory of Desired Responding and indicated it was lower or, similar to that of comparable scales (Tennant, R et al 2007).

Patient Health Questionnaire (PHQ**)** 9 items - is a reliable self reporting scale to monitor the severity of depression and response to treatment. (Kroenke K et al 2001). PHQ-9 scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe, and severe depression reflecting over a two-week period. PHQ-9 has shown to be 61% sensitivity and 94% specificity in adults. To assess the scales validity in a primary care setting the PHQ-9 was completed by 6,000 patients in 8 primary care clinics and 7 obstetrics-gynaecology clinics. Construct validity was assessed using the 20-item Short-Form General Health Survey, self-reported sick days and clinic visits, and symptom-related difficulty. The internal reliability of the PHQ-9 was excellent, with a Cronbach's α of 0.89 in the PHQ Primary Care Study and 0.86 in the PHQ Ob-Gyn Study. Test-retest reliability of the PHQ-9 proved to be excellent (Kroenke, K et al 2001).

Perceived Stress Scale (PPS-10) - evaluates the perception of participant's stress over a one-month period (Cohen et al 1983). The self -reporting outcome measure is to assess the stressfulness of situations, including how the individual has perceived life as unpredictable uncontrollable and overloading. A total score ranging from 0 to 40 is computed by reverse scoring the four positively worded items and then summing all the scale items. Higher scores indicate greater levels of perceived stress.

Originally constructed by Cohen et al (1983) and updated by Cohen and Williamson (1988) the scales demonstrated adequate internal consistency reliability (α = .78). In more recent tests PSS-10 have confirmed good internal consistency reliability (Reis et al., 2010) Reliability coefficients, using Cronbach's alpha, ranged from .86 to .9 (Golden-Kreutz, D.M, et al, 2004).

General Anxiety Disorder 7 (GAD-7): is a self-reporting tool for screening and assessing the severity of generalised anxiety disorder as outlined by the *Diagnostic and Statistical Manual of Mental Disorders – Fourth Edition – Text Revision* (DSM-IV-TR; (American Psychiatric Association [APA], 2000). Each item asks the individual to rate the severity of his or her symptoms over the past two weeks on a four-point scale ranging from (0) *Not at All* to (3) *Nearly Every Day*. Total scores range from 0 to 21, with higher scores indicating greater severity of anxiety (Swinson R.P, 2006).

The effectiveness and reliability of GAD-7 was examined in a sample of 232 patients enrolled in a partial hospital programme for before and after treatment, GAD-7 demonstrated good sensitivity (.83), specificity was poor (.46) in identifying patients with GAD (Kertz S, et al 2013). Finding also suggest it performs moderately well at detecting three other common anxiety disorders, including panic disorder (sensitivity 74%, specificity 81%), social anxiety disorder (sensitivity 72%, specificity 80%), and post-traumatic stress disorder (sensitivity 66%, specificity 81%) (Splitzer R, et al 2006).

Insomnia Severity Index (ISI-7): Designed to assess the nature, severity, and impact of insomnia and monitor treatment response. The ISI is a 7-item self-report questionnaire reporting over the last month on severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A 5-point Likert scale is used to rate each item ranging from 0 = no problem to 4 = very severe problem. Evaluation of the ISI 7 found internal consistency was excellent (Cronbach α of 0.90 and 0.91) for two sample populations. Furthermore, convergent validity was supported by significant correlations between total ISI score and measures of fatigue, quality of life, anxiety, and depression (Morin C., et al 2011).

PTSD Checklist (PCL-5): The PCL-5 is a 20-item self-report measure that assesses the 20 Diagnostic and Statistical Manual of Mental Disorders (*DSM-5* symptoms of PTSD) (Weathers et al., 2013). Measurements highlight exposure to Trauma and Stressor-Related Disorders (US department of Veteran Affairs) threefold: Monitoring symptom change during and after treatment; Screening individuals for PTSD; Making a provisional PTSD diagnosis.

Psychometric properties of the PCL-5 were examined in studies involving trauma-exposed college students where PCL-5 scores exhibited strong internal consistency (α = .94), test-retest reliability (r = .82), and convergent (rs = .74 to .85) and discriminant (rs = .31 to .60) validity. Results indicate that the PCL-5 is a psychometrically sound measure of PTSD symptoms (Blevins, C. A., et al 2015).

