University of Westminster

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The blue text is for information and guidance only. Any sections not relevant please delete.

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SHORT TITLE/ACRONYM

PSRP Protocol template 2.0 130422

FULL/LONG TITLE OF THE STUDY
RESTORING RESILIENCE: A TRIAL OF MEDITATION TO REDUCE DISTRESS AND ABSENTEEISM IN AMBULANCE WORKERS

SHORT STUDY TITLE / ACRONYM
AMBTM

RESEARCH REFERENCE NUMBERS

STUDY REGISTRY NUMBER AND DATE

PROTOCOL VERSION NUMBER AND DATE

OTHER RESEARCH REFERENCE NUMBERS

SPONSOR / CO-SPONSORS / JOINT-SPONSORS Univ of Westminster FULL/LONG TITLE OF THE STUDY
RESTORING RESILIENCE: A TRIAL OF MEDITATION TO REDUCE DISTRESS AND ABSENTEEISM IN AMBULANCE WORKERS

SHORT STUDY TITLE / ACRONYM
AMBTM

PROTOCOL VERSION NUMBER AND DATE: 0.5 16/12/26

RESEARCH REFERENCE NUMBERS

IRAS Number: 357646

ISRCTN Number / Clinical Studys.gov Number: n/a

SHORT TITLE/ACRONYM

SPONSORS Number: Generated by the Sponsor. Enter if applicable

FUNDERS Number: Generated by the funder. Enter if applicable

SHORT TITLE/ACRONYM

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the national guidelines for the conduct of clinical research.
I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.
I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:

Date:
16/02/2026

Name (please print):
Muriel Swijghuisen Reigersberg
Position: Head of Research & Knowledge Exchange Office **Chief Investigator:**

Signature:

Date:
11/06/2025

.
Name: (please print):
Veruska Oppedisano
Position: Reader of Economics, University of Westminster

Statistician:
Signature:

Name: (please print):
Gabriella Conti

Position: Professor of Economics, University College London

SHORT TITLE/ACRONYM

KEY STUDY CONTACTS

Insert full details of the key study contacts including the following

Chief Investigator	Veruska Oppedisano 07865669760 v.oppedisano@westminster.ac.uk
Study Co-ordinator, if appropriate	na
Sponsor	University of Westminster
Joint-sponsor(s)/co-sponsor(s), if relevant	na
Funder(s)	David Lynch Foundation UK British Academy, if grant awarded Contact: Deirdre Parsons Executive Director, David Lynch Foundation UK dparsons@davidlynchfoundation.org.uk 07711311616
Clinical Trial Unit, if using	Full contact details including phone, email and fax numbers (If applicable)
Key Protocol Contributors	Full contact details including phone, email and fax numbers (If applicable) For example: imaging lead, pathology lead.
Statistician	Prof Gabriella Conti 07768288756 Gabriella.conti@ucl.ac.uk
Committees (if applicable)	Full contact details including phone, email and fax numbers

i. LIST of CONTENTS

ii. LIST OF ABBREVIATIONS Define all unusual or 'technical' terms related to the Study. Add or delete as appropriate to your Study. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
CRF	Case Report Form
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
ICF	Informed Consent Form
ICH	International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use.
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Studys Number
NHS R&D	National Health Service Research & Development
PI	Principal Investigator

SHORT TITLE/ACRONYM

PIC	Participant Identification Centre
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
SMG	Study Management Group
SSC	Study Steering Committee

iii. STUDY SUMMARY

Study Title	Restoring Resilience: A Trial of Meditation to Reduce Distress and Absenteeism in Ambulance Workers	
Internal ref. no. (or short title)	AMBTM	
Clinical Phase, if relevant		
Study Design	Randomised Control Trial	
Study Participants	Ambulance workers from the London Ambulance Service NHS Trust (LAmb), the Yorkshire Ambulance Service NHS Trust (YAS), the South East Coast Ambulance Service NHS Trust (SECAmb) and the West Midlands Ambulance Service (WMAS)	
Planned Sample Size	350	
Intervention duration	9 months	
Follow up duration	9 months	
Planned Study Period	9 months	
	Objectives	Outcome Measures

Primary	Stress-related absence reduction Stress reduction	Stress-related absences, assessed through twice monthly self-report. Psychological distress, assessed through the General Health Questionnaire (GHQ-12) scale.
Secondary	PTSD, Professional fulfilment, Insomnia, Turnover intention, Health related quality of life	PTSD symptoms, assessed through the Post-traumatic Checklist for DSM-5. Professional fulfilment, including burnout, assessed through the Professional Fulfilment Index. Insomnia, assessed with the Insomnia Severity Index (ISI); Turnover intention, assessed through the Turnover Intention Scale. Health related quality of life, measured through the standardised EuroQol-5 Dimensions-5 Levels scale (EQ-5D-5L).

iv. FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
David Lynch Foundation UK	Delivery of the intervention and financial compensation for TM teachers
British Academy	Incentive to participants in the form of £30 to each participant, if funds secured

v. ROLE OF STUDY SPONSOR AND FUNDER

The study sponsor is the University of Westminster, which assumes overall responsibility for the initiation, management, and conduct of the study in accordance with Good Clinical Practice (GCP) and institutional policies. The sponsor will provide governance oversight, ensure regulatory and ethical compliance, and monitor adherence to approved protocols.

The funder, the David Lynch Foundation UK, will deliver the intervention (Transcendental Meditation instruction) and provide financial support for teacher compensation and delivery costs. The British Academy, if funding is secured, will contribute participant incentives.

Neither the sponsor nor the funders will have any role in data collection, statistical analysis, or interpretation of results. The sponsor will oversee data management and ensure that the Chief Investigator retains full academic independence in the preparation of publications and dissemination of study findings. Final decisions regarding study design, data interpretation, and publication will rest with the Chief Investigator.

vi. ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS. If required

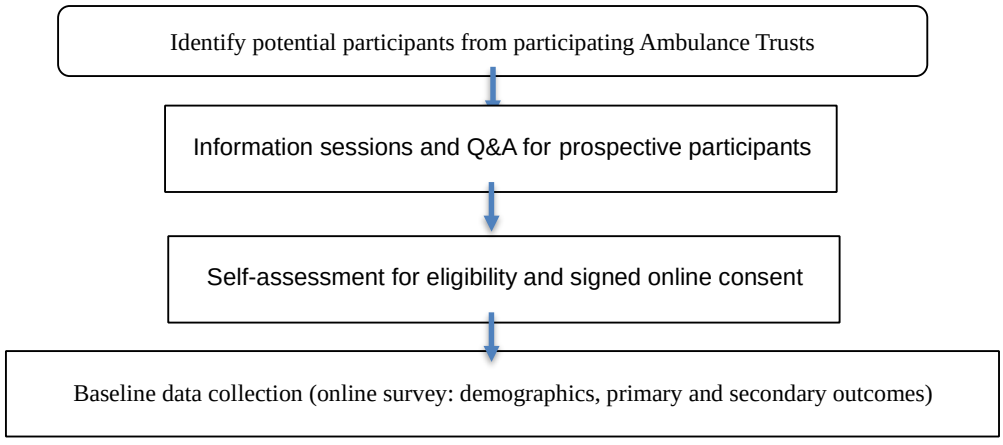
n/a

vii. Protocol contributors

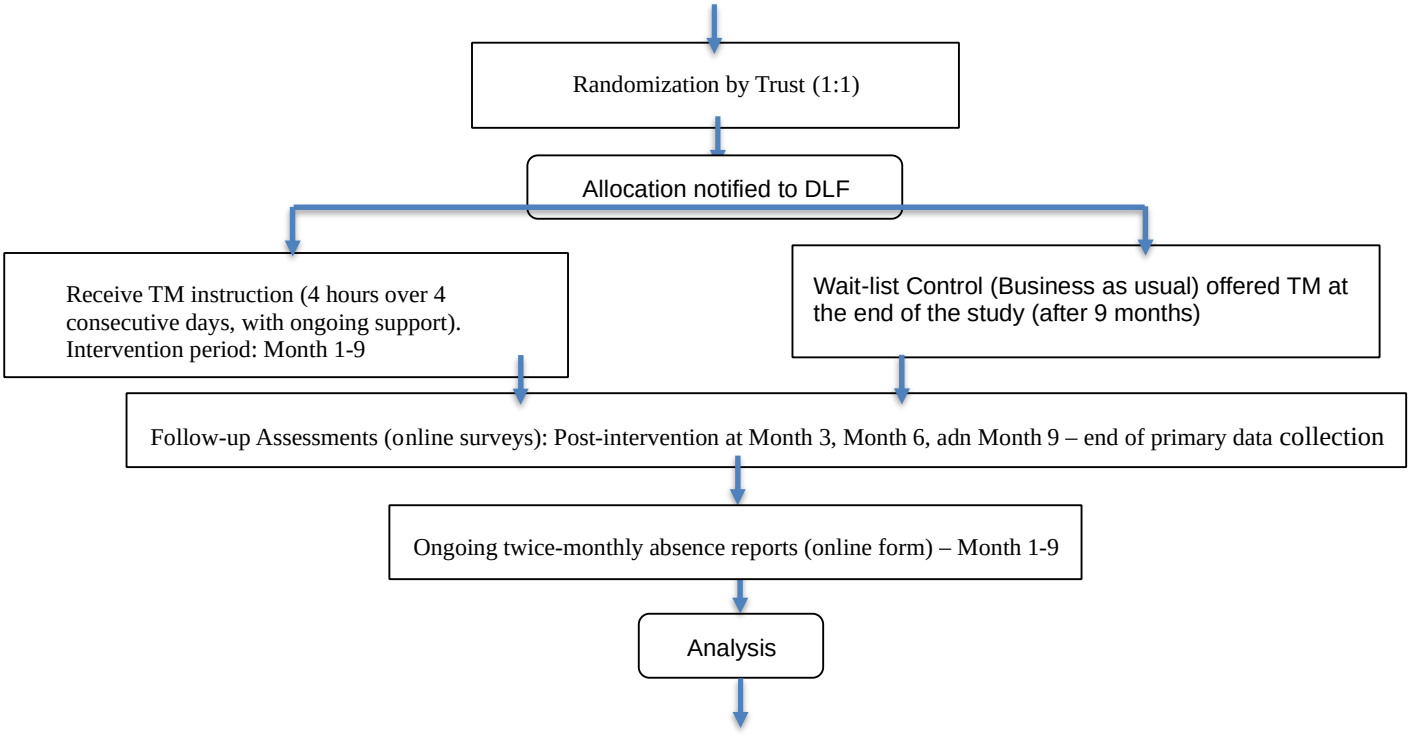
Veruska Oppedisano was the main contributor to the protocol, with Gabriella Conti providing input as the statistician.

viii. KEY WORDS: Meditation, Ambulance Workers Distress, Ambulance Workers Absenteeism

ix. STUDY FLOW CHART



SHORT TITLE/ACRONYM



1 BACKGROUND

Ambulance service staff face unique occupational stressors that place them at elevated risk of psychological distress, burnout, and mental health-related sickness absence. NHS data consistently show that ambulance personnel report the highest sickness absence rates among staff groups, with mental health conditions, particularly anxiety, stress, and depression, being the primary drivers. The intervention we propose is to give ambulance workers access to the Transcendental Meditation technique, a simple practice performed for 20 minutes twice daily. TM has shown promise in reducing stress and burnout among healthcare professionals, although the quality of evidence varies. Evidence from a randomised controlled trial (RCT) at Duke University Medical Center in Durham, North Carolina, has demonstrated significant reductions in psychological distress, anxiety, and insomnia among healthcare workers (Joshi et al., 2022). An RCT by Nestor et al. (2023) at three South Florida hospitals found that healthcare providers practising TM during the COVID-19 pandemic experienced substantial reductions in depression, anxiety, insomnia, and emotional exhaustion compared to a nonintervention control group. Improvements were observed within two weeks and sustained over three months. Additional non-experimental studies and qualitative evaluations support these findings, highlighting enhancements in emotional regulation, work–life balance, and mental wellbeing among physicians and nurses (Loiselle et al., 2023; Calarco and Stratton, 2023; Bonamer et al., 2024). A UK-based study reported that ambulance workers practising TM experienced over a 50 percent reduction in psychological symptoms within three months (Parsons, 2024). In terms of feasibility, studies indicate high acceptability and uptake among emergency clinicians and nursing students, who report benefits in stress management, focus, resilience, and self-care (Azizoddin et al., 2021; Aquino-Russell et al., 2023; Bonamer and Aquino-Russell, 2019).

