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**Mindfulness-Based Cognitive Therapy for Life (MBCT-L) v. Stress-Reduction Psychoeducation (SRP) for the improvement of mental wellbeing in healthcare, social care and teaching professionals**

**Final Version**

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# SYNOPSIS

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| --- | --- |
| Title | Mindfulness-Based Cognitive Therapy for Life (MBCT-L) v. Stress-Reduction Psychoeducation (SRP) for the improvement of mental wellbeing in healthcare, social care and teaching professionals |
| Short title | Mindful Life-Well at Work |
| Chief Investigator | Dr Elena Nixon |
| Objectives | Primary objective: To assess the superiority outcome of Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) vs. Stress-Reduction Psychoeducation (SRP) in change on perceived stress from baseline at 20 weeks post randomisation.  Secondary objectives: To assess change on outcome measures of mental wellbeing and psychological state (i.e., perceived stress, anxiety, depression, trauma, burnout, mindfulness), and work engagement, satisfaction and performance (incl., presenteeism, absenteeism, turnover intention) from baseline (prior to the start of the intervention) at 6, 12 and 20 weeks post randomisation. It is also aimed to gather other participant characteristics and intervention-specific data, including health economics data for a future cost effectiveness analysis.  Additional objective: To gather qualitative outcomes through semi-structured interviews with a subsample of recruited staff at 20 weeks post randomisation: perceived impact regarding wellbeing and quality of life as well as job-related outcomes; the nature of support required; and the drivers and barriers to intervention access, engagement and acceptability, including recommendations for improved future delivery. |
| Trial Configuration | A single-blind, multi-centre, parallel-group, two-arm superiority RCT, in order to compare the effectiveness of Mindfulness Based Cognitive Therapy- for Life (MBCT-L) over Stress-Reduction Psychoeducation (SRP) in staff working in the public sector (healthcare, social care and teaching) who access integrated care systems/wellbeing Hub for staff through Trust services |
| Setting | The study will be based across 4 public care sites over 3 geographical regions, i.e., East Midlands (Nottingham University Hospitals NHS Trust; Nottinghamshire Healthcare NHS Foundation Trust); South of England (Sussex Partnership NHS Foundation Trust); and North of England (Tees, Esk and Wear Valleys NHS Foundation Trust). |
| Sample size estimate | 5 points on PSS-14 (Perceived Stress Scale; primary outcome) will be considered as the minimum clinically important difference. To test such a treatment effect from baseline at 20 weeks post randomisation, at two-tailed 0.05 significance level with 90% power using ANCOVA, and assuming that SD=7.7, the correlation between baseline and follow-up is 0.2 and the correlation among follow-up measures is 0.7, 76 participants in total will be needed. Assuming the average group size is 8, ICC=15% and attrition rate=38% (considering potential loss to follow-up), the final sample size will be inflated to 260 participants to be recruited from 26 groups (1:1 ratio) across all sites. The interview subsample of n=30 is deemed to be sufficient for thematic analysis as per previous studies [38] |
| Number of participants | 260 participants to be recruited from 26 groups (1:1 ratio) across all public care sites; 130 participants from 13 groups in each arm/intervention. A subsample of 30 participants (15 in each arm/intervention) will be recruited for the interview part of the study. |
| Eligibility criteria | Inclusion criteria: (a) in part-time/full-time or honorary/voluntary employment and seeking access to well-being support through one of the four sites; (b) currently in work (i.e., not on sickness absence); (c) aged 18 years or over; (d) competent command of verbal and written English language; (e) access to stable internet connection on a pc/laptop/tablet.  Exclusion criteria: (a) concurrently attending or planning to attend a psychological or well-being programme in the next three months. (b) current diagnosis of a mental health condition from a GP or specialist mental health professional or (c) experience of significant life events currently causing significant distress). If participants meet exclusion criteria, the therapist team will direct them to other MBCT/Stress Reduction programmes that are routinely offered by the respective public care provider or to other available support as appropriate. |
| Description of interventions | A Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) programme which includes 8 two-hour weekly sessions plus a half day online practice. The programme will run over 9 consecutive weeks, or over 10 weeks if a one-week break is included (e.g., due to school break or holidays).  A Stress-Reduction Psychoeducation (SRP) programme which includes 4 two-hour weekly sessions. The programme will run over 4 consecutive weeks, or over 5 weeks if a one-week break is included (e.g., due to school break or holidays).  Both interventions will be delivered online via Microsoft Teams or Zoom and will require daily home practice (30-45 mins). Both interventions will start in the same week for the purposes of synchronising the follow-up data collection. |
| Duration of study | The study duration will be 24 months. The study terminates in September 2024. Participant participation is 20 weeks post randomisation with follow-up questionnaires at 6, 12 and 20 weeks. Participation in the interviews (for a subsample of 30 participants) will be at Week 20 post randomisation (allowing an 8-week time window for interviews to be carried out around Week 20). |
| Randomisation and blinding | Once participants have consented on the Research Electronic Data Capture (REDCap) platform, researchers assessing outcome measures will be blinded to treatment allocation. The project administrator who will be involved in the randomisation will be notified through RedCap so as to enable the facilitation of participant recruitment on the intervention groups running during each of the three recruitment waves. Randomisation will be conducted via a Clinical Decision Support System (CDSS) offered through the University of Nottingham (sponsor).  Single blinding: Researchers/research team members will be blind to the participant allocation arm. It is not possible for participants to be blind to the intervention because of its evident nature. There will be 3 recruitment waves with interventions starting at various time points during a given recruitment wave but with both interventions starting in the same week (to allow synchronised data collection). |
| Outcome measures | QUANTITATIVE OUTCOMES  Primary  Perceived Stress Scale-14 (PSS-14; [39])  Secondary  *Mental Wellbeing*  Generalised Anxiety Disorder scale-7 (GAD-7; [40])  Patient Health Questionnaire- 9 (PHQ-9; [41])  The International Trauma Questionnaire (ITQ; [42])  Five Facet Mindfulness Questionnaire (FFMQ; [43])  Copenhagen Burnout Inventory (CBI; [44])  *Work engagement, satisfaction and performance*  Utrecht Work Engagement Scale- 9 item (UWES–9; [45])  *Health-related quality of life (HRQoL)*  EQ-5D-5L [50]  Health economics assessment (CSRI-adapted): outcomes include presenteeism, absenteeism, turnover intention, mental health service/care uptake, staff tariff, etc.  QUALITATIVE OUTCOMES  •Perceived changes in wellbeing, psychological state and quality of life (i.e., beneficial impacts, any adverse events);  •Perceived changes in work satisfaction and performance (i.e., beneficial impacts, any adverse effects);  •Nature of support sought and on whether the given intervention has met participants’ expectations  •Barriers and drivers to intervention route to uptake, attendance, engagement and adherence (including aspects related to the intervention delivery and content/structure, personal or work circumstances, managerial support, etc.);  •Recommendations for future improvement of intervention design and implementation. |
| Statistical methods | Quantitative data: All analysis will be conducted on an Intention-to-Treat (ITT) basis. Participants’ outcomes, demographic and other intervention-related variables will be summarised by intervention arm and across the follow up times, if repeatedly measured, with mean (SD) for normally distributed variables, median (IQR) for skewed variables and frequency (percentage) for categorical variables. Missing values will be explored and imputed using a Multiple Imputation approach under Missing At Random assumption for missingness mechanism [52]. Sensitivity analyses will be performed to explore the robustness of treatment effect estimate sensitive to the method of handling missing values, various limitations of the data, assumptions, and analytic approaches to data analysis. A detailed trial Statistics Analysis Plan (SAP) setting out full details of the proposed analyses will be finalised before the trial database is locked for final analysis. The latest STATA software version will be used for the data analysis;  The outcome measure used for a within trial economic evaluation will be QALYs, estimated using the EQ-5D-5L and valued using the recommended tariff at the time of analysis [47]. Using this information on costs and benefits, an incremental cost utility analysis will be conducted and reported using accepted methodology, including cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at a range of threshold values for the willingness to pay per QALY [48]  Qualitative data: Based on the appropriateness of data as per previous studies and our pilot data, Thematic Analysis is intended to be applied to the transcribed data from the semi-structured interviews, guided by key principles of Grounded Theory and the Braun & Clarke 6-step thematic analytical approach [38] and using N-Vivo coding software. |