Professional Fulfilment Index a 16-item instrument to measure professional fulfilment, and two dimensions of burnout: work exhaustion (4 items) and interpersonal disengagement (4 items) (Trockel M., et al 2018). Each PFI item is scored **from** 0 (not at all true) to 4 (completely true). The professional fulfilment scale assesses the degree of positive rewards the individual derives from his or her work, including happiness, meaningfulness, contribution, self-worth, satisfaction, and feeling in control when dealing with difficult problems at work. Used to measure physician burnout (Trockel, M., et al 2018), the PFI has indicated is a suitable tool for assessing well-being pre- and post-intervention efforts to prevent burnout. PFI has also demonstrated good internal consistency and test-retest reliability. The index have also found to be relevant to health professionals, short and easy to use, suitable for assessment of changes concerning interventions, and include a focus on positive aspects such as professional fulfilment, as well as negative aspects, i.e. burnout.. The PFI correlates well with other widely used measurement tools (Trockel, M., et al 2018).

Outcome Measures	**Baseline**	**Post treatment – 2 weeks**	**Post treatment - 3 months**
Warwick Wellbeing Scale	X	X	X
Patient Health Questionnaire	X	X	X
Perceived Stress Scale	X	X	X
General Anxiety Disorder	X	X	X
Insomnia Severity Index	X	X	X
PTSD Checklist	X	X	X
Professional Fulfilment Index	X	X	X
Semi-structured interviews			X

Procedures
Staff will be asked to register their interest and select from a list of convenient dates to attend a group online video TM introductory presentation given by the TM teachers. At this time the research team will explain the study protocol. Following the introductory presentation, if the attendee selects to learn TM then the TM teacher will meet individually with each attendee online to assess their eligibility to learn TM and participate in the study. Subsequently, a choice of starting dates and location of their TM instruction will be offered to the participants.

Prior to learning TM, each participant will be emailed a weblink to complete the consent form, a release form for DLF UK to use quotes, video recordings, and photography of TM experiences for future promotion. The participants will also be emailed a link to complete the online survey for baseline testing. Later, the participates will be emailed a link to access the second survey at 3 weeks, and 3 months after instruction.

Data will be collected online through seven standard survey measurements. The survey will take about 15 minutes in total to complete. For research analysis the participants will maintain anonymity when completing the online surveys by using coded data.

The software platform, *Jotform,* will be used for encryption of all data. To comply with General Data Protection Regulations (GDPR), the linking of codes to participants names will be restricted to the research assistant only. Any personal details of participants will be destroyed on competition of the research.

After the initial three-month period of TM practice, eligible participants will be invited for a 30–40 minute, one-to-one online semi structured interview to evaluate their experience of learning and practicing TM and any benefits. Participants for the interviews will be selected to represent different types of employment within the ambulance service,

As part of the TM instruction the individuals will be asked by their TM teacher to complete evaluation forms relating to their experience of TM. This is a process independent of the study and any information is held confidentially by their personal TM teacher.

ETHICAL AND REGULATORY CONSIDERATIONS

Assessment and management of risk
The study is considered to be low risk. The study involves instruction in Transcendental Meditation, self-reporting online surveys and with some participants an online one-to-one interview (which lasts approximately 30-40 minutes) regarding their experiences and opinions of Transcendental Meditation. The study involves the personal experiences of the ambulance staff and does not involve NHS patients. It does not involve substances being administered to participants, nor will it involve invasive, intrusive, or potentially harmful procedures of any kind. Blood or tissue samples will not be obtained from participants. Study participants will not be vulnerable or unable to give informed consent (e.g., children or people with learning disabilities). The study is not likely to induce psychological stress or anxiety, or cause harm or negative consequences beyond that experienced in the participants' everyday lives.

If potential malpractice is reported by a participant during the study, the participants will be asked to contact the Chief Investigator. Contact details for complaints and malpractice will be given at the time of signing the consent form.