As is often the case in emerging fields, existing studies vary in methodological rigour and are rarely tailored to the context of British workers; notably, none assess the impact of meditation on sickness absence, limiting their relevance for policy. This study seeks to address these gaps by rigorously estimating the causal effects of Transcendental Meditation on a broad range of outcomes among UKbased ambulance personnel.

The study will recruit 350 frontline staff and call handlers from London, Yorkshire, South East Coast and West Midlands NHS Ambulance Services Trusts.

2 RATIONALE

Ambulance services in the UK are experiencing critical challenges related to workforce health and sustainability. High levels of absenteeism due to stress and mental health issues are placing significant strain on staffing capacity, operational performance, and patient care. These pressures not only affect staff morale but also undermine the resilience of the wider healthcare system. The health and well-being of ambulance staff have therefore become a national concern.

Persistent shortages in the paramedic workforce—exacerbated by high attrition rates and vacancies (with up to one-third of posts unfilled in some regions as of 2017; Public Health England, 2017)—are linked to the increasing demands and pressures of frontline emergency care (Health Education England, 2019). In addition to their exposure to traumatic events, ambulance staff face operational stressors including unpredictable shift patterns, long driving hours, and limited recovery time between calls. These working conditions contribute to chronic stress and mental health difficulties such as burnout, anxiety, depression, and PTSD.

While these risks are well recognised, there has been insufficient progress in identifying and implementing effective, evidence-based strategies to prevent or manage stress in ambulance services. Ambulance organisations are not currently meeting recommended standards for workforce well-being (Health Education England, 2019), and there is a lack of coordinated, scalable interventions that address both individual and organisational needs. A further barrier is the stigma surrounding mental health in the sector, which discourages staff from seeking support (Lawn et al., 2020). The sustainability of the NHS depends on its ability to retain a healthy, motivated workforce, and supporting staff well-being is a core commitment of the NHS People Plan (NHS England, 2019). There is an urgent need for rigorous, policy-relevant research that evaluates the effectiveness of interventions designed to reduce psychological distress and promote resilience among ambulance staff. The current evidence base remains fragmented, and few studies provide robust estimates of impact or cost-effectiveness that could inform a sector-wide response (Phung et al., 2022).

To address this gap, we propose a pragmatic randomized controlled trial (RCT) to assess the impact of Transcendental Meditation (TM) on a range of psychological and occupational health outcomes. TM is a non-pharmacological, low-risk stress-reduction technique with growing international evidence supporting its potential in high-stress populations.

The principal research question for this study asks is whether learning Transcendental Meditation helps reduce psychological distress and time off work due to stress-related sickness for those who learn it, compared to those who don’t. This study also looks at whether learning Transcendental Meditation (TM) helps improve participants’ mental health and wellbeing— PTSD symptoms, depression, anxiety, insomnia, burnout, and health related quality of life as well as professional fulfilment and turnover intention —compared to those who don’t learn TM. It also explores whether TM affects how fulfilled people feel at work and whether they are thinking about leaving their job.

This trial will provide robust evidence to inform NHS strategies for workforce well-being and retention, and evaluate a scalable intervention with potential long-term benefits for staff health and system performance.

2.1 Assessment and management of risk

This study presents minimal physical risk, as Transcendental Meditation (TM) is a non-invasive, nonpharmacological behavioural intervention. However, ethical, legal, and operational considerations have been identified and addressed.

1. Justification for Randomised Controlled Trial (RCT): RCTs are the most rigorous way of determining causal relationships between interventions and outcomes. This design is necessary to assess not only the mental health effects of TM but also its potential impact on workplace absenteeism. Given the scale of stress-related sickness absence in the NHS, the study has the potential to generate valuable evidence to support scalable interventions in a high-need population.

2. Informed Consent and Voluntariness: Participation is voluntary. All participants will receive a detailed Participant Information Sheet and have the opportunity to ask questions before giving informed consent. Participation will not affect employment status, job performance reviews, or access to existing support services. All participating Ambulance Service have agreed to support recruitment by promoting awareness of the study through internal communications, staff wellbeing leads, and newsletters.

3. Psychological Risk: While Transcendental Meditation is generally considered safe, we acknowledge the systematic literature indicating that minor adverse effects—such as temporary cold sores, or reports of the body feeling heavy—can occur (Orme-Johnson et al., 2025). Furthermore, rare reports exist regarding the potential for meditation practices to precipitate psychiatric problems in vulnerable individuals (Lazarus, 1972). To proactively minimize these risks, the DLF employs a strict exclusion criterion: individuals who are currently psychiatrically unstable will be excluded from the trial. The TM instructors involved are highly trained and experienced in working with individuals experiencing, or who have experienced, traumatic stress and in high-stress environments. Crucially, participants will be clearly advised that the practice does not replace medical or psychological treatment. Those needing additional clinical support will be immediately signposted to appropriate NHS services by the study team. Participants will be reminded that the study is a research intervention, is not part of their clinical care pathway, and participation is not intended to replace or delay access to formal NHS mental health services.

4. Confidentiality and Data Protection: All data will be managed in accordance with UK GDPR and the Data Protection Act 2018. Personally identifiable data will be stored separately from research data and accessible only to authorised team members. Data will be stored securely on encrypted universityapproved servers and retained in accordance with institutional policy for a period of 10 years before secure deletion. Any published results will be anonymised and aggregated to prevent identification of individuals.

5. Equity of Access and Scheduling Challenges: Due to the shift-based nature of ambulance work, session times will be offered flexibly—including evenings and weekends—and options for online delivery will be provided. Every effort will be made to ensure equitable access across roles and

sites. Small group sizes and individual follow-up will be managed to ensure participants' privacy and comfort. All responses will be anonymised to prevent identification within workplace teams.

6. Waitlist Control Design: The waitlist control group will continue with usual care for the duration of the study, which consists of carrying out their regular duties as NHS ambulance staff and accessing any standard occupational health or wellbeing services made available through their Trust. They will be offered the full TM course upon completion of follow-up assessments, ensuring equal access to the intervention.

7. Organisational Complexity:

Delivering an RCT in a 24/7 healthcare setting involves complex logistics. To mitigate this, we will work closely with the the Ambulance Trusts to coordinate scheduling, recruitment, and follow-up while minimising disruption to clinical operations. In line with Trust policies, staff participation will only take place in their own time and not during scheduled shifts. The study will be designed to accommodate this constraint, ensuring flexibility and accessibility for participants. We will provide ongoing support and maintain regular contact with participants to encourage continued engagement. Additionally, we will collect data on reasons for withdrawal to inform the feasibility of larger-scale implementation.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

The principal research question for this study asks is whether learning Transcendental Meditation helps reduce in 9 months psychological distress and time off work due to stress-related sickness for ambulance workers who learn it, compared to those in the control group who don't.

3.2 Secondary objectives

This study also looks at whether learning Transcendental Meditation (TM) helps improve ambulance workers' mental health and wellbeing— PTSD symptoms, depression, and health related quality of life as well as professional fulfilment and turnover intention —after 9 months of treatment compared to those in the control group who don't learn TM. It also explores whether TM affects how fulfilled people feel at work and whether they are thinking about leaving their job.

3.3 Outcome measures/endpoints

3.4 Primary endpoint/outcome

Primary outcomes – beneficial effects, measured through change from baseline

a. Stress-related absences, assessed through twice monthly self-report. Total absences at 3, 6 and 9 months.

b. Psychological distress, assessed through the General Health Questionnaire (GHQ-12) scale. Total score at 3, 6 and 9 months.

Stress-related absence is a key organisational metric and of particular relevance to NHS Trusts, given the operational and financial implications of high sickness rates among ambulance workers. To date, no randomised controlled trial has evaluated the impact of a psychological intervention on reducing stress-related absences in this population, making it a novel and policy-relevant outcome. However, since there is limited existing literature on interventions targeting this outcome, there is no consensus on expected effect sizes. To complement this, psychological distress was included as a second primary outcome. It is commonly used in studies evaluating similar interventions, and existing evidence provides reliable benchmarks for detecting clinically meaningful changes. Including both outcomes allows the study to detect both direct individual benefits (distress) and organisational-level effects (absences), supporting a more comprehensive evaluation of the intervention.

3.5 Secondary endpoints/outcomes

Secondary outcomes – beneficial effects, measured through change from baseline

a. PTSD symptoms, assessed through the Post-traumatic Checklist for DSM-5. Total score at 3, 6 and 9 months.
b. Professional fulfilment, including burnout, assessed through the Professional Fulfilment Index. Total score at 3, 6 and 9 months.
c. Insomnia, assessed through the Insomnia Severity Index. Total score at 3, 6 and 9 months.
d. Turnover intention, assessed through the Turnover Intention Scale. Total score at 3, 6 and 9 months.
e. Health related quality of life, measured through the standardised EuroQol-5 Dimensions-5 Levels scale (EQ-5D-5L). Total score at 3, 6 and 9 months.

3.6 Exploratory endpoints/outcomes

3.7 Table of endpoints/outcomes

Objectives	Outcome Measures	Timepoint(s) of evaluation of this outcome measure (if applicable)
Primary Objective To compare the effect of TM versus business as usual on stress related absences. To compare the effect of TM versus business as usual on psychological distress.	Total days of stress-related absences Score of the general Health questionnaire scale	Total days of stress-related absences at 3, 6 and 9 months post-treatment Score of the general Health questionnaire scale at 3, 6 and 9 months post-treatment

Secondary Objectives To compare the effect of TM versus business as usual on PTSD symptoms	Score of the DMS-5 checklist	Score of the DMS-5 checklist at 3, 6 and 9 months post-treatment
To compare the effect of TM versus business as usual on Professional fulfilment	Score of the PFS scale	Score of the PFS checklist at 3, 6 and 9 months post-treatment
To compare the effect of TM versus business as usual on Turnover intention	Score of the Turnover intention scale	Score of the Turnover intention checklist at 3, 6 and 9 months post-treatment
To compare the effect of TM versus business as usual on Health related quality of life	Score of the Euro-QAL 5 scale	Score of the Euro-QAL 5 scale at 3, 6 and 9 months posttreatment

4 STUDY DESIGN

This study will employ a **randomized controlled trial (RCT) design**, with participants **stratified by Ambulance Trust**. A **wait-list control group** will be utilized, meaning that individuals assigned to the control arm will receive the intervention after a 9-month waiting period, following the completion of the primary study observation period.

This study design is specifically chosen to:

- The randomized nature of the trial is crucial for minimizing bias and allowing us to infer a causal relationship between the intervention and any observed outcomes. By randomly assigning participants to either the intervention or control group, we aim to create comparable groups, ensuring that any differences in outcomes are likely due to the intervention itself, rather than confounding factors.
- The primary goal is to determine the efficacy and effectiveness of the intervention in the target population. Comparing the outcomes of the intervention group to the control group will provide robust evidence on whether the intervention produces the desired effects.
- The wait-list design addresses ethical considerations by ensuring that all participants, including those initially in the control group, eventually have access to the intervention. This is particularly relevant for interventions believed to have beneficial effects, as it avoids permanently denying treatment to a segment of the study population. While the control group initially serves as a comparison, they will ultimately benefit from the intervention.
- Stratification by Ambulance Trust is essential to account for potential differences across trusts that might influence the study's outcomes. This ensures that the randomization is balanced within each trust, preventing any one trust from having a disproportionate number of

participants in either the intervention or control group, thereby increasing the generalizability and robustness of the findings across different operational environments.

5 STUDY SETTING

London Ambulance NHS Trust (LAS), the Yorkshire Ambulance Service NHS Trust (YAS), the South East Coast Ambulance Service NHS Trust (SACAS) and the West Midlands Ambulance Service (WMAS)**.** These trusts were selected due to their agreement to participate and their geographical and operational diversity, which enhances the generalizability of our findings.
The London Ambulance Service, Yorkshire Ambulance Service, South East Coast Ambulance Service and the West Midlands Ambulance Service will serve as recruiting sites. At each trust, study personnel will collaborate with the research team to send potential participants invitation to participate in the study and registration links, shared via staff newsletters, wellbeing bulletins, intranet posts, and communications from staff wellbeing leads.