# ABBREVIATIONS

AE Adverse Event

AHSN Academic Health Science Network

ARC Applied Research Collaboration

BAME Black, Asian and Minority Ethnic

CBT Cognitive Behavioural Therapy

CDSS Clinical Decision Support System

COVID-19 Coronavirus Disease 2019

CI Chief Investigator overall

CLAHRC Collaboration for Leadership in Applied Research and Care

Co-I Co-Investigator

Co-PI Co-Principal Investigator

CBI Copenhagen Burnout Inventory

CRF Case Report Form

CSRI Client Service Receipt Inventory

DMC Data Monitoring Committee

EM East Midlands

EQ-5D-5L EuroQol- 5 Dimension- 5 Level

FFMQ Five Facet Mindfulness Questionnaire

FLO Florence telehealth texting system

GAD-7 Generalised Anxiety Disorder scale- 7 item

GCP Good Clinical Practice

HEE Health Education England

HRQoL Health-Related Quality of Life

IAPT Improving Access to Psychological Therapies

ICF Informed Consent Form

ICS Integrated Care Systems

ITQ International Trauma Questionnaire

ITT Intention To Treat

MBCT Mindfulness-Based Cognitive Therapy

MBCT-L Mindfulness-Based Cognitive Therapy- for Life

MBSR Mindfulness-Based Stress Reduction

NHS National Health Service

NICE National Institute for Health and Care Excellence

NIHR National Institute for Health and Care Research

NHNFT Northamptonshire Healthcare NHS Foundation Trust

NHFT Nottinghamshire Healthcare NHS Foundation Trust

NUH Nottingham University Hospitals NHS Trust

PHQ-9 Patient Health Questionnaire- 9 item

PI Principal Investigator at a local centre

PIS Participant Information Sheet

PPI/E Patient and Public Involvement/Engagement

PSS Perceived Stress Scale

RCT Randomised Controlled Trial

REC Research Ethics Committee

REDCap Research Electronic Data Capture

R&D Research and Development department

SAE Serious Adverse Event

SAP Statistics Analysis Plan

SPFT Sussex Partnership NHS Foundation Trust

SRP Stress-Reduction Psychoeducation

TAU Treatment As Usual

TEWV Tees, Esk and Wear Valley NHS Foundation Trust

UWES-9 Utrecht Work Engagement Scale- 9 item

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# TRIAL / STUDY BACKGROUND INFORMATION AND RATIONALE

**The problem being addressed/why this research is important in terms of improving the health or social care service provision:**

Public sector employees, particularly in healthcare teaching and public care services, present with higher levels of stress compared to those in other industries, with healthcare staff in particular experiencing disproportionately high stress levels [1; 2]. Work-related stress, defined as ‘a harmful reaction that people have to undue pressures and demands placed on them at work’ [1: p4], has been reportedly further exacerbated by the COVID-19 pandemic which has imposed additional stressors in the workplace, especially in healthcare staff [3; 4; 5]. In 2020/21 stress, depression or anxiety accounted for 50% of all work-related ill health, with the total number of cases of work-related stress, depression or anxiety being 822,000, a prevalence rate of 2,480 per 100,000 workers in human health, social care and education industries [1: p5]. Excessive stress and mental health problems such as anxiety and depression in public sector staff have been broadly associated with negative individual-level outcomes, such as emotional labour, burnout, compassion fatigue and reduced quality of life; as well as negative organisational outcomes, such as poor job satisfaction, presenteeism, absenteeism and leaving work, including also poor care provision [6; 7; 8].

**How the research addresses NHS/STP/Integrated Care Systems and other commissioning priorities:**

The ARC-EM Mental Health and Well-being Theme in its response to the COVID-19 pandemic has organised a programme of work around the mental health and wellbeing of National Healthcare Service (NHS) and other public service staff during and after the pandemic to address the NHS priority on preventing, improving and promoting mental wellbeing. This work included the Wellcome-funded study GAINS study involving an online game of Tetris used to prevent traumatic memory formation in intensive care unit staff, and the large-scale observational NHS Check study with over 25,000 staff from 18 NHS Trusts across the UK, 3 of which were based in the East Midlands. Preliminary cross-sectional data analysed from a cohort study of 4378 healthcare (clinical and non-clinical) staff showed high rates of psychological distress during the COVID-19 pandemic, with 58.9% of the cohort reporting case levels of anxiety, depression or post-traumatic stress disorder symptoms [9]. Standardised psychiatric interviews showed that actual cases of mental disorder were substantially lower suggesting that the case levels of psychological distress represent an ‘at risk group’ for mental disorder, burnout, sickness absence or leaving the health service early. Especially affected were recently qualified nurses and were as high in community settings as in intensive and critical care units and emergency rooms. There was also evidence to suggest that participants from certain demographic and occupational groups (i.e., racial and ethnic minority groups and men) were less likely to take part in the study. Preliminary data extended nationally from the NHS Check study survey also seem to indicate that in addition to the standard stress-reduction courses, of the most common individual-level staff interventions NHS Trusts use to improve their staff wellbeing during the pandemic were online mindfulness-based approaches.

Mindfulness-based and stress-management training are two approaches that have been recently recommended by the National Institute for Health and Care Excellence (NICE) [10], as effective individual-level psychotherapeutic interventions to be delivered in either online or face-to-face group modality to healthcare or other public care employees who have or are at risk of poor mental health. While NICE recognises that organisational and managerial level policies and practices are important to address work-related issues, particularly in relation to ensuring equality and job satisfaction, the committee highlighted that local commissioners and healthcare providers have a responsibility towards enabling staff to take up such wellbeing interventions within a supportive organisational culture and climate. This is of particular importance given the ongoing impact of COVID-19, and especially in consideration of its impact on individuals from BAME or deprived socio-economic backgrounds. The committee also stressed the potential resource impact for offering such interventions at work.

**What is already known about the issue/how the existing literature supports the proposal/how stakeholders have influenced the proposal:**

In the NICE review conducted to establish the evidence base for the effectiveness (and cost effectiveness) of psychological interventions in preventing ill-health and/or improving mental health, 5 Randomised Controlled Trials (RCTs) on the use of mindfulness-based interventions [11; 12; 13; 14; 15] and 5 RCTs on the use of stress reduction or management interventions [16; 17; 18; 19; 20] were reported in targeted occupational sector groups. On the basis of the reviewed evidence, the committee recommended both intervention approaches as effective for improving mental health and work-related outcomes in public sector staff who are at risk of poor mental health [10].