Follow-up post study:
Participants will be offered complimentary regular group and personal "meditation check-ups" and knowledge meetings for up to 6 months post-course completion. These sessions will be available remotely or in-person through their local TM centres or TM teachers. The aim is to ensure that participants find their TM practice easy and enjoyable while gaining the full benefits.

Additionally, participants will be encouraged to access the TM Community app, which offers a wealth of resources including a library of videos on various aspects of TM and the development of consciousness. This app is regularly updated to provide fresh insights and offers information on local and national events and courses, further supporting and enhancing participants' TM practice.

Expected outcomes
Reduction in PTSD Symptoms: Participants who regularly practice Transcendental Meditation (TM) are expected to demonstrate significant reductions in symptoms of Post-Traumatic Stress Disorder (PTSD), as measured by standard scales.

Decrease in Stress-related Symptoms: The study anticipates observing a decrease in stress-related symptoms such as sleep issues, depression, burnout, and anxiety among participants who engage in TM practice.

Improvements in Professional Fulfillment: With the reduction of stress and other stress-related conditions, TM practice is hypothesised to lead to improvements in greater job satisfaction among ambulance service personnel.

Enhanced Sleep Quality: It is expected that TM practitioners will experience improvements in sleep quality, as regular TM practice has been shown to reduce stress, which can positively impact sleep patterns.

Positive Mental Health and Wellbeing: The quantitative and qualitative aspect of the study anticipates improvements in general mental health and wellbeing among TM practitioners.

By investigating these outcomes, the study seeks to provide valuable insights into the potential effectiveness of TM as an intervention for improving the mental health and wellbeing of ambulance service personnel over a three-month period, ultimately informing future interventions and support strategies in this high-stress profession.

Problems anticipated:
Recruitment Difficulty: It may be challenging to recruit a sufficient number of participants from the ambulance service personnel due to their demanding schedules and concerns about time commitment.

Participant Retention and compliance: Maintaining participant engagement and adherence to the TM practice throughout the study period may be difficult. Ambulance service personnel often face high levels of stress and may struggle to prioritise participation in the study amidst their demanding work responsibilities.

Time and attention:
Although TM is taught as a standardised course with a set number of follow up sessions the study will rely on the TM centres/instructors to know if the participants attended all the TM instruction and follow-up sessions.

Seasonal effects:

Considering the seasonal effects, possible confounds will be diminished by offering a choice of several TM courses throughout 12 months.

Experimenter bias quantitative interviews:
While confounds will be minimised in the quantitative research using anonymous self-repeating measures, in the qualitative interviews, interviewees will not be linked to their quantitative results to prevent bias. Additionally, to prevent participants from providing expected responses, the interviewer will read a statement before each interview to encourage truthful, objective answers and will ask semi-structured questions to allow participants to share their personal experiences openly.

Statistical analysis:
The study will not include randomisation or a control group. To address this, analysis will be employed alongside paired T-tests to assess the effects of TM as the single treatment on the dependent variables. Standard measures will be utilised to prevent ceiling or floor effects, enabling differentiation between increases or reductions in participants' conditions related to mental health, stress, anxiety, depression, PTSD symptoms, insomnia, professional fulfilment, and burnout.

Other treatments:
For this study, participants are not required to adjust their usual habits -- participants will not be required to discontinue other treatments or coping strategies during the 3-month testing period, such as exercise, prescribed medications, counselling, or other meditation or relaxation techniques. This could potentially demonstrate the effectiveness of TM working alongside other techniques and does not necessitate a change in lifestyle.

Informed Consent:
The participants must personally sign and date the online version of the Informed Consent form before they participate in the study (https://form.jotform.com/211894520663357)

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants at the time of the TM introductory talk. This will include details detailing of the study; what it will involve for the participant; the implications and constraints of the protocol; the known side effects and any risks involved in taking part.

It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

The participant will be allowed as much time as wished to consider the information, and the opportunity to question the Investigator, to decide whether they will participate in the study.

The person who obtained the consent will have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent will be available to the participant online. The original signed form will be retained by the research team.

Early Discontinuation/Withdrawal of Participants
Participants may choose to stop TM practice/ or decide not to continue to be part of the study. Participants may also withdraw their consent and withdraw from the study completely. In the case of withdrawal from both TM and active follow up the following options will be available.