The primary eligibility criterion for participating trusts was their formal agreement (via email) to facilitate staff recruitment and allow for the implementation of the study intervention within their operational environment. This includes providing access to eligible staff and supporting communication regarding the study.

The target participant population consists of ambulance workers (e.g., call handlers and front line workers) directly employed by the participating Ambulance Trusts. This population is found within secondary care (or a similar emergency pre-hospital care setting) due to the nature of their employment.

- Identification: Participants will be identified directly within the Ambulance Trusts through internal communication channels and collaboration with trust management.
- Usual care pathways**:** For the specific condition of interest, usual care pathways for ambulance workers typically involve internal occupational health services, employee assistance programs, and self-referral to primary or secondary care. The study intervention aims to augment or optimize existing support mechanisms rather than replace them.

6 PARTICIPANT ELIGIBILITY CRITERIA

6.1 Inclusion criteria

Participants will be selected on a first-come, first-served basis, with the first 350 individuals who satisfy all inclusion criteria (listed below), none of the exclusion criteria, and provide consent for study participation being enrolled.

Participants (in both the treatment and control group) must meet all of the following inclusion criteria to be eligible for the study.

1. Age 18 years or older: Participants must be adults legally able to provide informed consent.
2. Currently employed by one of the participating Ambulance Service Trusts. This includes all frontline ambulance staff and call handlers working in operational roles.

3. Willing and able to attend TM instruction sessions. Participants must be able to commit to the four consecutive initial instruction sessions (in-person or blended format), as well as regular TM practice.
4. Willing to complete all required assessments and track their TM practice, as described below

   Post-Intervention Data Collection (both treated and control groups):

   - Surveys: Psychological and wellbeing outcomes will be measured via three post-intervention online surveys at 3, 6 and 9 months, each taking no more than 15 minutes via Jotform. - Twice monthly Absence Self-Reports: participants will submit twice monthly absence reports including reasons, using a secure online form via Jotform. Twice monthly reminders will be sent by email

   A small subset of 20-25 participants in the treated group will be invited will be invited to a 30–40-minute semi-structured interview to explore their experiences of learning and practising TM. Interviews are held online via video conference. A small incentive (Amazon gift voucher) is offered for participation.

   Participants in the treated group will be asked to use the TM app during their meditation practice. To help monitor adherence to the intervention, they will be requested to share monthly screenshots of their app usage.

5. Access to a device with internet connection: Required to complete online surveys, attend virtual sessions, participate in app-based or video-based TM instruction (for those choosing the blended option) and record TM practice.
6. Fluent in English: Sufficient proficiency in English is needed to understand study materials, instructions, and to complete assessments and participate in interviews.
7. Provides informed consent: Participants must review the Participant Information Sheet and give written informed consent prior to enrolling in the study, on the following aspects of the project:
   - confirm that they have read the information sheet for the study, had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
   - understand that the participation is voluntary and that he is free to withdraw at any time without giving any reason, without his employment being affected.
   - commit to completing the TM course and the home practice of two 20-minute TM sessions daily - morning and evening throughout the evaluation period (9 months), tracking your practice on the TM app.
   - participate in this evaluation and complete the required surveys and the twice monthly absence self-report as outlined in the consent form
   - understand that the information collected about the participant may be used to support other research in the future and may be shared de-identified with other researchers.

6.2 Exclusion criteria

1. Not currently employed by the Ambulance Service Trusts participating in the study. Only staff employed by these NHS Trusts are eligible to take part.

2. Unable to commit to the TM instruction schedule. Individuals who cannot attend the four consecutive days of initial TM instruction (whether in-person or blended format) will be excluded, as consistent attendance is essential for correct instruction and adherence.

3. Previously trained in Transcendental Meditation (TM). This study is intended for individuals new to TM. Those who have already learned TM will be excluded.

4. Individuals who are within nine months of retirement or are planning to leave employment with the ambulance service within nine months.

5. Individuals on sick leave lasting more than 30 consecutive days at the beginning of the study.

6. Individuals who were currently psychiatrically unstable per self-report, or reported a psychiatric hospitalization in the past 9 months. Participants will be excluded if, on self-report screening carried out by TM instructors, they indicate that they are currently experiencing *unstable or severe mental health difficulties* that require active clinical management. For the purposes of this study, "psychiatrically unstable" includes any of the following:

- Current suicidal thoughts with plan or intent, or a suicide attempt/self-harm episode requiring medical attention in the past 3 months.
- Current or recent (past 3 months) psychotic symptoms (e.g. hallucinations, delusional beliefs) or a manic/hypomanic episode.
- Severe depression, anxiety, or post-traumatic stress symptoms that the participant reports as markedly interfering with day-to-day functioning (e.g. unable to work, care for self, or maintain basic routines).
- Current care under an NHS crisis team, Home Treatment Team, or recent psychiatric in-patient admission in the past 9 months.
- A major change in psychiatric medication in the past 4 weeks initiated in response to symptom deterioration.

Screening will be carried out via brief self-report questions. The TM instructors will not undertake diagnosis or treatment, but where screening indicates possible psychiatric instability, the individual will not be enrolled and will be encouraged to seek, or continue with, appropriate NHS mental health care.

7 STUDY PROCEDURES

Participants allocated to the intervention group receive the standardised TM course delivered over four consecutive days, followed by six months of twice-daily self-practice (20 minutes per session). Instruction is offered either in person or in a blended remote format:

In-Person Course

- Day 1: One-to-one instruction (75–90 min) with TM instructor, including first meditation experience and guidance on daily practice.
- Day 2: Group session (60-90 min) with individual check-in, Q&A, and group meditation.

- Day 3: Group session (60-90 min) focusing on TM's physiological and psychological benefits.
- Day 4: Group session (60-90 min), meditation, final Q&A, and personalised feedback.

Remote/Blended Course

- After the in-person Day 1 instruction, Days 2–4 are completed using the TM app, which includes pre-recorded instructional videos and interactive Q&A segments.
- Daily 30-minute online check-ins are held with TM instructors to support progress and ensure correct practice.

Post-Instruction Support

Participants are offered optional individual and group follow-up sessions via video conference and in person. These occur 7–10 days post-instruction and monthly for up to 6 months. Ongoing engagement is supported through:

- Access to daily online group meditations
- Local TM centre sessions
- A closed Facebook group offering further resources and Q&A with experienced teachers

TM instructors track practice frequency via the TM application and participant reflections via evaluation forms. Participants are encouraged to maintain regular practice throughout the follow-up period.

Waitlist Control Group

Participants assigned to the waitlist control group continue with usual care, , which consists of carrying out their regular duties as NHS ambulance staff and accessing any standard occupational health or wellbeing services made available through their Trust, and complete the same assessment schedule. They are offered the full TM course after the 9-month followup.

7.1 Recruitment

This section should give details of the participant eligibility screening process for the project including

Participants for this study will be identified and recruited through a multi-channel communication strategy targeting all operational staff within the Ambulance Service Trusts (London, Yorkshire, South East Coast and West Midlands). Study invitations will be disseminated via internal staff newsletters, wellbeing bulletins, intranet announcements, and direct communications from staff wellbeing leads. All these Ambulance Service Trusts have formally committed to supporting recruitment through their internal communications and wellbeing teams.

Interested staff members will be invited to register their interest in the study by accessing a secure registration link. Upon registration, individuals will be asked to select a date to attend a live online group introductory session. These sessions will be co-delivered by certified Transcendental Meditation (TM) instructors and a member of the research team. The sessions will provide an overview of the study aims, a description of the TM programme, an outline of the study implementation timeline, and

details of participant responsibilities. These sessions are designed to support informed decisionmaking and allow potential participants to ask questions prior to enrolment.

All attendees will be provided with a detailed Participant Information Sheet and a Consent Form outlining the purpose of the study, what participation involves, risks and benefits, and data handling procedures. Informed consent will be obtained electronically via a secure online platform (Jotform). Participation is entirely voluntary; individuals are free to decline without any consequence to their employment, performance evaluations, or access to staff support services.

Only participants who provide full informed consent will be eligible for randomisation. We will not collect detailed information on individuals who attend an introductory session but choose not to enrol, to preserve anonymity and minimise unnecessary data collection. However, we will record aggregate counts of:

- Staff invited via internal communications
- Number of staff who attend an introductory session
- Number of staff who provide consent and are randomised

7.1.1 Participant identification

Participants will be identified through self-referral following organisation-wide invitations distributed via internal staff communication channels. The identification process will not involve individual-level screening by the clinical team or researchers prior to consent. No identifiable personal information will be accessed until participants voluntarily register and provide informed consent.

Internal communication systems of the participating Ambulance Service Trusts will be used, including staff newsletters, wellbeing bulletins, intranet platforms, and communications disseminated by wellbeing leads. These channels ensure broad and equitable access to study information for all eligible staff.

Participants will be recruited exclusively through publicity methods, including electronic communications, digital posters, and newsletters circulated by the Ambulance Service Trusts (Participant Identification Centres) internal communications and wellbeing teams. There will be no use of external databases, registers, or patient records.

This study will not involve pre-screening or reviewing any identifiable personal information without explicit consent. Only after individuals voluntarily register for the study will any personal data be collected, and this will be limited to what is required for consent, eligibility confirmation, and study participation.

No existing identifiable staff or patient records will be accessed for recruitment purposes. All information will be collected via voluntary self-registration on a secure online platform (Jotform) after the participant has reviewed the study information and attended an introductory session. Access to this data will be restricted to the research team, and only after consent has been obtained.

No member of the research team will access individual-level data or make direct contact prior to consent. After consent, participants will be contacted by the research team only for the purposes of study participation, scheduling, or data collection.

Eligibility criteria will be simple and confirmed at the point of registration, through self-report.

7.1.2 Screening

n/a

7.1.3 Payment

To ensure high response rates and data completeness in this randomised controlled trial, we propose offering a £30 voucher incentive to participants who complete all scheduled questionnaires (administered at three, six- and nine-months post-intervention) and all twice monthly absence selfreports. These incentives are a crucial component of the study design, as they help maximise participant engagement and minimise attrition over the nine-month follow-up period. A grant has been submitted to the British Academy to pay for vouchers. Payment is conditional to the grant being awarded.

7.2 Consent – see *Informing participants and seeking consent - Health Research Authority (hra.nhs.uk)*

And HRA transparency wording *Transparency wording for all sponsors - Health Research Authority (hra.nhs.uk)*

Responsibility and delegation:
The Principal Investigator retains full responsibility for ensuring that informed consent is obtained in accordance with the ethically approved protocol. Delegation of consent is not permitted in this trial.

Consent process:
Eligible ambulance staff will be invited to attend an online group introductory session on Transcendental Meditation, led by certified instructors and a member of the research team. These sessions will outline the study's aims, the TM intervention, data collection processes, and participant expectations. Participants will be given access to the Participant Information Sheet in advance of the session and encouraged to ask questions during or after the presentation.

Following the session, participants who wish to enrol will be directed to an online secure platform (Jotform) where they will complete the informed consent form. The form will include statements clarifying that participation is voluntary, non-participation will not affect their employment, and that they may withdraw at any time.

Right to withdraw:
Participants have the right to decline participation or withdraw from the study at any time, without having to give a reason and without impact on their job or access to support services. Participants will be informed of a designated contact point for further queries and support related to the study. Data collected up to the point of withdrawal will be retained and analysed unless the participant specifically requests otherwise. This is clearly stated in the consent form.

Participants requiring additional support:
The study population comprises adult ambulance staff who are expected to have capacity to consent and speak fluent English. Although the study is not expected to include participants lacking capacity or minors, the research team will remain alert to any instances where extra protections may be needed to avoid coercion or undue influence.

Assessment of capacity:
Participants will self-register via an online system, which presumes capacity unless there is a clear indication otherwise. The information session and follow-up opportunities to ask questions are designed to support understanding, promote autonomous decision-making, and ensure that consent is fully informed.

No use of routine care or medical records without consent:
The trial does not involve medical interventions or use of existing patient records. Consent is required before the collection of any data, and only anonymised and self-reported data will be used throughout the study.

Updates and re-consent:
There are no type of new information that can emerge from the trial, which could affect a participant's decision to take part.

7.3 The randomisation scheme

Method of Randomisation: Individual-Level Stratified Randomisation

7.3.1 Method of implementing the randomisation/allocation sequence

This study will employ individual-level stratified randomisation. Participants will be stratified by Ambulance Trust. This stratification is crucial to ensure that a balanced number of participants from each trust are allocated to both the intervention and control groups, accounting for potential sitespecific differences in demographics, operational procedures, or existing support systems that could influence outcomes. Within each stratum, participants will be individually randomised.