While a broad range of organisational- and individual- level wellbeing interventions are being offered in NHS Trusts and other public sector workplaces, stress reduction psychoeducation (SRP) is the standard usual care group programme offered widely to NHS, as well as to other public sector staff where applicable (e.g., social care and teaching staff), across all 15 regions in England. SRP may vary in its content or structure and in the extent to which it will be taken up by staff at different sites but is routinely available as a programme of 4 sessions offered through Improving Access to Psychological Therapies (IAPT) or NHS Trust or other integrated services; for example, a 4-session SRP is being offered to all staff in Northamptonshire Healthcare NHS Foundation Trust (NHFT) as well as in other regions, based on preliminary findings of the national NHS Check study of 18 NHS Trusts across the UK [9]. Mindfulness-based Cognitive Therapy-for Life (MBCT-L) [31] is a newer, third-wave intervention, based on the mindfulness approach and is becoming increasingly popular in NHS and other public sector services. MBCT-L borrows its premises from the standard MBCT variant which was originally developed to prevent relapse in recurrent depression [21] and is now a NICE-recommended treatment option for recurrent [22] as well as mild-to-moderate active depression [50], and is also included in the clinical guidelines as a relapse prevention option in other countries too [23; 24;25]. However, MBCT-L is an adaptation tailored to non-clinical populations and has been shown to be effective in improving wellbeing and mental health outcomes in various samples, including healthcare workers, as evidenced by the published work of members of the research team too [26; 27; 28; 29; 30]. It is currently being offered as a group programme through Integrated Healthcare Services for healthcare and other public care staff in a limited number of sites across the UK (e.g., Nottinghamshire, Oxford, Teeside and York, Exeter, Sussex) while commissioners seem to be keen on investing increasingly more resources to provide this type of intervention to staff within their services.

The presumed advantage of MBCT over other mindfulness-based variants such as Mindfulness-Based Stress Reduction (MBSR) programmes, and over CBT and stress reduction psychoeducational approaches, is that it is an enhanced approach that combines both stress reduction and cognitive behavioural elements in one programme, embedding mindfulness practice too [32]. The MBCT-L variant, in particular, having been adapted to apply to non-clinical mental health needs, consists of a behavioural element that utilises relaxation and mindfulness techniques to reduce stress and a cognitive element focussed especially on cultivating a long-term change in one’s attitude to stress promoting a more positive outlook to stressful experiences and life more generally. Compared to stress-reduction approaches, MBCT-L goes beyond transient relaxation and utilises MBCT-based cognitive techniques with mindfulness practice so as to teach individuals how to become aware of their cognitive reactivity patterns, which result from habitual thinking and behavioural reactions associated with stress and negative thinking; and how to ‘decenter’ themselves from that negative thinking by treating stressful events and reactions as transient mental events –rather than facts as in CBT- that will eventually resolve themselves; this psychological detachment that comes with acceptance of all experiences –positive and negative- and compassion towards oneself and others helps build up adaptive coping techniques, resilience to future stressors and an overall positive psychology outlook to life [21, 32, 33, 34]. On the other hand, stress-reduction psychoeducation (SRP) or stress management approaches are based on core stress-reduction elements which employ behavioural relaxation techniques; the psychoeducational premises embedded in such approaches adopt the view that stress is a concept with negative implications and hence needs to be targeted upon and alleviated [51]. Psychoeducation on available exercises and techniques to reduce stress coupled with wellbeing and goal setting typically form the basis of a SRP programme.

The two approaches differ in their conceptual and practical premises but have not yet been compared to one another in terms of their effectiveness in improving stress and other wellbeing aspects and job-related outcomes. The reviewed study findings of the recent NICE guidance [10] indicated larger effects of face-to-face mindfulness-based approaches on stress and other mental health and job-related outcomes than stress-reduction interventions which were delivered either face-to-face or online, in at risk public sector populations. Moderate quality evidence suggested that mindfulness-based approaches are effective in improving mental wellbeing, mental health symptoms and absenteeism in targeted populations (including healthcare staff). Very low-quality evidence suggested that such mindfulness interventions may improve job stress in a targeted population. None of the mindfulness studies were UK based. As for stress-reduction approaches, moderate quality evidence indicated that SRP was effective in improving job satisfaction, quality of life, and mental health literacy in targeted high-risk populations (including healthcare staff). Low and very low-quality evidence hinted that stress management might be effective in improving job stress and mental health symptoms in targeted populations. There was only one UK study [20] in a healthcare sector (student nurses). While all mindfulness trials included in the review were delivered face-to-face, stress management interventions were either face-to-face or online. All five mindfulness and all five stress management studies had a wait-list or usual care as a comparator, or no wellbeing comparator intervention. The five mindfulness-based studies included in the NICE review contained elements of mindfulness-based stress reduction, with one study [15] reporting using mindfulness-based stretching and deep breathing exercises. All five stress-management interventions used stress-management techniques (e.g., relaxation exercises, psychoeducation, etc.) but it appears that at least in a couple of studies cognitive-behavioural elements were also included [16; 20]. It is therefore not clear what elements are contributing to the effectiveness of either intervention, i.e., whether these are merely relaxation-based behavioural techniques or are aided by cognitive-behavioural elements. Finally, there is a lack of qualitative data on the two interventions in the studies reviewed by NICE. The qualitative data reviewed were derived from only one study that used a digital CBT approach in employees (of not specified sector) and indicated that there are a number of positive aspects of the digital modality of such an intervention such as convenience and discreteness or anonymity while specific barriers (e.g., time pressures) and drivers (e.g., managerial support) were reported to impact on engagement with the intervention.

In a recent study that was not included in the NICE review, led by a Co-I on this proposal (CS) (MBCT-L was compared against a wait-list control in healthcare staff (face-to-face; prior to COVID-19) and showed beneficial effects, i.e., moderately large effects on the primary outcome of stress and large effects on secondary outcomes of anxiety, depression, wellbeing, mindfulness and compassion. The programme did not address though work-related outcomes of burnout, presenteeism and absenteeism [36]. Preliminary work led by the PI on this proposal (EN) shows comparable effects of an online MBCT-L intervention in NHS healthcare staff to the benefits shown in the NICE review of face-to-face mindfulness interventions in the public sector workplace (see Pilot data below).

Pilot data from healthcare staff (n=25) based at Nottinghamshire Healthcare NHS Foundation Trust and having completed one of 5 online MBCT-L groups since COVID-19 have shown: a statistical trend for clinically important post-MBCT-L improvements on perceived stress (Mean (SD) change=8.84 (0.06), with a drop from upper end [Mean=28.52 (7.41)] to lower end [Mean=19.68 (7.35) of ‘moderate’ stress on PSS-14 [39]; on depression [Mean (SD) change= 4.42 (2.20)], with a drop from M=9.26 (5.82) to M=4.84 (3.63) on PHQ9 [41]; and on mindfulness [M (SD) change=32 (0.75)], with an increase from M=108.32 (15.09) to M=140.32 (15.84) on the FFMQ [43]. Qualitative data (n=22/25) obtained through semi-structured interviews and analysed using thematic analysis denoted that staff found the MBCT-L sessions to be overall enjoyable and helpful. Participants reported a range of perceived beneficial impacts, including markedly reduced stress levels, a sense of empowerment due to enhanced coping ability, increased mindfulness levels leading to a more positive mind frame and outlook to life as well as increased job performance in terms of increased concentration and efficient task delivery at work. Staff perspectives on the group delivery were overall positive, with some expressing a need for the group size to remain small/become smaller (group numbers ranged from 7 to 12) to keep engagement levels optimal and with the majority reporting the length and amount of home practices (homework) as a barrier to full commitment to MBCT-L practice outside the sessions. Of the 43 participants who enrolled on the MBCT-L programme, all completed at least 4 out of the 8 sessions, with 5 participants attending only 1 to 3 sessions (11.63% attrition rate). Further research funded in part by NIHR CLAHRC East Midlands by members of our research group showed that the incorporation of text messaging prompted more frequent practice of mindfulness practice during the intervention and afterwards [37]. Such increased practice enhanced the effects of mindfulness CBT on other outcomes. Since this text-based approach is now being incorporated into NHS MCBT-L at Nottingham, we are embedding it into the MCBT-L intervention in this trial. This texting service is not being used in SRP as no role for it in this intervention has been identified.