1) Participants may withdraw from active follow-up and further communication but allow the research team to continue to access data already collected.

2) Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

3) Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal where the data and samples already collected would not be used in the final study analysis.).

Research Ethics Committee (REC) and other Regulatory review & reports
This study involves recruiting and collecting data from ambulance staff on their personal experiences and does not involve recruiting and collecting data from NHS patients. Therefore, the study does not need NHS REC approval.

Prior to study commencement, ethical approval will be sought from the Maharshi International University Research Ethics Approval Committee for the study protocol and all other study documents (e.g., data collection tools).

Regulatory Review & Compliance
Before participants are recruited into the study, the Chief Investigator will ensure that consent forms are in place. (Online consent form: https://form.jotform.com/211894520663357)

For any amendment to the study, the Chief Investigator, in agreement with the sponsor, will submit information to the appropriate body for them to issue approval for the amendments.

Protocol compliance
Accidental protocol deviations will be adequately documented and reported to the Chief Investigator and Sponsor immediately.

Data protection and patient confidentiality
All investigators will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing, and disclosure of personal information and will uphold the Act's core principles.

All data which we will collect from our participants will be stored securely and confidentially (by 'data', we mean the recording of participants' consenting to take part, the recording of their interviews, and a form which will be used to record participants' background information such as their age and gender). Identifiable data will not be shared outside of the research team.

Online interviews will be audio-recorded and transcribed word for word. The consent process will also be recorded, at the beginning of the participants' interview. Once an interview has been conducted, the consent recording and the interview recording will immediately be uploaded to the David Lynch Foundation UK data storage platform, in a protected folder which is only accessible by the research team. The recordings will then be deleted from the recording device. Consent recordings will be retained for at least 5 years following completion of the study,

All participants will be allocated a unique identification number, and their data will be labelled with their unique number instead of their name. A spreadsheet (Excel document) which links participants' unique ID number and their name will be kept separate from their study data. This will be stored on a password-protected secure server which is only accessible by the research team.

All personally identifiable information will be removed during transcription (e.g., names, places of work). This will ensure that the data is anonymous.

Identifiable data will not be shared outside of the research team, and the data custodian will be the research. Team. Data will be stored and archived in the David Lynch Foundation UK's secure managed data storage platform. aper copies of data will be locked in a filing cabinet which is only accessible to the research team. Electronic data will be stored on a password-protected server, which is also only accessible to the research team.

Participants' contact details will be stored separately from their interview data,and contact details will be destroyed securely at the end of the project. Electronic documents will be deleted, and paper documents will be shredded.

At the end of the study participants will be given the option of receiving the results of the study once they become available. If they agree to this, they will be made aware that this will involve the research team retaining their preferred contact details until the results have been disseminated. They will also be informed that, as per the study period, their contact details will be kept securely by the David Lynch Foundation UK and will only be accessible to the research team. Their contact details only will be kept securely with each participant's TM instructor for the purpose to arrange further follow-up meditation sessions after completion of the study.

Indemnity
TM instructors involved in the research hold their own Professional Indemnity insurance to cover their legal liability whilst instructing their clients and the participants.in this research.

The David Lynch Foundation UK holds Charity and Community insurance to cover the legal liability of their work engaged in their activities which includes public and products, employers' liability and professional indemnity.

Dissemination policy

The data arising from the study will be owned by the David Lynch Foundation UK. On completion of the study, the data will be analysed, and a final study report prepared. The anonymised data will be archived with the David Lynch Foundation UK. A data access statement will be included in the publication of the study.

All participants who take part in the study will be asked if they would like to receive the publication of the study, when it becomes available. Those participants who express a desire to see the publication will be sent a copy via email or post (whichever they prefer).

Authorship eligibility guidelines and any intended use of professional writers

The following individuals will be granted authorship on the final study report:

Deirdre Parsons MSc, Executive Director, David Lynch Foundation UK
Sandy Nidich Phd, Professor, Physiology and Health, and Education
Director, Center for Social-Emotional Health & Consciousness, Maharishi International University, Iowa, USA

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