Allocation Ratio: Equal Treatment Allocation
Participants will be allocated to the Transcendental Meditation intervention group or the control group in a 1:1 ratio. This equal allocation ratio is chosen to maximize statistical power for detecting differences between the two groups.

Allocation Concealment
To ensure rigorous allocation concealment and prevent selection bias, the randomisation process will be managed by a member of the research team who is not involved in participant recruitment, consent, or delivery of the intervention. The process will be as follows:

1. After participants have been deemed eligible and provided informed consent, their unique study IDs (without any personally identifiable information, such as names) will be provided to the member of the research team.
2. This member of the research team will then use these anonymized IDs to randomly allocate participants to either the Transcendental Meditation intervention group or the control group in a 1:1 ratio.

3. Following randomisation, the member of the research team will provide a list of the unique study IDs assigned to the intervention group to the David Lynch Foundation UK.
4. The David Lynch Foundation UK, holding the link between study IDs and participant names, will then be responsible for contacting these specific participants to schedule and deliver the Transcendental Meditation intervention.

This process ensures that those involved in recruitment and assessment of outcomes remain blinded to the treatment assignment until after allocation, thus minimizing the risk of bias.

7.4 Blinding (If relevant)

Given the nature of the intervention—Transcendental Meditation (TM) instruction versus wait-list control—complete blinding of all parties involved in the trial is not feasible. Participants will inherently be aware of whether they have received TM instruction. Similarly, those delivering the intervention will necessarily be unblinded. However, rigorous procedures will be implemented to ensure the blinding of data analysts, and to otherwise minimise the risk of bias throughout the study.

Blinded Parties

- Data analysts**:** While not explicitly stated, the method of collecting self-report outcome measures via secure online platforms, without researcher interaction during data collection, implicitly ensures that the individuals assessing outcomes (i.e., collecting the data via these platforms) are functionally blinded to group assignment. This minimizes assessment bias. The data analysis team will work exclusively with de-identified datasets containing only unique participant ID numbers. They will gain access to group allocation (TM vs. waitlist) to begin data analysis after the first follow-up data collection is complete and the initial dataset for analysis is prepared.

Unblinded Parties

- Participants: Participants will know whether they are receiving TM instruction or are in the waitlist control group.

- Deirdre Parsons (Director of the DLF): As the Director of the David Lynch Foundation UK managing session scheduling, Deirdre Parsons will have access to group assignments. However, she will not participate in any outcome data analysis or interpretation.
- TM Instructors: Due to the direct nature of the intervention delivery, TM instructors and other intervention delivery staff will be unblinded.

Procedures to Maintain Blinding and Minimise Bias

Several key procedures are in place to preserve blinding where feasible and to mitigate potential biases:

- All participants will be assigned a unique, non-sequential ID number at the point of registration.
- The file linking participant names to their unique ID numbers and group allocation will be securely stored and encrypted by the DLF, which will serve as the sole custodian of this linkage file. The research team will *not* have access to this file at any stage of the study.

- All self-report outcome measures (e.g., stress, mental health, wellbeing) will be collected via secure online platforms using participant ID numbers only. No personally identifiable information will be included in the datasets provided to the research team for analysis.
- The research team will gain access to group allocation (TM vs. waitlist) only after the first follow-up data collection is complete and the initial dataset for analysis is prepared. This timing is chosen to allow preliminary analysis of initial outcomes.
- Since the research team does not interact directly with participants during follow-up data collection (as data is collected via online platforms), the potential for assessment bias due to early unblinding of researchers is minimal.
- All reports and analyses will continue to use de-identified data throughout the study. Data will be analysed strictly according to the pre-specified statistical analysis plan (SAP), which will be finalized prior to unblinding the analysis team.

7.5 Emergency Unblinding (If relevant)

This does not apply as there are unblinded parties – participants and TM instructors.

7.6 Baseline data

Baseline Data Collection:

1. Age
2. Ethnic Group
3. Gender
4. Length of Service in their Ambulance Service
5. Baseline primary outcomes
6. Baseline secondary outcomes

7.7 Study Intervention and Assessments

This section outlines the procedures for the study intervention and assessments, including their content, timing, and methods of data collection. All the assessments are non-invasive, pose minimal risk to participants, and are conducted remotely to ensure convenience and promote high retention rates.

The Intervention
The intervention is a 4-hour course of Transcendental Meditation (TM) instruction**.**

- TM instruction will be delivered by certified TM teachers affiliated with the DLF. This will involve a standardized course of instruction typically conducted over 4 days, followed by regular group or individual checking sessions and opportunities for ongoing support, primarily online or via remote platforms where feasible.

- The instruction covers the technique of Transcendental Meditation, which involves silently repeating a mantra for 20 minutes twice a day, typically once in the morning and once in the evening.
- The active intervention period for the TM group is 9 months from the start of instruction.
- Participants in the control group will be placed on a wait-list for 9 months. At the end of the 9month primary study period, these participants will be offered the opportunity to receive the same Transcendental Meditation instruction, consistent with the ethical considerations of the wait-list design.

Assessments Schedule
All assessments are conducted remotely via secure online surveys. Participants will receive automated prompts to complete surveys at each time point.

Time Point	Assessment	Method	Estimated Duration
Baseline (Pre-randomisation)	Demographic information, baseline psychological and wellbeing measures, work-related stress.	Online survey (Jotform)	~15 minutes
Post-Intervention (3 months after baseline)	Primary and secondary psychological and wellbeing outcomes, work-related stress.	Online survey (Jotform)	~15 minutes
6 months after baseline	Primary and secondary psychological and wellbeing outcomes, work-related stress.	Online survey (Jotform)	~15 minutes
9 months after baseline (End of trial)	Primary and secondary psychological and wellbeing outcomes, work-related stress, end-of -trial feedback on study experience.	Online survey (Jotform)	~15 minutes
	Semi-structured interviews with ~25 participants who completed all the assessments	Online video interviews	~30-40 minutes
Twice monthly **(Weeks 1–39)**	Absence reports including reason (e.g., mental health, physical health, other).	Online form (Jotform)	~2 minutes

No run-in or washout periods are required for this behavioural intervention. Participants are not required to cease any existing therapies or medications to participate.

All data will be collected via secure electronic patient-reported outcome (ePRO) platforms provided by **Jotform**, which are compliant with GDPR and NHS data protection standards. Jotform's interface is mobile-friendly to maximise accessibility and convenience, allowing participants to complete surveys using their personal devices.

- Data collected via Jotform will be automatically downloaded and stored on secure university servers accessible only to authorised members of the research team.
- The twice monthly absence reports will serve as a continuous, short "diary card" method of data collection, enabling participants to quickly log information. Automated reminders will be sent to prompt twice monthly completion, and data completeness will be monitored by the study team.

At the 9-month post-baseline (end of trial) assessment, in addition to the primary and secondary outcomes, participants will be asked to provide general feedback on their study experience, perceived benefits, and any challenges encountered. This qualitative feedback will inform future interventions and research.
To complement quantitative data, a sub-sample of approximately 25 participants from both arms will be invited to take part in a semi-structured interview. These interviews will explore:

- Personal experiences of the intervention and study process
- Perceived impacts of TM on stress, well-being, and professional functioning
- Engagement with the practice and any challenges or facilitators
- Suggestions for broader implementation in similar settings

Interviews will be recorded, transcribed, and analysed using thematic analysis to identify recurrent themes that help contextualise and enrich the interpretation of quantitative outcomes.

Open ended questions will be sent at the end of the study to explore participants' views on the acceptability of the programme, perceived effects on their wellbeing and work, and factors that influenced their ability to engage with and sustain the practice. Data will be anonymised, securely stored, and analysed in accordance with data protection regulations.

Methods and timing for assessing, recording, and analysing efficacy parameters

- Primary outcome: The primary efficacy outcome is total days of stress-related absences and psychological distress (GHQ-12). This will be assessed at 3, 6, and 9 months post-baseline. Success will be defined as a statistically significant reduction in absences and improvements in GHQ-12 score in the TM group compared to the control group at 9 months, controlling for baseline values.
- Secondary outcomes: Secondary outcomes include [PTSD symptoms (DSM-5); Professional fulfilment (PFI); Insomnia (ISI); Turnover (Turnover Intention Scale); Health related quality of life (EuroQOL-5). These will be assessed at 3, 6, and 9 months post-baseline. The values and scores will be interpreted according to the scale's scoring manual and compared between groups
- All outcome data will be recorded directly by participants onto the secure Jotform platform. Data will be automatically timestamped.
- Efficacy parameters will be analysed according to the pre-specified Statistical Analysis Plan. For all outcomes, regression analysis will be used. All analyses will be conducted on an intention-to-treat basis.
- As this is a behavioural intervention study and not a mortality study, specific survival endpoints or recording of cause of death are not applicable to this protocol.

7.8 Long term follow-up assessments n/a

7.9 Qualitative assessments *(If relevant)*

Open ended questions will be sent to participants at the end of the study. These questions will explore participants' views on the acceptability of the programme, perceived effects on their wellbeing and work, and factors that influenced their ability to engage with and sustain the practice. This will include identifying any barriers (e.g., challenges such as time constraints, shift work, or lack of private space) and facilitators (e.g., supportive workplace culture, feeling early benefits, or having a quiet environment) that may have shaped their experience. Participants will also be invited to suggest ways the programme could be improved for NHS frontline staff. This qualitative component will be undertaken as part of a service delivery evaluation, rather than as a formal component of the clinical trial. Findings will be summarised descriptively to inform refinement and assess the feasibility and scalability of the programme for wider NHS implementation.

7.10 Withdrawal criteria

All participants will be clearly informed that participation is entirely voluntary and that they may withdraw from the study at any time without giving a reason. Withdrawal will not affect their employment or access to any existing support services provided by their Trust.

7.11 Storage and analysis of clinical samples

n/a

7.12 Definition of the end of Study.

The trial ends after the completion of the second follow up.

8 SAFETY REPORTING – for full details on what to report see

8.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant to whom an intervention has been administered, including occurrences which are not necessarily caused by or related to that intervention.
Adverse Reaction (AR)	An untoward and unintended response in a participant to the intervention

Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of
	the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the Study treatments, based on the information provided.

As this is a low-risk, non-pharmacological behavioural intervention involving Transcendental Meditation, it is classified as a non-CTIMP. Therefore, traditional pharmacovigilance procedures relating to adverse drug reactions and serious adverse reactions do not apply. However, in line with Good Clinical Practice guidelines, participant safety will be rigorously monitored throughout the study. While Transcendental Meditation is generally considered safe, we acknowledge the systematic literature indicating that minor adverse effects—such as temporary cold sores, or reports of the body feeling heavy—can occur (Orme-Johnson et al., 2025). Furthermore, rare reports exist regarding the potential for meditation practices to precipitate psychiatric problems in vulnerable individuals (Lazarus, 1972).
Safety monitoring will be based on participant self-report rather than real-time analysis of research outcome data. Participants will be instructed to report any distress or adverse experiences to their Transcendental Meditation teacher, who will escalate concerns to the Chief Investigator as appropriate. The Chief Investigator will assess seriousness and relatedness and report qualifying SAEs to the Sponsor in accordance with Non-CTIMP reporting requirements. Outcome measures (e.g. sickness absence or distress scales) will not be used for active safety surveillance during the trial.

Reporting of Serious Adverse Events
For this non-CTIMP study, only Serious Adverse Events that meet *both* of the following criteria will be formally reported to the Sponsor:

1. The SAE resulted from the administration of any of the research procedures (e.g., participation in TM instruction, completion of study assessments).
2. The SAE is not listed in this protocol as an expected occurrence (e.g., transient mild discomfort sometimes associated with learning a new meditative technique) would be considered expected and not an SAE for reporting purposes.

Any SAE meeting these criteria will be emailed to the Sponsor using the designated "Non-CTIMP safety report to REC form" within **15 days** of the Chief Investigator becoming aware of the event.

9 STATISTICS AND DATA ANALYSIS

9.1 Sample size calculation

The planned sample size for this randomized controlled trial is **350 participants**, a pragmatic decision influenced by the feasibility of recruitment within the identified ambulance trusts. While the sample size is fixed, this section details the Minimum Detectable Effect Size (MDES) that the study is sufficiently powered to detect.