In light of the lack of studies comparing mindfulness-based and stress-reduction psycho-education approaches, and the lack of online mindfulness studies in the NICE review, it is imperative that the two interventions are assessed in an RCT for their effectiveness and cost effectiveness in an online modality. While the two approaches differ in their conceptual and practical premises, they are being implemented across the UK and increasingly in digital formats in light of the realisation that digital modalities can overcome main barriers to intervention uptake and adherence (e.g., reducing need of travel, reducing anxiety due to eliminating direct face-to-face exposure, etc.) and can reduce resource costs. Notably, MBCT-L is a longer programme and one that is not being offered across all regions while the 4-week SRP is available widely as standard care. MBCT-L also requires more highly skilled practitioners to run the sessions than SRP. All put in context, given the large effects on wellbeing of MBCT-L in the first and only RCT to date [36] and in light of the fact that it is supported by the NICE review findings of mindfulness based approaches, which we have locally replicated in an uncontrolled feasibility and acceptability study (EN pilot study), we believe that MCBT-L might be a better investment for NHS and other public sector staff if it was found to be more effective and cost effective. Finally, given the lack of qualitative data pertaining to the effectiveness and acceptability of such interventions, the inclusion a qualitative component is deemed to be pertinent in a comparison trial. The currently proposed superiority trial will assess the effectiveness and cost effectiveness of the two approaches, aiming to also gather in-depth qualitative data that can inform future practice, in order to guide NHS and other public sector organisations in their decisions about how to best retain and support their staff at risk of poor wellbeing.

Specifically the rationale for the proposed study is based on the following derived assumptions:

a) The NICE review did not include an evidence base to show how a mindfulness-based approach compares to a stress-reduction approach; there has since been 1 RCT study [36] publishing findings that demonstrate large wellbeing benefits of MBCT-L as compared to a waiting list control while the rest of the literature on online non-controlled MBCT studies also involved comparisons to waiting list controls which can inflate the effect size of the intervention;

b) MBCT-L combines both relaxation and mindfulness as well as cognitive elements to cultivate the view that stressful experiences should be viewed in a positive light by accepting them and nurturing a positive outlook to life; while SRP views stress as a negative experience aimed at reducing it mainly through relaxation techniques. MBCT-L hasn’t been compared yet to a psychoeducation approach in terms of its effectiveness (and cost effectiveness) while it is increasingly being implemented in public care sectors across the UK; and the NHS Check study provides evidence that online mindfulness-based approaches are of the most widely used individual interventions for staff;

c) The mindfulness studies reviewed seemed to rely on mindfulness-based stress reduction approaches (largely without cognitive elements embedded) while some of the SRP studies included cognitive elements in their content/exercises; the MBCT-L approach includes both stress reduction as well as cognitive elements and a comparison to a stress-reduction intervention per se is therefore required to shed light on whether stress reduction techniques alone as delivered through SRP can lead to improved wellbeing and other benefits;

d)The mindfulness studies reviewed by NICE were all face-to-face while some of the SRP studies reviewed were delivered digitally hence there is no evidence base for the effectiveness of mindfulness-based studies in an online modality;

e) The NICE review suggested that for healthcare and other employees mindfulness-based approaches had larger effects on stress and broader mental health outcomes plus work-related outcomes (absenteeism) than stress management interventions;

f) MBCT-L requires more skilled staff than SRP hence determining its effectiveness and cost effectiveness would inform the service providers which intervention would be best to invest on in terms of future practice;

g) The NICE review consolidated some qualitative data in relation to positive aspects and drivers and barriers to intervention uptake but only from 1 study which involved digital CBT. Our research team has acquired some preliminary thematic data from the reported pilot study on perceived impact and other factors including barriers and drivers to attendance and adherence. In light of the lack of qualitative evidence in this area, qualitative data are required in addition to the quantitative outcomes in order to get in-depth information on staff’s perceived impact of the interventions on their wellbeing and quality of life, on job-related outcomes, the nature of the support required as well as their views on the delivery and acceptability of such interventions.

# TRIAL / STUDY OBJECTIVES AND PURPOSE

## PURPOSE

The overall aim of the proposed RCT is to determine whether an online 8-week (plus 1 week top-up) MBCT-L is superior to an online 4-week SRP in reducing perceived stress and improving other mental health and job-related outcomes in national healthcare as well as other public sector service employees (i.e., social care and teaching staff).

## PRIMARY OBJECTIVE

To assess the superiority outcome of Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) vs. Stress-Reduction Psychoeducation (SRP) on perceived stress from baseline (prior to the start of the intervention) at 20 weeks post randomisation.

## SECONDARY OBJECTIVES

To assess change on outcome measures of mental wellbeing (i.e., stress, anxiety, depression, trauma, burnout), and work engagement, satisfaction and performance (i.e., presenteeism, absenteeism, turnover intention) from baseline (prior to the start of the intervention) at 6, 12 and 20 weeks post randomisation. It is also aimed to gather other participant characteristics and intervention-specific data, as well as health economics data for a future cost effectiveness analysis (if an additional funding of 6 months is awarded).

An additional objective will relate to gathering qualitative outcomes through semi-structured interviews with a subsample of recruited staff at 20 weeks post randomisation, within an 8 week time window. The aim is to gain more in-depth information into the perceived impact of the intervention on: wellbeing and quality of life as well as job-related outcomes; the nature of support required; and the drivers and barriers to intervention access, engagement and acceptability, including recommendations for future delivery.

**DETAILS OF PRODUCT(S)**

**Description**

This RCT will not involve the use of any medicinal/technological products. The products are digitally delivered Mindfulness-Based Cognitive Therapy- for Life (MBCT-L) and digitally delivered Stress-Reduction Psychoeducation (SRP); via synchronous Microsoft Teams or Zoom delivery. They are both NICE recommended interventions to reduce staff stress and burnout and such interventions are already procured by NHS providers.

# TRIAL / STUDY DESIGN

A single-blind, multi-centre, parallel-group, two-arm superiority RCT, in order to compare the effectiveness of Mindfulness Based Cognitive Therapy- for Life (MBCT-L) over Stress-Reduction Psychoeducation (SRP) in public care staff (healthcare, social care and teaching staff) seeking to access well-being support through Integrated Care Services/Wellbeing Hub or other communication channels through the Trusts. The study will be based across four public care sites over three geographical regions, i.e., East Midlands (Nottingham University Hospitals NHS Trust; Nottinghamshire Healthcare NHS Foundation Trust); South of England (Sussex Partnership NHS Foundation Trust); and North of England (Tees, Esk and Wear Valleys NHS Foundation Trust).

## TRIAL / STUDY CONFIGURATION

### Primary endpoint

The primary outcome for the study is change in the self-reported Perceived Stress Scale-14 (PSS-14) score from baseline to 20 weeks post randomisation. The primary endpoint will be to determine if there is a significant difference in change on the primary outcome of perceived stress (PSS-14) between the two groups on the Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) and Stress-Reduction Psychoeducation (SRP) arms from baseline (prior to the start of the intervention) at 20 weeks post randomisation. 5 points on PSS-14 will be considered as the minimum clinically important difference.

### Secondary endpointSecondary outcome measures will be collected at baseline, and 6,12 and 20 weeks post randomisation and will be the following.

### PSS-14, self-rated stress at 6, 12 and 20 weeks (Cohen et al, 1983)

### PHQ-9 , self rated depression at 6, 12 and 20 weeks (Kroenke et al., 2001).

### GAD-7, self-rated anxiety at 6, 12 and 20 weeks (Spitzer et al., 2006).

### ITQ, self-rated trauma at 6,12 and 20 weeks (Cloitre 2018)

### FFMQ, self-rated mindfulness levels at 6,12 and 20 weeks (Baer 2008)

### CBI measuring personal and occupational burnout at 6,12 and 20 weeks (Kristensen 2005)

### UWES-9, self-rated measure of work engagement at 6,12 and 20 weeks (Schaufeli 2006)

### EQ-5D-5L at 6, 12 and 20 weeks (EuroQol Group 2009).

### Measurement of costs from personal, health and social care perspectives using adapted version of the Client Service Receipt inventory (Beecham and Knapp 2001) at 6, 12 and 20 weeks.

### The secondary endpoints will be any significant differences in change in any of the secondary outcome measures (see secondary objectives) between the two groups from baseline (prior to the start of the intervention) at each follow-up time, i.e., 6, 12 and 20 weeks post randomisation.

### Safety endpoints

Any Serious Adverse Events (SAEs) will be reviewed and if there is any indication that these are linked to the intervention the research may be stopped on the advice of the independent ARC EM Scientific Committee.

### Stopping rules and discontinuation

## Data on the impact of the intervention on the primary and secondary outcomes will not be analysed until near the completion of the study period and therefore will not inform decisions to stop the research. However, any SAEs reported will be reviewed and if there is any indication that these are linked to the intervention consideration will be given to stopping on the advice of the ARC EM Scientific Committee and study Sponsor.

## Another reason for stopping the trial prematurely would be poor recruitment and engagement with the treatment intervention which does not improve despite attempts to engage the public care professionals across the four sites. If the targets for recruitment are not met at an interim recruitment wave review, the trial may be terminated on advice of the ARC EM Scientific Committee.

Should the trial stop prematurely, participants will be re-directed to alternative wellbeing courses offered through the integrated Care services/hub for staff or other organisations affiliated with the Trusts. The therapist team will support participants in directing them to appropriate programmes if needed.

## RANDOMIZATION AND BLINDING

Eligible and consented participants will be randomly allocated in a 1:1 ratio to either the MBCT-L or SRP intervention, at each or across the four sites in order to facilitate timely recruitment, until the two groups are full in each recruitment wave throughout the duration of the trial. Randomisation will be conducted via a web based randomisation system (set up by the University of Nottingham Clinical Database Support Service) The randomisation system will ensure that researchers/outcome assessors remains blind to intervention allocation notifications. All participants receive the same outcome measures so assessors will not know which group the participant is in by the measurements. The study statistician will also be blinded to treatment allocation. Participant allocation to either arm will be facilitated by the project administrator. In view of the interventions’ nature, participants will be informed of which treatment arm they have been randomised to and will be notified through a letter/email sent to them by the project administrator which will also include information on the delivery (e.g., dates and times, requirements for online attendance, etc.) of the intervention as well as instructions on how to set up/join MS Teams/Zoom for attending the intervention sessions.

### Maintenance of randomisation codes and procedures for breaking code

In case of a medical emergency, participants will be able to disclose to their health care professional (HCP) what treatment they received without unblinding the researchers. As such, an emergency unblinding system is not required for this study. Additionally, the participants will be having regular contact with therapists during the intervention who can provide further details on the intervention to a HCP if required.

At the end of the study treatment allocations will be revealed by the project administrator.

## TRIAL/STUDY MANAGEMENT

The Chief Investigator (CI), Dr Elena Nixon, has overall responsibility for the study and shall oversee all study management. The data custodian will be the Chief Investigator. To ensure the project runs to schedule, the project CI will hold 4-6 weekly meetings attended by the CI, trial statistician, Co-PI and other key Co-Is/members of the research team, Patient and Public Involvement and Engagement lead representative. Twice yearly meetings of all members of the research team will be held throughout the study. PPI groups consisting of 10 members of staff from various areas of the public sector (healthcare, social care and teaching) have already been formed and were consulted around the setting up of the trial. The PPI groups are intended to provide input into all key aspects of the research study, from study design to implementation, evaluation and dissemination through quarterly meetings and/or feedback via communication across the two years.

The trial will be overseen by the ARC EM Scientific committee and an independent Trial Steering Committee. We will report progress of the study to the ARC EM Scientific Committee who will monitor progress and will advise on any ethical or data-related issues that may arise. The study will be reviewed every 6 months through reports to this committee and presentations of progress to the committee by the research team. The members of the Trial Steering Committee are drawn from external institutions to ensure their independence to the research team. It will consist of an independent chair (subject expert), statistician and a Patient and Public Involvement/Engagement (PPI/E) staff representative. The sponsor will also be invited to the meetings as an observer. This committee will meet 5 times across the two years to review study progress and provide advice to the research team on strategic direction, informing and improving operational decisions and trouble-shooting where necessary.

## DURATION OF THE TRIAL / STUDY AND PARTICIPANT INVOLVEMENT

**Study Duration:** The total duration of the entire study will be 2 years, ending in September 2024. Recruitment of participants is expected to take place in three recruitment waves commencing in May 2023.

**Participant Duration:** Participant enrolment with the study will begin upon completion of the informed consent form and end upon the completion of the final follow-up questionnaire which will be at Week 20 post randomisation. For the subsample (n=30) of participants who will also take part in the interviews, end of participation will be upon the completion of the final interview at Week 20 post randomisation (allowing an 8-week time window at Week 20 to carry out interviews).

**End of the Trial:** The end of trial will be the date of the last follow up of the last recruited participant and/or the last interview of the last recruited participant.

## SELECTION AND WITHDRAWAL OF PARTICIPANTS

### Recruitment

Participants will be directed to the study through existing Integrated Care Services/Wellbeing Hubs which are accessed by public sector staff, i.e., in healthcare, social care and teaching, across the four public care sites, i.e., East Midlands Site: Nottingham University Hospitals NHS Trust & Nottinghamshire Healthcare NHS Foundation Trust; South of England: Sussex Partnership NHS Foundation Trust; and North of England: Tees, Esk and Wear Valleys NHS Foundation Trust. They will also receive information about the study through various other staff communication channels, e.g. through human resource communications, induction days and other staff wellbeing support sources or organisations affiliated with the Trusts. Communication of study information will be facilitated through a study flyer that will be circulated widely across the four sites by email and via other communication channels (e.g., staff communication hub, staff networks/newsletters, Facebook, Twitter, Induction days, etc).

Those expressing an interest in the study will be directed to a link which will include a copy of the Participant Information Sheet and an eligibility screening form. Potential participants will also be provided the contact details of the study researchers should they wish to ask any questions. Upon completion of the eligibility form eligible participants will be emailed a link to the participant consent form and the baseline assessment questionnaires.

It will be explained to the potential participant that entry into the trial is entirely voluntary and that their healthcare, work and legal rights will not be affected by their decision; and that we will not communicate to their employer their decision to participate in or withdraw from the trial. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. In the event of their withdrawal it will be explained that their data collected up to that point cannot be erased and we will seek consent to use the data in the final analyses where appropriate. It will be clearly stated in the PIS that potential participants who decide not to take part in the trial can proceed with enrolling on the respective or other wellbeing interventions delivered routinely at a given site (but are not part of the trial). For ITT purposes, as also stated in the PIS, participants will have the right to decide to not withdraw from the trial entirely but withdraw from the programme while they may still contribute to the trial by carrying on completing the online survey at the three follow-up time points; or that they can carry on with their participation in the programme but withdraw their partaking in the completion of the online survey at the follow-up time points.

### Eligibility criteria

We will aim to adopt minimal inclusion/exclusion criteria in order to mirror as closely as possible the routine enrolment policies already in place at the four sites.

### Inclusion criteria

(a) in part-time/full-time or honorary/voluntary employment seeking access to well-being support through one of the four sites

(b) currently in work (i.e., not on sickness absence)

© aged 18 years or over; no maximum age limit

(d) competent command of verbal and written English langua©(e) access to stable internet connection on a pc/laptop/tablet

### Exclusion criteria

(a) concurrently attending or planning to attend a psychological or well being programme in the next three months.