The MDES calculation was performed using PowerUp! software. The calculation aimed to determine the smallest effect size (Cohen's *d*) that the study would have 80% power to detect, given the specified sample size and statistical parameters for a two-group comparison (Transcendental Meditation vs. Wait-list Control) with a continuous outcome:

- Primary outcome: Change in psychological distress (scores on the GHQ-12) from baseline to 9 months post-baseline.

- Null hypothesis (**H0**): There will be no difference in the change in psychological distress scores between the Transcendental Meditation group and the control group over 9 months (i.e., absolute difference = 0).
- Alternative hypothesis (**H1**): There will be a difference in the change in psychological distress scores between the Transcendental Meditation group and the control group over 9 months, specifically a difference at least as large as the calculated MDES.
- Minimum Detectable Effect Size**:** Given a total sample size of 350 participants (175 per arm after accounting for attrition), the study is powered at 80% to detect a standardized mean difference (Cohen's ***d***) of approximately 0.3 for the change in the primary outcome over 9 months, relative to the standard deviation at post-test.
    - This magnitude is considered meaningfu**l** and compares favourably to the impact found on measures of psychological distress in a non-randomised intervention on healthcare providers (Nestor et al., 2023) and an RCT among health care workers (Joshi et al., 2022), providing a robust empirical basis for the expected impact of such an intervention.
- Significance Level (**α**): A two-sided alpha (α) of 0.05 was set, indicating a 5% risk of concluding that a difference exists when, in reality, there is none (Type I error).
- Power (1-**β**): The MDES is calculated for a power of 80%, meaning there is an 80% probability of detecting an effect of this magnitude, should it truly exist (Type II error rate of 20%).
- Proportion of variance explained by covariates**:** The calculation assumed that 20% of the variance in the outcome would be explained by covariates (e.g., baseline score of the outcome, age, gender, ethnicity groups).
- Allocation Ratio**:** A 1:1 allocation ratio was used, meaning 50% of participants will be assigned to the treatment group.

Sample Size

The PowerUp! software output indicates that with N=280 evaluable participants (reflecting the 350 recruited participants after accounting for 20% attrition), and the specified parameters, the minimum detectable effect size is approximately 0.3.

- Sample Size for Calculation: 280 evaluable participants.

- Attrition Rate: An attrition rate of 20% over 9 months was estimated for the total study duration. This is considered a conservative estimate and is based on empirical evidence from a pilot study conducted by Parsons (2022) among ambulance workers in the North East Ambulance Service. That pilot study observed a 12% dropout rate over a 3-month period. Our elevated estimate for the current study accounts for its longer 9-month follow-up timeframe, anticipating a naturally higher attrition rate over an extended period.
- Total Recruited Sample Size: To account for this attrition, a total of **350 participants** will be recruited (175 per arm).

This sample size ensures sufficient power to detect a small-to-moderate effect on stress-related sickness absence, which serves as a co-primary outcome despite the absence of prior evidence in this specific population. Critically, the study will also be adequately powered to detect similar effect sizes for psychological distress, for which consistent effects have been well-documented in the literature. Including both outcomes as co-primary addresses both clinical and scientific relevance while pragmatically acknowledging the inherent uncertainty surrounding expected effect sizes for absence-related outcomes.

9.2 Planned recruitment rate

The study aims to recruit a total of 350 ambulance workers across four NHS ambulance services in England: the London Ambulance Service (LAS), the Yorkshire Ambulance Service (YAS), the South East Coast Ambulance Service (SECAMB), and the West Midlands Ambulance Service (WMAS).

Recruitment will take place via email invitation, planned for spring 2026, targeting frontline staff and call handlers within each service. The total eligible population includes approximately:

- 9,000 staff at LAS,
- 7,000 staff at YAS,
- 3,600 staff at SECAMB,
- 4,500 staff at WMAS, for a combined total of approximately 24,100 individuals.

Based on this population, the overall eligibility coverage is expected to be high, as the intervention is designed for the general frontline workforce. We anticipate a conservative consent rate of less than 2 percent, which would yield a pool of approximately 480 potential participants, allowing for some attrition or screen failure.

We do not anticipate formal screening exclusions beyond basic eligibility (active employment and consent), so the screen failure rate is expected to be low. Recruitment will be monitored on a rolling basis, and the projected recruitment window is 4 to 8 weeks, depending on response rates at each site.

This recruitment plan is designed to ensure feasibility across the four participating services and to support timely enrolment of the target sample within the study timeline.

9.3 Statistical analysis plan

9.3.1 Summary of baseline data and flow of patients

Baseline Comparability of Randomised Groups

To assess the baseline comparability of the randomised groups and characterize the study population, the following variables will be collected and reported. Tests of baseline differences between groups will be performed, to assess that randomisation balances these characteristics. Instead, descriptive statistics will be presented for each group.

Demographic and Occupational Characteristics

1. **Age** o Definition: Participant's age in years at the time of baseline data collection.
   - o Calculation: Calculated directly from self-reported date of birth.
   - o Form for Analysis: Continuous.
   - o Reporting**:** Mean (± Standard Deviation) for each group.
2. **Ethnic Group** o Definition: Participant's self-identified ethnic background. Participants will select from categories typically used in UK official statistics (White; Mixed or Multiple ethnic groups; Asian or Asian British; Black, African, Caribbean or Black British; Other ethnic group).
   - o Calculation: Generated dummy values for each category. o Form for Analysis: Categorical, o Reporting: Proportion (%) for each category within each group.

3. **Gender** o Definition: Participant's self-identified gender. Participants will be offered standard categories (e.g., Male, Female, Non-binary, Prefer not to say).
   - o Calculation: Generated dummy values for each category. o Form for Analysis: Categorical.
   - o Reporting: Proportion (%) for each category within each group.
4. **Length of Service** (in the Ambulance Trust were employed) o Definition: Total number of years the participant has been employed by their respective Ambulance Trust.
   - o Calculation: Calculated from self-reported start date of employment. o Form for Analysis: Continuous. o Reporting: Mean (± Standard Deviation) for each group.

Baseline Outcome Measures

All baseline outcome measures will be assessed via online self-report surveys and will be included as covariates in the primary analyses to adjust for any residual imbalances and to increase statistical power.

5. **Baseline Primary Outcomes** o
   a. Stress-related absences
   - Definition: Total number of self-reported days absent from work due to stressrelated reasons (e.g., anxiety, depression, burnout) in the past month preceding baseline.
   - Calculation: Sum of self-reported days for specified reasons.
   - Form for Analysis: Continuous
   - Reporting: Mean (± Standard Deviation) for each group.

- **b. Psychological distress**
  - Definition: Total score on the General Health Questionnaire (GHQ-12) at baseline. The GHQ-12 assesses general psychological health and the presence of common mental health problems over the past few weeks.
  - Calculation: Scored using the standard method (e.g., 0-0-1-1 method, yielding a range of 0-12, or Likert scoring 0-3 for each item, yielding a range of 0-36). Reference: Goldberg, D. P., & Williams, P. (1988). *A User's Guide to the General Health Questionnaire*. NFER-Nelson.
  - Form for Analysis: Continuous (score).
  - Reporting: Mean (± Standard Deviation) for each group.

6. **Baseline Secondary Outcomes**
   - **a. PTSD symptoms**
     - Definition: Total score on the Post-traumatic Stress Disorder Checklist for DSM5 (PCL-5) at baseline. The PCL-5 is a 20-item self-report measure of PTSD symptoms.
     - Calculation: Scored by summing item scores. Reference: Weathers, F. W., Litz, B. T., Keane, T. M., Palmieri, P. A., Marx, L. P., & Schnurr, B. P. (2013). *The PTSD Checklist for DSM-5 (PCL-5)*. National Center for PTSD.
     - Form for Analysis: Continuous (score).
     - Reporting: Mean (± Standard Deviation) for each group.
   - **b. Professional fulfilment, including burnout**
     - Definition: Total score on the Professional Fulfilment Index (PFI-16) at baseline. The PFI measures professional fulfilment, burnout, and interpersonal disengagement.
     - Calculation: to calculate Professional Fulfillment, average responses to items 1–6. To calculate Work Exhaustion, average items 7–12. To calculate Interpersonal Disengagement, average items 13–16. Higher scores on items 1–6 indicate greater professional fulfillment. Higher scores on items 7–16 indicate greater burnout.
     - Form for Analysis: Continuous subscale scores.
     - Reporting: Mean (± Standard Deviation) for each group.
   - **c. Insomnia:**
     - Definition: Total score on the Insomnia Severity index (ISI) at baseline.
     - Rules/Calculation: Scored by summing item scores. Reference (Bastien, C.H., Vallières, A. and Morin, C.M., 2001. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. Sleep medicine, 2(4), pp.297307.)
     - Form for Analysis: Continuous (score).
     - Reporting: Category of total score. a total score of 0–7 indicates “no clinically significant insomnia,” 8–14 means “subthreshold insomnia,” 15–21 is “clinical insomnia (moderate severity),” and 22–28 means “clinical insomnia (severe).”
   - **d. Turnover intention**
     - Definition: Total score on the Turnover Intention Scale (TIS) at baseline. The TIS measures an individual's likelihood of leaving their current employment.
     - Rules/Calculation: Scored by summing item scores. Reference (Bothma, C.F. and Roodt, G., 2013. The validation of the turnover intention scale. SA journal of human resource management, 11(1), pp.1-12.) Form for Analysis: Continuous (score).

- Reporting: Mean (± Standard Deviation) for each group.

- **e. Health-related quality of life**
  - Definition: Total score (or utility score) from the standardised EuroQol-5 Dimensions-5 Levels scale (EQ-5D-5L) at baseline. This scale assesses five dimensions of health.
  - Calculation: Scored according to the EQ-5D-5L manual, typically generating a descriptive profile and a single index value (utility score). Reference: EuroQol Group. (1990). EuroQol—a new facility for the measurement of health-related quality of life. *Health Policy, 16*(3), 199-208. (And specific manual for 5L version).
  - Form for Analysis: Continuous (utility score); also categorical for individual dimensions.
  - Reporting: Mean (± Standard Deviation) for the utility score, and proportions (%) for each level

9.3.2 Primary outcome analysis

Descriptive statistics
The primary outcome will be summarized using appropriate descriptive statistics. For continuous outcomes, this will include the mean and standard deviation. For categorical outcomes, percentages will be reported. These summaries will be presented for each treatment arm (intervention and control) at baseline and at all pre-specified follow-up time points.

Analysis
The primary outcome will be analysed using regression analysis, specifically linear regression for continuous outcomes. This method is justified given the continuous nature of the primary outcomes and allows for the adjustment of relevant covariates.
The analysis will control for key baseline covariates, including age, gender, ethnicity and length of service. These covariates are included to increase the statistical power and precision of our estimates by reducing unexplained variance in the outcome. Baseline values of the primary outcome will also be included as a covariate to increase statistical power and account for individual differences.

To account for the hierarchical structure of the data, with participants clustered within trusts, and recognizing that randomization was stratified at the Trust level, residual terms will be clustered at the Ambulance trust level**.** This approach addresses the potential for non-independence of observations within the same trust, which could lead to underestimated standard errors and inflated type I error rates if ignored. This method assumes independence between clusters and accounts for within-cluster correlation.

Multiple Comparisons, Missing Data, Non-Compliers, Spurious Data, and Withdrawals

Multiple Comparisons: To account for the two primary outcomes and the potential correlation between them, we will use the Romano-Wolf stepdown procedure to control the family-wise error rate (FWER) at α=0.05. This method, based on resampling techniques (e.g., wild bootstrap to account for clustering), will explicitly incorporate the dependence structure of the test statistics. The adjusted pvalues will be calculated by comparing the observed test statistics to their bootstrapped null distributions, providing a more powerful approach than traditional fixed-threshold methods. We will use the rwolf package in Stata. To address potential issues arising from multiple comparisons among the

secondary outcomes and one of the primary outcomes, which are all measures of psychological distress, we will construct a composite index aggregating these measures.

Missing Data: To address the issue of missing data, we will first explore whether missingness can plausibly be considered Missing At Random (MAR) by conducting diagnostic checks. Specifically, we will examine whether attrition differs between the treatment and control groups, and whether treatment assignment itself predicts the probability of missingness. This is important because the intervention may affect participants' likelihood of remaining in the study (e.g., by improving engagement or wellbeing), which would violate the MAR assumption.