(b) current diagnosis of a mental health condition from a GP or mental health professi©l

(c) experience of significant life events currently causing significant distress

Exclusion criteria will be flagged up in the screening form upon registering interest for participation by the therapist team. The therapist team will manually check the content that has been included in the screening form by every participant and will initiate a meeting with the participant to discuss further and/or to refer ineligible participants to other MBCT/Stress Reduction programmes that are routinely offered by the respective public care provider or to other available support as appropriate.

### Expected duration of participant participation

Study participants will be participating in the study for 20 weeks post randomisation. Participants who will also take part in the interviews will be expected to partake in the trial until Week 20 post randomisation (within an 8 week time window).

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### Removal of participants from therapy or assessments/Participant Withdrawal

Participants will be informed (via the participant information sheet and consent form) that they are free to withdraw from the trial at any point and without having to give a reason for their withdrawal. Participants will be made aware that withdrawal from the study will not affect their current or future care, work or legal rights. Participants will be also be informed that should they withdraw their consent to participation in the trial/study, the data collected up to that point cannot be erased and may still be used in the final analysis.

Participants may be withdrawn from the trial either at their own request or at the discretion of the chief investigator in the very unlikely case of the participant’s welfare being at risk from continued participation in the study. If participants indicate to the research team/therapist on the intervention arm that they would like to withdraw from the trial entirely, they will be sent a non-obligatory withdrawal form by the research team to indicate the reason for their withdrawal (this will help inform the future development of trials and the intervention). Participants will not be requested to complete any further measures in the event that they withdraw from the trial. The reason, if given, will be recorded in a log of withdrawals, on their CRF and on the trial master file database. Once participants have withdrawn from the study it will not be possible to re-enter the trial or resume treatment. Withdrawn participants will not be replaced into the study. To meet our ITT purposes, participants will have the right to decide to not withdraw from the trial entirely but withdraw from the intervention whilst still carrying on completing the online survey at the three follow-up time points; or they can carry on with their participation in the intervention but withdraw their partaking in the completion of the online survey at the follow-up time points.

Any participant who experiences an AE may be withdrawn from the study at the discretion of the investigator. Every withdrawal will be examined by the ARC EM Scientific Committee which will be made aware of any AEs.

### Informed consent

Potential participants expressing an interest in the study will be provided with a study flyer consisting of a link to access information about the study. Upon accessing the link participants will be provided with a Participant Information Sheet. The contact details of the study researchers will be provided should the participant wish to discuss the study in more detail or ask any questions. Interested participants will then be directed to a screening form to determine eligibility. Eligible participants will be prompted to access an online survey link that will be built on a Research Electronic Data Capture (REDCap) platform through a notification e-mail; once they enter the online survey platform, they will be requested to complete a participant Consent Form (CF). All participants will provide informed consent that will be signed and dated online by the participant before they complete the baseline data and will be advised that they can exit and return to the survey at a later time point, although they will be instructed to aim to fill it in within one week. Participants will not be able to proceed to the completion of the questionnaires unless they have completed the CF agreed to participate in the study. In the CF, there will also be an option for participants to tick should they wish to be contacted by the research team at a later time point for participation in the semi-structured interview component of the study. Following online consent on the survey, participants will be prompted to proceed with the online completion of the baseline data (online survey/questionnaires). A link to the online survey will be sent to participants again at the three follow-up time points for completion; repeated assessment completion is clearly stated in the PIS as a requirement of the trial.

There will be a separate PIS and CF for the interview part of the study to be accessed in the same way as for the online survey, through a notification e-mail sent by the research team. Participants will be informed (via the PIS) that the research team can be contacted prior to giving consent or at any point throughout the study to answer any questions or address any concerns that they may have concerning study participation. Participants are informed that they do not have to answer any questions on the online survey or interview that they do not wish to answer and that they can offer as much or as little information they feel comfortable with. Participants can get a copy of the PIS and CF should they request this. Should there be any subsequent ethically approved amendment to the final protocol which might affect a participant’s participation in the trial, continuing consent will be obtained using an amended CF which will need to be signed again by the participant through the online survey link.

# TRIAL / STUDY TREATMENT AND REGIMEN

The study will recruit staff (healthcare, social care and teaching staff) based across four public care sites over three geographical regions, i.e., East Midlands (Nottingham University Hospitals NHS Trust; Nottinghamshire Healthcare NHS Foundation Trust); South of England (Sussex Partnership NHS Foundation Trust); and North of England (Tees, Esk and Wear Valleys NHS Foundation Trust). A total of 208 participants will be recruited from 26 groups (13 groups per arm) across the four public care sites within three recruitment waves.

Consented participants will complete primary and secondary measures at baseline (prior to the intervention), up to two weeks prior to randomisation; and at follow-up time points at Weeks 6, 12 and 20 post randomisation. A subsample of 30 participants (n=15 in each arm) will be recruited for the semi-structured interviews at 20 weeks (allowing an 8-week data collection window). See Trial Flowchart below.

**MBCT-L intervention:** The MBCT-L programme to be implemented integrates conventional Cognitive-Behavioural Therapy (CBT) techniques with stress reduction techniques as well as mindfulness practice, as in the original MBCT version, but has been adapted to apply to the general population as per established protocol [31]. The programme includes 8 two-hour weekly sessions plus a half day online practice session. The programme will run over 9 consecutive weeks, or over 10 weeks if a one-week break is included (e.g., due to school break or holidays). The programme will be run online (via MS Teams/Zoom) in a group-based format (~average of 8 participants per group; see sample size justification). Content includes weekly session theme teaching/discussions and guided meditation practices (e.g., breathing practice, body scan, etc.); as well as 30-45 minute everyday homework practices. Participants will receive frequent automated text reminders about their upcoming sessions and homework/home practices through the Florence telehealth texting system [37] which will be utilised to boost adherence to treatment, including home practice. The programme will be delivered by approximately 8 trained MBCT practitioners across the three sites who are part of the teaching team involved in the MBCT-L interventions already being offered to public sector staff through the services.

The MBCT-L programme broadly follows an overarching structure of: developing mindfulness skills intended to enhance attentional control and awareness; cultivating a deeper understanding of how distress is created and maintained and how mindfulness training can address factors that contribute to its maintenance; learning skilful ways of relating to experience developed through awareness and practice; learning to recognise unhelpful reactive patterns in everyday life and cultivate the capacity to respond to these with mindfulness and compassion. In the second part of the programme, participants practice on applying this learning to everyday life -including work- to combat stressors and enjoy the positive aspects of life.

SRP intervention: The SRP will be delivered in 4 2-hour weekly sessions run over 4 consecutive weeks, or 5 weeks if there is a one-week break (e.g., school break or other holidays) as it is currently being offered as standard care across Nottinghamshire IAPT services and across all the other regions in England (whether through IAPT or Trust or other services). Its content will be focused on psychoeducation combined with relaxation strategies. The programme will build through sessions focused on areas of: ‘stress’, wellbeing and goal setting; sleep hygiene; anxiety and depression; activity scheduling; physical activity and becoming physically active; problem solving; thinking errors; and a final recap, review of goals and thoughts for future wellbeing. Participants will be encouraged to work between sessions by engaging in a stress-reduction technique of their preference on a daily basis for approx. 30 minutes; and through diary activity (e.g. exercise or gratitude diaries). They will receive e-mail reminders for completing these and for the upcoming sessions. Following PPI discussion on enhancing engagement with SRPs, there will be more emphasis on practicing relaxation techniques and allocating time to discuss homework activity, allowing greater scope for interactivity whilst adhering to the core concepts of stress reduction (psychoeducation, relaxation and coping techniques).