We will also assess whether the randomisation achieved balance on baseline covariates among the subset of participants who remain in the study at each follow-up. This will help determine whether the observed data are still representative of the initial randomised groups.

If these diagnostics suggest that data may be Missing Not At Random (MNAR)—for example, if treatment status predicts attrition or if baseline balance breaks down among retained participants—we will conduct a sensitivity analysis using Inverse Probability Weighting (IPW). This method involves estimating the probability of observation (i.e., of remaining in the study) using a model that includes relevant baseline covariates, and then weighting observations by the inverse of these probabilities. This approach reweights the data to account for systematic differences between observed and unobserved cases, helping to assess the robustness of estimated treatment effects under plausible departures from MAR. The covariates used in the IPW model will be pre-specified based on theoretical and empirical considerations related to their association with attrition.

In sensitivity analyses, we may also estimate treatment effects using augmented inverse probability weighting (AIPW), which offers robustness against misspecification of either the outcome model or the missingness model. We will also consider conducting a pattern-mixture model sensitivity analysis under MNAR assumptions, where we specify plausible offsets (e.g., assuming participants lost to follow-up would have worse outcomes than observed participants), following Carpenter & Kenward's framework.

Non-Compliers: The primary analysis will adhere to the intention-to-treat (ITT) principle, meaning all participants will be analysed in the group to which they were originally randomized, regardless of their adherence to the intervention or protocol deviations. This provides an unbiased estimate of the treatment effect in a real-world setting.

Spurious Data: Data cleaning procedures will be implemented prior to analysis to identify and address spurious data points (e.g., extreme outliers, data entry errors). This will involve visual inspection of distributions and range checks. Outliers will be investigated for potential errors; if confirmed to be errors, they will be corrected or treated as missing. If plausible but extreme, their influence on the results will be assessed through sensitivity analyses (e.g., by performing analyses with and without these points).

Withdrawals: Participants who withdraw from the study will be included in the ITT analysis up to the point of withdrawal if their primary outcome data is available. For data after withdrawal, the plans for handling missing data (described above) will apply.

Intention-to-Treat (ITT) analysis

As stated above, the primary analysis will strictly adhere to the intention-to-treat (ITT) principle. All participants will be analysed in the treatment group to which they were randomized, regardless of actual treatment received, adherence, or withdrawal.

Non-Statistical Methods

In addition to the quantitative statistical analyses, open ended questions will be sent to participants at the end of the study.

These questions will explore participants' views on the acceptability of the programme, perceived effects on their wellbeing and work, and factors that influenced their ability to engage with and sustain the practice. This will include identifying any barriers (e.g., challenges such as time constraints, shift work, or lack of private space) and facilitators (e.g., supportive workplace culture, feeling early benefits, or having a quiet environment) that may have shaped their experience. Participants will also be invited to suggest ways the programme could be improved for NHS frontline staff. This qualitative component will be undertaken as part of a service delivery evaluation, rather than as a formal component of the clinical trial. Findings can be analysed with natural language processing methods or summarised descriptively to inform refinement and assess the feasibility and scalability of the programme for wider NHS implementation.

9.3.3 Secondary outcome analysis

For each secondary outcome, the analysis will generally follow the same regression-based approach as the primary outcome to ensure consistency and facilitate comparison across measures.

For each secondary outcome, descriptive statistics (mean, standard deviation for continuous scores; percentages for categorical components) will be reported for each treatment arm at baseline and at all follow-up time points.

Each secondary outcome (PTSD symptoms, Professional Fulfilment, Turnover Intention, and HealthRelated Quality of Life) will be analyzed using linear regression. Each model will control for the same covariates used for the primary outcome analysis, and the respective baseline value of the secondary outcome being analyzed. Residual terms will be clustered at the trust level for each secondary outcome analysis.

All analyses will adhere to the intention-to-treat (ITT) principle, meaning participants will be analyzed in the group to which they were randomized, regardless of adherence or withdrawal. Missing data for secondary outcomes will be handled consistent with the primary outcome analysis (i.e., primary analysis using complete-case data adjusted for attrition predictors, with sensitivity analysis using Inverse Probability Weighting if MNAR is suspected).

Each secondary outcome will be analysed at each specified follow-up time point (3, 6, and 9 months) separately.

9.4 Subgroup analyses

Predefined subgroup analyses will be conducted to assess the consistency of the intervention's effect across different participant characteristics. These analyses will involve testing for an interaction between the treatment arm and the subgroup variable in the primary regression model.

- Gender: We aim to assess whether and to what extent the impact varies according to gender (male vs. female).
- Ethnicity**:** We aim to assess whether and to what extent the impact varies according to ethnicity (White, Black, Asian, Mixed, Other)

It is important to note that subgroup analyses are exploratory in nature and findings should be interpreted with caution due to reduced power and the increased risk of false positives.

Mechanisms (Mediating effects)
The project will examine how the intervention works by assessing the mediating effects of the following mechanisms on the primary outcome:

- Stress: Assessed through the Perceived Stress Scale. We will use a mediation analysis approach (e.g., regression-based mediation) to determine if the intervention's effect on the primary outcome is significantly mediated by changes in perceived stress.
- Meditation practice**:** Assessed through the usage of the TM App. Similarly, mediation analysis will be conducted to investigate whether the intervention's effect on the primary outcome is mediated by the extent of meditation practice (e.g., frequency of app usage).

These mediation analyses will help elucidate the pathways through which the intervention exerts its effects.

9.5 Adjusted analysis

As the outcomes of interest are effects of stress, we may control for baseline stress assessed through the perceived stress scale.

9.6 Interim analysis and criteria for the premature termination of the Study

An interim analysis will be performed after the first and second follow-up period, at approximately 3- and 6-months post-randomisation, once the data from all participants at these time points are available. The primary aim of these interim analyses is to monitor data quality, assess participant retention, evaluate early trends in the outcome measures, and identify any unforeseen operational challenges. This analysis is descriptive in nature and is intended to provide an early understanding of any emerging effects of the intervention.

Given the non-pharmacological, low-risk nature of the Transcendental Meditation intervention and the primary focus on observing effects over the full study duration, formal statistical stopping rules for overwhelming benefit or futility will not be applied at this interim stage. Similarly, specific statistical criteria for early stopping due to harm will not be employed, as the intervention is not expected to cause serious adverse events that would warrant premature termination.

The interim analysis will be performed by members of the research team, not directly involved in the delivery of the intervention. It will be conducted after the 3- and 6- month follow-up data has been collected and cleaned for all participants.

Given the nature of the intervention (TM instruction versus wait-list control), complete blinding of all parties involved is not feasible. Participants will inherently be aware of their group assignment, as will the TM Instructors and Deirdre Parsons (Director of the DLF, managing session scheduling). During the interim analysis at 3- and 6- months, only the research team will have access to unblinded outcome data for group-level assessment.

To maintain the integrity of the study and minimize bias, several key procedures will be followed:

- All participants are assigned unique, non-sequential ID numbers.
- The secure linkage file associating participant names with their unique ID numbers and group allocation will be exclusively managed by the DLF and will not be accessible to the research team.
- All self-report outcome measures are collected via secure online platforms using participant ID numbers only, ensuring that the research team does not interact directly with participants during follow-up data collection, thereby minimizing assessment bias.
- The data analysis team will work exclusively with de-identified datasets. Access to group allocation (TM vs. wait-list) for the analysis team will be granted after the first follow-up data collection is complete and the initial dataset for analysis is prepared.
- All reports and analyses will continue to use de-identified data throughout the study, strictly adhering to the pre-specified Statistical Analysis Plan (SAP). No adaptations to the study design will be made based on these interim findings.

The ultimate authority to stop or significantly modify the study rests with the **Chief Investigator**, in consultation with the Sponsor. While this authority is in place, it is considered highly unlikely that early termination or significant modification would be required, given the non-pharmacological and low-risk nature of the intervention.

Stopping Guidelines:

- Due to the known safety profile of Transcendental Meditation as a non-pharmacological intervention, no specific criteria for stopping for harm are pre-specified, as serious adverse events attributable to the intervention are not anticipated. All adverse events will be collected and reported in accordance with standard operating procedures, and any safety concerns will be continually monitored by the Chief Investigator.
- Formal statistical criteria for early stopping due to overwhelming benefit or clear futility will not be employed. The study is designed to run to full recruitment and follow-up to provide robust evidence on the intervention's effects.

9.7 Participant population

The primary analysis of this study will be based on an Intention-to-Treat (ITT) population. This approach means that all participants who are randomised into the study will be included in the analysis, irrespective of whether they received the study intervention (Transcendental Meditation

instruction) or the duration or extent of their adherence to the intervention. Participants will be analysed in the group to which they were originally allocated by randomisation.

9.8 Procedure(s) to account for missing or spurious data

To minimise attrition and prevent missing data, several strategies will be implemented. Participants will receive regular reminders to complete follow-up surveys. Additionally, an incentive of a £30 voucher (contingent on grant award) will be provided to participants who complete all three follow-up surveys and submit twice monthly absence self-reports throughout the study period.

Due to logistical constraints, specific reasons for participant non-response at follow-up time points or withdrawal from the study will generally not be able to be systematically recorded.

Missing data for both primary and secondary outcomes will be primarily handled using a completecase approach for the main analysis, with regression models adjusted for identified attrition predictors (e.g., baseline demographics, initial stress levels, and other baseline characteristics that predict missingness). To assess the robustness of the study results to different assumptions about the missing data mechanism, a sensitivity analysis using Inverse Probability Weighting will be conducted. This method will be applied particularly if missingness is suspected to be Missing Not At Random (MNAR). The weights for the IPW analysis will be derived from a model predicting the probability of remaining in the study, based on a range of available baseline characteristics.

It is important to note that single imputation methods (such as Last Observation Carried Forward or Baseline Observation Carried Forward) will **n**ot be used, given their known limitations in introducing bias and underestimating variance. While multiple imputation methods are widely preferred, the chosen approach of complete-case analysis with IPW sensitivity analysis is deemed appropriate for this study given the nature of anticipated missingness.

9.9 Other statistical considerations.

9.10 Economic evaluation *(If relevant)*

A comprehensive economic evaluation will be undertaken as an integral part of this study, aiming to assess the value for money of the Transcendental Meditation intervention for ambulance workers.

The primary form of economic evaluation will be a Cost-Benefit Analysis. This approach will allow for the direct comparison of the monetized benefits of the intervention against its costs.

Means of Assessment:

- Costs**:** The direct costs associated with the delivery of the Transcendental Meditation intervention will be quantified. This includes, but is not limited to, instructor fees, and any associated administrative costs.
- Benefits: The primary measure for assessing the health-related benefits of the intervention will be the EQ-5D-5L score. This widely recognized and validated instrument assesses healthrelated quality of life, enabling the calculation of Quality-Adjusted Life Years (QALYs). For the purpose of the Cost-Benefit Analysis, these QALYs (and potentially other relevant health outcomes or productivity gains, such as reduced absenteeism) will be assigned

monetary values using established economic valuation methods to allow for direct comparison with the intervention's costs.

10 DATA MANAGEMENT

10.1 Data collection tools and source document identification

All information gathered in this study, originating from participants' direct input, will be managed as source data. This ensures that all findings are reconstructable and verifiable for the purposes of confirmation and quality control. Data and their records will adhere to principles of being Accurate, Legible, Contemporaneous, Original, Attributable, Complete, Consistent, Enduring, and Available when needed.

The majority of outcome and covariate data will be collected using **standardised, validated tools and questionnaires** administered through secure online platforms.

The key non-standard data collection involves **twice monthly self-reported absences**. Participants will record their absences and the associated primary reason for each absence on a twice monthly basis, also via a secure online platform. This method was chosen following conversations with head researchers at the ambulance trusts, who indicated that self-reported reasons for absence are considered more reliable than HR-recorded data. This is due to a perceived tendency among staff not to report the true underlying reasons for absence to HR, often driven by fear of repercussions. Therefore, this self-report method represents the most accurate and feasible approach for capturing absence data for this specific population within the study's constraints.

To maximise data completeness and minimise missing data, proactive strategies will be employed. Automated reminders will be sent to participants who have not completed their scheduled online surveys or twice monthly absence reports. As detailed in Section 9.8, incentives will also be provided for sustained engagement across follow-up periods.