Diagram, text

Description automatically generated

Recognizing that SRP programmes can vary in their content and format or structure in how they are being offered across NHS and other organisations, the standard 4-session structure will be adopted as an optimised form of its delivery. The SRP will also explicitly avoid embedding any techniques based on mindfulness or CBT approaches as these are not core or essential elements of a stress-reduction approach while it is important for the RCT trial to adhere to the NICE recommended standards which indicate 4 sessions being optimal as set out by experienced practitioners. Where there is overlap in themes with MBCT-L, for example in gratitude, this will be approached through the SRP technique of keeping a diarised record rather than mindful meditation on individual experience, therefore maintaining a clear difference between interventions. The SRP sessions will be co-facilitated by two senior Band 6 PWPs employed by the University of Nottingham as casual workers who are aware through their practice of the important differences between SRP and MBCT and have previous experience of on-line delivery of this type of intervention.

The same SRP programme will be delivered online via MS Teams/Zoom centrally by the appointed PWPs to randomised participants across all sites in the proposed trial. SRP groups will start at the same time as MBCT-L groups within each recruitment wave to allow for synchronised data collection. The SRP/MBCT-L sessions will not be recorded.

Data collection methods:

Screening: An adapted screening form will be used that is administered routinely to interested staff who apply for a place on the MBCT-L to keep consistency in the procedural aspects already in the workplace. We will direct interested participants to this online screening form through a link that will appear on the flyer. Questions enquire into any significant life event experience (e.g., bereavement, unresolved trauma) currently causing distress, current diagnosis of depression, anxiety or difficulties with stress and any concurrent psychotherapy uptake. A consultation will be sought by practitioners with a given member of staff in the event of their reporting significant difficulties or issues of potential concern to decide what alternative support would be appropriate. Staff may also be directed to a MBCT-for Depression (MBCT-D) programme run routinely at each of the involved sites if they experience high levels of depression (routine practice in Trusts). As this is the mechanism already in place for staff recruitment on these interventions through the Trusts (e.g., Integrated Care Services/Wellbeing Hubs), we will not add any measure threshold exclusion criteria.

Quantitative data: Primary and secondary outcome data will be collected at baseline (prior to the intervention), up to two weeks prior to randomisation; and at follow-up time points at Weeks 6, 12 and 20 post randomisation. Participants will be randomised immediately after they have completed the baseline assessments allowing for 2 weeks post randomisation for the intervention groups to start. All quantitative data will be entered and stored on the Research Electronic Data capture (REDCap) platform. Seven days prior to when the outcome assessment is due participants will receive a reminder to complete the assessment. If a response is not received from the participant within 7 working days a reminder will be sent out. An additional one reminder will be sent out. Data specific to the intervention (e.g., session attendance, adherence to home practice, service satisfaction, etc.) will be collected electronically via MS Online Form (where applicable) as per protocol during the course of the MBCT-L/SRP intervention and will be saved on password-protected, restricted access (to the research team) online folders on the University of Nottingham OneDrive server.

Qualitative data: The semi-structured interviews will be carried out at 20 weeks post randomisation (within a 2-week data collection time window), online via MS Teams (giving a choice to participants to have both their camera and mic switched on or just their mic) or via phone call. The Teams videoconferencing platform has been used effectively for the online delivery of such interventions in Trust sites since the outset of Covid-19 (and as per our pilot data too). Interviews will be conducted on Microsoft Teams or via phone call and video and/or audio recorded depending on the participant preference as to whether the camera is kept on during the interview.. Interview transcripts will be saved with any identifiable information removed- as word documents on password-protected and restricted-access online folders on the University of Nottingham OneDrive server.

Outcome Measures:

QUANTITATIVE OUTCOMES

***Primary***

* Perceived Stress Scale-14 (PSS-14; [39]): a self-report scale that assesses the degree to which the respondent has perceived situations in their life as stressful within the past month. Responses are obtained through 14 items requiring ratings of statements from 0 (never) to 4 (very often).

***Secondary***

Mental State/Wellbeing

* Generalised Anxiety Disorder scale-7 (GAD-7; [40]): a 7-item instrument used to measure or assess the severity of Generalised Anxiety Disorder. Each item asks the individual to rate the severity of their symptoms over the past two weeks. Response options range from 0 (not at all) to 3 (nearly every day).
* Patient Health Questionnaire- 9 (PHQ-9; [41]): a 9-item scale used to measure the severity of depression. Each item asks the individual to rate how often they have been bothered by the listed symptoms over the past two weeks, with responses ranging from 0 (not at all) to 3 (nearly every day).
* The International Trauma Questionnaire (ITQ; [42]): a brief measure asking respondents to think of an experience that troubles them most and indicate how much they have been bothered by that experience in the past month by responding to 18 questions on a scale from 0 (not at all) to 4 (extremely). Questions refer to ways people typically feel, ways people typically think about themselves and ways people typically relate to others.
* Five Facet Mindfulness Questionnaire (FFMQ; [43]): items require participants to rate statements on a 5-point scale from 1 (never or very rarely true) to 5 (very often or always true). Items are subcategorised into 5 facets of mindfulness, i.e. describing, observing, non-reacting, acting with awareness, and non-judging.
* Copenhagen Burnout Inventory (CBI; [44]): measures personal and occupational burnout in 19 items; overall physical and psychological fatigue (6 items), physical and psychological fatigue related to work (7 items) and client-related burnout (6 items). Answers include ‘always, often, sometimes, rarely, and never/almost never’ or ‘to a very high degree, to a high degree, somewhat, to a low degree and to a very low degree’. Possible score range for the burnout scales is 0–100 (response options are coded in scores of 100, 75, 50, 25, and 0). Higher scores indicate a higher degree of exhaustion.

Work engagement, satisfaction and performance

* Utrecht Work Engagement Scale- 9 item (UWES–9; [45]): measures three dimensions of work engagement: Vigor (3 items), Dedication (3 items), and Absorption (3 items). Items are presented as statements to which persons respond on a seven-point scale with anchors 0 (never) and 6 (always or every day).

Health-related quality of life (HRQoL)

HRQoL measures will used at baseline and at 6, 12 and 20 weeks post randomisation. These will include the EQ-5D [46] and a health economics assessment adapted from the Client Service Receipt Inventory (CSRI; [47]), which has been successfully used in a wide variety of studies of mental health community-based health and social care services. A mental health customised version will be administered to collect self-reported resource utilisation for 6 months preceding data collection at baseline and at 20 weeks follow up. The data gathered from these measures will be utilised for a future cost effectiveness analysis (cost-utility and cost consequences analyses based on relative changes in the primary outcome measure).

Other data acquisition: We will also aim to collect demographic data (age, gender, ethnicity, socioeconomic background, work sector, duration in post, etc.); service satisfaction data; MBCT therapist feedback data. Data will also be collected on recruitment uptake/rate, session attendance, compliance to treatment (incl. adherence to home practice), retention/loss to follow-up, reasons for attrition and/or non-compliance (including any diversity and inclusion barriers to intervention uptake and implementation).

QUALITATIVE OUTCOMES

Semi-structured interview data will elicit qualitative outcomes on participants’:

• Perceived changes in their wellbeing and quality of life (i.e., beneficial impacts, adverse effects);

• Perceived changes in their work satisfaction and performance (i.e., beneficial impacts, adverse effects);

• Nature of support sought and on whether the given intervention has met their expectations

• Barriers and drivers to intervention route to uptake, attendance, engagement and adherence (including aspects related to the intervention delivery and content/structure, personal or work circumstances, managerial support, etc.);

• Recommendations for future improvement of intervention design and implementation.

Other unintended outcomes: High attrition/drop-out rates (mid-intervention; loss to follow-up); AEs.