Data will be entered directly by participants or study personnel onto electronic Case Report Forms (eCRFs) hosted on the secure Jotform online platform. These eCRFs will serve as the primary source documents for the study data. The design of these eCRFs ensures adequate collection of all data required by the protocol, and prevents the capture of unnecessary secondary data.

The investigator will maintain secure records of all participating patients, including their unique participant IDs. All electronic informed consent records (consent IDs/forms submitted online) will be securely stored in a access-controlled digital folder/ maintained by the investigator. The confidential file linking participant names to their unique ID numbers and group allocation will be exclusively kept and securely managed by the David Lynch Foundation UK, ensuring that the research team accesses only de-identified data for all analyses.

10.2 Data handling and record keeping

All study data will be meticulously collected, managed, and stored to ensure accuracy, integrity, confidentiality, and compliance with relevant data protection regulations (e.g., GDPR) and Good Clinical Practice (GCP) guidelines.

Primary study data, including participant self-reports from standardized and non-standardized tools, will be collected using the **JotForm platform**, a secure and validated electronic data capture (EDC) system. This platform is designed to facilitate direct data entry by participants, minimize errors, and ensure the quality of collected data.

Data will be downloaded from the JotForm platform in its original, raw format. This original downloaded data will be preserved in an unaltered state and securely archived on encrypted and secure working laptops, accessible only by members of the research team, ensuring its integrity as the definitive source. For the purpose of analysis, transformed or edited working copies of the data will be created by the research team using written code (e.g., in Stata). This systematic approach ensures full reproducibility of all data manipulation steps and allows for seamless traceability back to the original raw data at any point. These working datasets will be stored and processed exclusively on encrypted and secure working laptops, accessible only by members of the research team.

The chosen EDC system (JotForm) will capture and record the final submitted data input. Due to the nature of the platform, the system will not maintain a detailed audit trail of modifications or deletions made to data entries after their initial submission. Therefore, once data is submitted, the recorded version is considered final for that entry.

Access to both the JotForm platform and the securely stored downloaded data (original and working copies) will be strictly controlled and limited to members of the research team. Access will be password-protected. All systems will employ encryption protocols to protect data in transit, safeguarding against unauthorized access.

A robust data backup and recovery plan will be in place. Regular, automated backups of all study data (both on the JotForm platform and the securely archived original downloads) will be performed and stored securely off-site to prevent data loss due to system failures or unforeseen events.

Participants will be identified using unique, unambiguous participant identification codes throughout the data collection and analysis process. No personally identifiable information will be included in the analytical datasets. The data management system will be configured to safeguard the blinding of study groups for those personnel who are meant to remain blinded, as detailed in Section 9.6.

Upon completion of the study and final analysis, all electronic source data and records (including the original downloaded data and the final analytical datasets) will be securely archived in accordance with regulatory requirements and institutional policies for the specified retention period, ensuring longterm accessibility for verification and reconstruction if needed.

10.3 Access to Data

No identifiable personal data will ever be shared with external organisations or individuals beyond those explicitly authorised within the consent processes. All data shared for analysis purposes will be in a

deidentified or anonymised format. For wider research dissemination and reproducibility, the anonymised version of the full dataset will be deposited in a recognised data repository, the UK Data Archive (UKDA), three years after the completion of the project.

10.4 Archiving

The anonymised version of the study's full dataset will be deposited in the UK Data Archive (UKDA) three years after project completion for wider research dissemination and reproducibility (as detailed in Section 10.3).

All essential study documents, which are crucial for the reconstruction and evaluation of the study, will be securely archived. This includes original informed consent records, raw (non-anonymised) data, ethical approvals, key study correspondence, and the final study report.

Archiving will be formally authorised by the **Chief Investigator** following the submission of the end-ofstudy report. The **Chief Investigator and the host institution** will be jointly responsible for the secure archiving of all essential study documents. These documents will be stored in a dedicated, secure institutional electronic archive (electronic) at the University of Westminster.

All essential documents will be retained for a minimum of **5 years after the completion of the study** (defined as the date of the final study report submission). Destruction of essential documents after the specified retention period will require explicit authorisation from the Chief Investigator or relevant institutional authority, unless otherwise notified by regulatory bodies or the Sponsor.

11 MONITORING, AUDIT & INSPECTION *(If relevant)*

Any part of the study may be audited by the funder, where applicable. On site monitoring will not be performed as the intervention does not envisage any risk for participants. No formal auditing is planned for this project.

12 ETHICAL AND REGULATORY CONSIDERATIONS

12.1 Research Ethics Committee (REC) review& reports

No work on the study will commence without full ethical approval. The research team is currently preparing and will submit applications for ethical approval to the **University of Westminster Ethics Board** and the **Health Research Authority (HRA)**. Approval will be sought for the Study protocol, informed consent forms, participant information sheets and surveys.

Substantial amendments to the Study protocol or associated documents that require review by the University of Westminster Ethics Board or the HRA will not be implemented until a favourable opinion is granted by the respective body.

All correspondence with the University of Westminster Ethics Board and the HRA, including initial applications, approval letters, and communications regarding amendments or reports, will be diligently retained in the Study Master File.

It is the Chief Investigator's responsibility to produce and submit annual progress reports as required by the Health Research Authority (HRA) guidance. The Chief Investigator will notify the HRA of the end of the Study.

Within one year after the end of the Study, the Chief Investigator will submit a final report with the results, including any publications or abstracts, to the HRA, in line with their guidance on ending projects.

12.2 Peer review

The study has undergone a rigorous peer review process as part of its grant proposal submission to the British Academy, ensuring its scientific quality, methodological soundness, and feasibility. This review was instigated and approved within the framework of the funding application procedures.

The study, as proposed in the grant application, was peer-reviewed by the following independent experts:

- Nominated Referee**:** The study proposal was reviewed by Ainhoa Aparicio Fenoll, Professor of Economics at the University of Turin. This reviewer is external to the investigators' host institution and is not involved in the study in any capacity, thereby ensuring independence. Their expertise contributes to the assessment of the study's overall design, methodological rigor, and academic merit.
- British Academy Grant Reviewers**:** The comprehensive study proposal was further subjected to rigorous peer review by experts appointed by the British Academy as part of their grant application assessment. These reviewers operate independently of the research team and the host institution.

Dr. Sanford Nidich, Ed.D., is a Professor and Director of the Center for Social-Emotional Health at Maharishi International University and serves as Chief Scientific Officer of DLF. He has extensive experience researching the effects of Transcendental Meditation on mental health, particularly in populations exposed to high stress and trauma. His research includes randomized controlled trials demonstrating significant reductions in PTSD symptoms among veterans and prison inmates through TM practice. In this project, Dr. Nidich will provide scientific oversight and methodological guidance, drawing on his expertise in evaluating TM interventions and mental health outcomes.

This multi-layered review, involving both an academic referee and a rigorous funding body assessment, ensures that the peer review applied to the study is independent, expert, and proportionate to the size and complexity of this Randomised Controlled Trial.

12.3 Public and Patient Involvement

Service users have been/will be involved in the following aspects of the research process:

- Design of the research
- Analysis of results

- Dissemination of findings

Details of involvement:
In 2022, we pilot-tested key elements of the study—including participant information materials and the acceptability of the intervention delivery—with a small group of ambulance workers in Norfolk. Their feedback informed refinements to the research design and delivery approach adopted in the current project.

Throughout the study, we will maintain active collaboration with the Ambulance Service involved in the study, as well as with NHS England, to ensure the research remains relevant to frontline needs and findings are widely disseminated. Regular updates will be shared with our NHS partners, Professor Rachel Fothergill (LAS), Dr Fiona Bell (YAS), Craig Mortimer (SECAMB) and Andy Rosser (WMAS) and we will engage their wider staff networks to support interpretation and communication of results.

At the dissemination stage, we will co-produce tailored summaries and presentations with ambulance staff to ensure findings are accessible, meaningful, and actionable for practitioners and public audiences alike.

12.4 Regulatory Compliance

Before any participating site can enrol individuals into the study, the Chief Investigator will ensure that all necessary local approvals from the participating organisations are in place. Specific arrangements for gaining these approvals will comply with the relevant guidance for NHS research.

In this study, the Chief Investigator and the Director of the David Lynch Foundation UK have met with the Heads of Research and Development (R&D) at the Ambulance Service NHS Trust. Following their review and comments on the HRA submission and the study protocol, the Ambulance Service NHS Trusts have agreed to participate in the study. Their approval was obtained in the form of an email from the participating NHS Trust before any recruitment or study activities commence at that site.

For any amendment to the study protocol or related documents, the Chief Investigator, in agreement with the Sponsor, will promptly submit the necessary information to the appropriate regulatory and ethical bodies (e.g., the HRA and the University of Westminster Ethics Board) for their review and approval. Substantial amendments will not be implemented until a favourable opinion or approval has been issued by the relevant body.

The Chief Investigator will work closely with the participating sites, including their R&D departments at the NHS Trust, to ensure that all necessary arrangements are put in place to implement the approved amendments.

12.5 Protocol compliance

Maintaining strict adherence to the approved study protocol is paramount for ensuring the validity, integrity, and ethical conduct of the research. Protocol non-compliances are defined as any departure from the approved protocol.

- Prospective, planned deviations from or waivers to the protocol are strictly prohibited. It is not acceptable, for instance, to enrol a participant who does not meet the eligibility criteria or adhere to the restrictions explicitly specified in the study protocol.
- Accidental protocol deviations can occur at any time during the course of the study. When such deviations happen, they will be adequately documented and reported to the Chief Investigator and the Sponsor.
- Deviations from the protocol that are found to frequently recur are not acceptable. Such recurring deviations will require immediate corrective action by the research team and could potentially be classified as a serious breach of Good Clinical Practice (GCP) or regulatory requirements, necessitating prompt reporting to all relevant authorities.

12.6 Notification of Serious Breaches to GCP and/or the protocol

A "serious breach" is defined as a breach that is likely to affect to a significant degree: (a) the safety or physical or mental integrity of the participants of the Study; or (b) the scientific value of the Study.

- The Chief Investigator or designee will notify the Sponsor immediately of any case where the above definition of a serious breach applies or is suspected to apply during the Study conduct phase.
- The Sponsor of the study will notify the HRA in writing of any serious breach of:
    - The conditions and principles of Good Clinical Practice in connection with that Study; or
    - The protocol relating to that Study, as amended from time to time. This notification will occur within 7 days of the Sponsor becoming aware of that breach.

12.7 Data protection and patient confidentiality

All investigators and study site staff involved in this research are committed to upholding the highest standards of data protection and patient confidentiality. The study will comply fully with the requirements of the Data Protection Act 2018 and the General Data Protection Regulation (GDPR), adhering to their core principles regarding the collection, storage, processing, and disclosure of personal information.

To safeguard participant confidentiality, a robust de-identification strategy is implemented from the point of data collection:

- Participants will be assigned unique identification (ID) numbers upon enrolment. These ID numbers will be used in place of names on all study materials, data collection forms, and datasets.
- The file linking participants' names to their unique ID numbers will be created and securely stored as an encrypted digital file within password-protected folders. This linkage file will be maintained separately from all study data by the David DLF, which will act as the custodian of this sensitive linkage information.

- Crucially, researchers involved in data analysis will not have access to this linkage file at any point, ensuring the analysis team remains blinded to participant identities and group assignment, thereby helping to minimise bias.
- Online forms, for which participants will receive a secure email link, will be completed using these assigned ID numbers. This ensures that no personally identifying information is collected alongside the research responses, effectively anonymising data at the point of collection.

When data are transmitted between co-investigators and the DLF only the coded, anonymised versions of the data will be shared. All data transmissions will occur through secure, encrypted channels to preserve confidentiality and prevent unauthorised access.

In line with institutional policy and the archiving plan detailed in Section 10.4, all essential study data and documentation will be retained securely for a minimum of 5 years after the completion of the study. The precise duration will adhere to the policies of the host institution and any relevant funder requirements.

The **Chief Investigator** will serve as the **Data Controller** for the main study data, responsible for its overall processing and compliance with data protection legislation. The DLF will act as the custodian specifically for the secure linkage file, as outlined above.

To further protect participant anonymity, an anonymised version of the full dataset will be deposited with the UK Data Archive (UKDA) three years after project completion (as detailed in Section 10.3). All published findings from the study will be anonymised and reported in aggregate to ensure that no individual participant can be identified.

12.8 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall Study management

For this study, no conflict of interest is present for any investigator or member of the study team. All involved personnel have reviewed potential areas of conflict. No interests have been identified that could compromise the integrity or objectivity of the study.

12.10 Amendments

For **substantial amendments** (those likely to have a significant impact on participant safety, scientific value, ethical conduct, or data integrity), written approval will be sought from the appropriate bodies *before* implementation. This includes:

- The Health Research Authority (HRA).
- The University of Westminster Ethics Board.
- The amendment will also be updated on relevant study registries (e.g., ISRCTN, if applicable) and communicated to all relevant stakeholders, including the R&D departments of the participating Ambulance Service NHS Trust the research team. This ensures that the amendment affects the NHS permission for that site is assessed.

For **non-substantial amendments** (minor changes not significantly impacting safety, ethics, or scientific value), these will be formally documented and communicated to the participating Ambulance Service NHS Trust R&D department and the research team. It is acknowledged that some amendments considered non-substantial for ethical review purposes may still require notification to NHS R&D departments (e.g., changes to funding arrangements or administrative updates) to ensure ongoing site permission.

The Chief Investigator or designee will work closely with the participating sites to ensure they are fully informed of all approved amendments. Sites will be responsible for putting the necessary arrangements in place to implement the amendment and confirming their support for the study as amended. The amendment history will be meticulously tracked within the protocol itself and in the Study Master File to ensure the most recent protocol version is always identifiable and in use.

12.11 Post Study care

Upon completion of the study:

- For Participants in the Comparison Group: Individuals assigned to the comparison group during the study will be offered the opportunity to learn the Transcendental Meditation technique at the end of the study. This ensures that all participants have the chance to benefit from the intervention if it is found to be effective.
- For Participants in the Intervention (Treated) Group**:** Participants who received the Transcendental Meditation intervention during the study will continue to receive ongoing support sessions from certified TM teachers as needed, beyond the formal study period. This ensures continued practice and support for those who have already learned the technique.

These post-study provisions demonstrate the DLF commitment to the well-being of all participants, ensuring continued access to the intervention and its associated support structure, should they choose to avail themselves of it. Funding for these continued provisions is provided by the David Lynch Foundation UK.

12.12 Access to the final Study dataset

Access to the full, non-anonymised study dataset will be strictly limited to the research team directly involved in the statistical analysis, and reporting. This includes the Chief Investigator and the statistician listed in this protocol.

Access to the full dataset is highly restricted to ensure data confidentiality and to prevent premature or unauthorised disclosure of overall study results. All members of the research team with access to the full dataset will adhere to strict data security protocols and confidentiality agreements. No individual study site personnel or collaborators not explicitly part of the core data analysis team will have access to the full, identifiable dataset.

Given the study's design and operational structure, the research team responsible for the final dataset manages the data centrally. Therefore, the concept of separate "site investigators" requiring

independent access to the full, non-anonymised dataset through a formal request is not applicable in the same way as in a large multicentre study.

To promote transparency and enable wider research, a de-identified version of the final dataset, stripped of any personally identifiable information, will be deposited in the UK Data Archive (UKDA) three years after the formal end of the study, as outlined in Section 10.3 (Access to Data) and Section 12.7 (Data Protection and Patient Confidentiality).

13 DISSEMINIATION POLICY

13.1 Dissemination policy

Data Ownership: The data arising from this study will be owned by the University of Westminster. On completion of the study, all collected data will be rigorously analysed and tabulated. A comprehensive Final Study Report will be prepared, detailing the methodology, results, discussion, and conclusions. This report will be accessible via academic publications once published.
The core research team, including the Principal Investigator (Oppedisano) and Co-Investigator (Conti), will retain the primary rights to publish the study data.

The research team aims for timely dissemination of findings. All publications will undergo internal review by the research team and the David Lynch Foundation UK for accuracy and compliance with confidentiality and ethical guidelines prior to external submission.
All publications and presentations arising from this study will acknowledge the funding provided by the British Academy (if obtained) and the support from the David Lynch Foundation UK. The DLF will be offered the opportunity to review manuscripts for factual accuracy and acknowledgment prior to submission for publication, though they will not have the right to veto publication content.

Dissemination Plans:

- Academic Audiences: The research team will first disseminate findings through the working paper series of the Institute for Fiscal Studies (IFS), where the PI (Oppedisano) and the Co-I (Conti) are Research Associates. Further dissemination is planned through the IZA, CEPR, and CESifo networks, allowing wide exposure among labour and health economists. We plan to submit the main academic article to high-impact, peer-reviewed journals such as the Journal of Health Economics, the Economic Journal, or Social Science & Medicine. The project will also be presented at leading conferences including the Royal Economic Society (RES), the European Association of Labour Economists (EALE), and relevant NHS wellbeing events.

- Policy-Makers: A short, plain-English policy briefing will be prepared and made available on the IFS website. This will synthesise the implications of our findings for workforce wellbeing policy, particularly within the NHS. The briefing will be distributed to over 2,500 contacts on the IFS policy mailing list, which includes civil servants, NHS managers, and parliamentarians. The research team will also use IFS and UCL's established channels to engage directly with policymakers, including meetings with MPs and Department of Health officials. These will include both formal briefings and informal roundtable discussions aimed at exploring scalable workforce wellbeing interventions.

- NHS and Practitioner Stakeholders: Throughout the project, we will maintain active communication with the Ambulance Service Trusts that joined the study as well as with NHS England, to ensure findings are relevant and visible to the professional community. Regular updates will be shared with our NHS collaborators (Lead of the R&D units at the Ambulance Trusts), and we will present findings to their broader staff networks. The DLF, through its UK Executive Director Dr Deirdre Parsons, will support dissemination to other NHS Trusts and global health organisations already partnering with DLF. As part of this effort, we will share study updates and findings at DLF-affiliated events and in their newsletters.
- Media and Public Engagement: Once key findings are available, we will coordinate press releases via UCL, IFS, and DLF. These will be tailored to highlight different aspects of the study (health outcomes, economic relevance, and organisational impact), targeting both mainstream media and professional outlets like Health Service Journal and British Medical Journal Opinion. This multi-pronged dissemination strategy ensures the research reaches stakeholders who can act on the evidence—from policymakers and NHS decision-makers to scholars and wellbeing practitioners.

Dissemination to Study Participants: Participants will be notified of the study outcomes via a summary of the key findings, provided in plain English. This summary will be sent to them directly via email after the Final Study Report has been compiled and the main results have been publicly disseminated through academic publications.

Public Availability of Study Documents and Data:

- The Study protocol will be made publicly available on a suitable study registry (e.g., ISRCTN) and/or the host institution's research repository upon ethical approval.
- The full Study report will be accessible through academic publications, working paper series, and the host institution's repository.
- The anonymised participant-level dataset will be made publicly available for secondary research through deposit in the UK Data Archive (UKDA) three years after the completion of the project, with access under standard UKDA terms and conditions.
- The statistical code used for generating the results will be made publicly available in the journal that publishes the results to facilitate reproducibility and transparency.

13.2 Authorship eligibility guidelines and any intended use of professional writers

The primary authors of the final Study report and main academic publications will be Veruska Oppedisano (Principal Investigator) and Gabriella Conti (Co-Investigator), as the two researchers leading the study. Other individuals who meet the ICMJE criteria for authorship will be included as named authors. Those who contribute to the study but do not meet all criteria for authorship will be acknowledged appropriately. No professional medical writers will be hired for the preparation of the final Study report or any publications stemming from this research. All writing will be undertaken by the named authors and the core research team.

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15. APPENDICES

Study management / responsibilities

Data management

Veruska Oppedisano (Chief Investigator) holds the overall responsibility for data management within the study. All data management activities will be conducted internally by the research team; no part of the data management process (e.g., database hosting, data entry, external quality control, or statistical programming) will be outsourced to a third party or centralised beyond the immediate research team.

Data will be collected directly from participants via Jotform, a secure online platform. Participants will enter their responses using their unique study ID numbers, ensuring that personally identifying information is not collected alongside their responses, as detailed in Section 12.7 (Data Protection and Patient Confidentiality).

The research team will perform systematic quality checks on the collected data. These checks will be conducted at each follow-up point (3, 6, and 9 months) to monitor data completeness, accuracy, and consistency. Key data management activities include: quality checks (regular review of submitted data to identify any inconsistencies, errors, or outliers); handling missing data as specified Statistical Analysis Plan.

Following the completion of the final 9-month follow-up data collection the study database will undergo a final quality review. The database is anticipated to be locked approximately 1 month after the final participant's 9-month follow-up data has been received and verified. No further changes to the data will be permitted after database lock without formal amendment and documentation.

All study data will be stored securely, adhering to the principles outlined in Section 12.7 (Data Protection and Patient Confidentiality), including the use of encrypted digital files within passwordprotected folders and restricted access to authorised personnel only.

Data protection/confidentiality

For example, describe the potential sharing of personal confidential data and sensitive information between participating sites and the Sponsor organisation or with the CRO/CTU acting on their behalf. It should address the difference between data entered into a secure and validated database with access restricted to key study personnel in line with whatever the participants have consented to in the ICF OR, alternatively, the lawful basis for sharing without consent. Data that may be sent directly e.g. via NHSmail should also be handled in accordance with local organisation policies and processes and guidance is available here https://digital.nhs.uk/services/nhsmail/guidance-for-sending-secure-email

The study operates on a principle of data minimisation, ensuring that personal confidential data is accessed only by those strictly necessary for specific, defined purposes.

- The **David Lynch Foundation UK**, as the entity responsible for delivering the Transcendental Meditation (TM) intervention, will necessarily have access to participants' names and contact details. This access is solely for the purpose of scheduling, facilitating, and delivering the TM training and subsequent support sessions to the allocated participants. The lawful basis for this processing is for the performance of the intervention delivery.
- The research team will not have access to participants' names or any directly identifying information. All research data collected, primarily through online forms via Jotform, will utilise the unique study ID numbers assigned to participants. This ensures that the data analysed by the research team is de-identified at the point of collection, thereby preventing the reidentification of individuals.
- As outlined in Section 12.7, the file linking participant names to their unique study ID numbers will be securely stored and encrypted by the DLF, acting as the custodian of this linkage file, entirely separate from the de-identified research data accessed by the research team.

Data Flow and Security Measures:

- Participant recruitment and initial consent will occur online via the Jotform platform.
- Contact details (names and necessary contact information) will be securely shared from the recruiting sites with the David Lynch Foundation UK for the sole purpose of intervention delivery.
- All research data related to outcomes and assessments, using only participant ID numbers, will be entered directly by participants into a secure and validated online database (Jotform) with access restricted to key study personnel in line with what participants have consented to in the Informed Consent Form.
- Any transmission of personal confidential data, where absolutely necessary (e.g., for initial setup or query resolution), will be handled in strict accordance with local organisation policies and processes, utilising secure methods such as NHSmail, adhering to guidance available from NHS Digital.

Study documentation and archiving

Veruska Oppedisano (Chief Investigator) will be responsible for overseeing the archiving of the essential study data and documentation. This includes the final study dataset, the secure linkage file

(as detailed in Section 12.7), and all key study-related documentation (e.g., final protocol, consent forms, ethical approvals, final study report).

The main study dataset and all essential study documentation will be archived securely at University of Westminster in accordance with institutional policies. These documents and data will be retained for a minimum period of **5 years after the completion of the study**, as further specified in Section 10.4 (Access to Data) and Section 12.7 (Data Protection and Patient Confidentiality).

Appendix –Schedule of Procedures

Time Point	Assessment	Method	Estimated Duration
Baseline (Prerandomisation)	Primary and secondary psychological and wellbeing outcomes, work-related stress.	Online survey (Jotform)	~15 minutes
Post-Intervention (3 months after baseline) 6 months after baseline	Primary and secondary psychological and wellbeing outcomes, work-related stress.	Online survey (Jotform)	~15 minutes
9 months after baseline (End of trial)	Primary and secondary psychological and wellbeing outcomes, work-related stress, end-of -trial feedback on study experience.	Online survey (Jotform)	~15 minutes
Twice monthly **(Weeks 1–39)**	Semi-structured interviews with ~25 participants who completed all the interviews assessments	Online video	~30-40 minutes
	Absence reports including reason (e.g., mental health, physical health, other).	Online form (Jotform)	~2 minutes

Demographic information, baseline

Online survey

Protocol_RCT_nonCTIMP_TM_v7

Final Audit Report 2026-07-10

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