Study deliverables:

The trial will generate data that is required for NICE, networks of nursing and medical directors of NHS organisations, social care directors and head-teachers, Academic Health Science Network (AHSN) East Midlands, Health Education England (HEE); and to mental health, occupational health and psychological wellbeing practitioners who deliver these interventions. Participant data will be anonymised, and any identifying features will be removed. Only the broadest of descriptors will be used when discussing the findings*.* We will publish the trial protocol and statistical analysis plan prior to the end of the recruitment period and before analysis. We will disseminate our research findings as soon as the results are published by a peer reviewed academic publication. A Final Trial Report will be submitted to NIHR ARC EM and the sponsor. Participants in the trial will receive a summary of the findings. In addition, we will present the findings at national and international conferences. The NHS will be the primary consumer of this research and we will hold focussed events for NHS providers, commissioners, and training organisations. All proposed publications will be approved by the NIHR ARM EM prior to publishing, and they will be acknowledged in publications.

### Compliance

Intervention adherence and/or compliance rates (i.e., session attendance and adherence to home practice) as well as follow-up retention rates and turnover by randomised group will be determined at the point of data analysis; we will consider all participants as adherent once they start on the trial and we will prompt participants to complete their daily home practice in-between intervention sessions and to remind them of the upcoming intervention session(s) (through e-mails in the SRP group and through the Florence text service in the MBCT-L group).

### Criteria for terminating trial

### Data on the impact of the intervention in terms of changes on the primary outcome and other secondary measures will not be analysed until the end of the data collection period and therefore will not inform decisions to stop the research. However, AEs will be reviewed during the period of the trial and, in the unlikely indication that these are linked to either of the two interventions, consideration will be given to stopping the trial at all four public care sites on the advice of the ARC EM Scientific Committee.

Another reason for stopping the trial prematurely would be very poor recruitment and engagement with the treatment intervention which does not improve despite attempts to engage public care staff across all four sites. This will be reviewed after the first recruitment wave and if the targets for recruitment or retention are not met, the trial may be terminated on advice of the ARC EM Scientific Committee.

# STATISTICS

### Methods

Quantitative data: Exploratory analysis for both primary and secondary outcomes will be conducted first before an analysis is conducted on an Intention To Treat (ITT) basis; Participants’ outcomes, demographic and other intervention-related variables will be summarised by intervention arm across the follow up times, with mean (SD) for normally distributed variables, median (IQR) for skewed variables and frequency (percentage) for categorical variables. A detailed trial Statistics Analysis Plan (SAP) setting out full details of the proposed analyses will be finalised before the trial database is locked for final analysis. All the trial data will be stored on UoN secure platforms and analysed on a secure UoN computer. The latest available version STATA software will likely be used for all data analysis.

Health economics analysis The outcome measure used for a future (beyond the 24-month duration of this trial) within trial economic evaluation will be QALYs, estimated using the EQ-5D-5L and valued using the recommended tariff at the time of analysis [47]. Using this information on costs and benefits, an incremental cost utility analysis will be conducted and reported using accepted methodology, including cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at a range of threshold values for the willingness to pay per QALY [48].

Qualitative data: Semi-structured interviews will be carried out online via Microsoft Teams at 20 weeks post randomisation (within an 8 week data collection window). Thematic Analysis is intended to be applied to the transcribed data from the semi-structured interviews, guided by key principles of Grounded Theory and the Braun & Clarke 6-step thematic analytical approach [38]. A codebook will be created with codes under the relevant broad conceptual categories, upon which respective themes. The storage of data will comply with the data protection arrangements detailed in the Ethical and Regulatory Aspects section of this protocol.

### Sample size and justification

### Quantitative data: With reference to the pilot data and clinician’s advice, 5 points on PSS-14 (Perceived Stress Scale; primary outcome) will be considered as the minimum clinically important difference. To test such a treatment effect from baseline at 20 weeks post randomisation, at two-tailed 0.05 significance level with 90% power using ANCOVA, and assuming that SD=7.7, the correlation between baseline and follow-up is 0.2 and the correlation among follow-up measures is 0.7, 76 participants in total will be needed. Assuming the average group size is 8, ICC=15% and attrition rate=25% (considering potential loss to follow-up), the final sample size will be inflated to 208 participants to be recruited from 26 groups (1:1 ratio) across all public care sites.

After about 1/3 patients were randomised, it was noticed by a blinded independent statistician that the follow up rate was just about 62% and groups size is about 10, the trial management group also decided to update the sample size with 85% power. The final sample size will be 260 in total from 26 groups.

### Qualitative data: A subsample of 30 participants (n=15 in each arm) will be recruited for the semi-structured interviews at 20 weeks post randomisation (within an 8 week data collection window), the size of which should suffice for a thematic analytical approach to be adopted, as per previous protocols and guidelines [38].

### Assessment of efficacy

The primary endpoint is change on the perceived stress (PSS-14 [39]) outcome from baseline at 20 weeks post randomisation. All final data analyses will be conducted on an Intention-to-Treat basis. All analysis will be conducted on an Intention-to-Treat (ITT) basis. Participants’ outcomes, demographic and other intervention-related variables will be summarised by intervention arm and across the follow up times, if repeatedly measured, with mean (SD) for normally distributed variables, median (IQR) for skewed variables and frequency (percentage) for categorical variables. Missing values will be explored and imputed using a Multiple Imputation approach under Missing At Random assumption for missingness mechanism [52]. Sensitivity analyses will be performed to explore the robustness of treatment effect estimate sensitive to the method of handling missing values, various limitations of the data, assumptions, and analytic approaches to data analysis. A detailed trial Statistics Analysis Plan (SAP) setting out full details of the proposed analyses will be finalised before the trial database is locked for final analysis.

Treatment effects on secondary outcomes will be quantified by assessing change on all outcomes from baseline at 6, 12 and 20 weeks post randomisation. A similar approach to data exploration will be employed as outlined above.

We will collect the data for a health economics analysis and involve a health economist in the design of such data collection (see Health economics analysis in ‘Methods’). We currently do not have the resource or time to complete the analysis before NIHR ARC EM ends. However, as has been the usual experience with CLAHRCs and almost all NIHR infrastructure such as BRCs, MTCs, we will prioritise health economics analysis if the ARC EM is extended and given additional resources to cover the extension. It is desirable for a health economics analysis to be performed and a specific NICE guideline research recommendation. On discussion with NHS providers, the small differences in the cost of delivery of these interventions would not be a major factor in any choice of the intervention; more important would be the availability of these interventions and preferences of staff for one approach over another.

### Assessment of safety

AEs will be reviewed and if there is any indication that these are linked to the intervention the research may be stopped on the advice of the independent ARC EM Scientific Committee (see also Adverse Events section below).

Procedures for missing, unused and spurious data

Missing values in all outcomes will be checked and reported across treatment group and follow up time. The missing value patterns and the results from multilevel logistic regression modelling will be used to inform missing value imputation under Missing At Random assumption [52]. Although multilevel modelling for repeated measures could be automatically taken into account, missing outcomes under Missing At random assumption may be used to give sensible results [53]. To make sure all randomised patients will be included in the analysis, the missing values will be imputed using multilevel modelling to quantify the treatment effect estimates [54]. Results of modelling on observed data will be used as sensitivity analysis to check the robustness of results sensitive to missing value [55]. STATA 16 and REALCOM-IMPUTE software will be used to impute missing values by means of Markov chain Monte Carlo (MCMC) approach for multilevel data [54].

### Definition of populations analysed

The analysis will be conducted on an ITT basis for both primary and secondary analyses, with all randomised participants on either intervention arm being included in the analysis. Participants will be included in the analysis if they have not completed any follow-up assessments. Participants will also be included in the analysis if they decide to withdraw from the programme or the online survey completion (assessment completion at follow up time points), without withdrawing from the trial, and if they withdraw from the trial; using any data collected up to the point of withdrawal.

# ADVERSE EVENTS

### An adverse event is any unfavourable and unintended sign, symptom, syndrome or illness that develops or worsens during the period of observation in the study.

### An AE does include a / an:

### 1. exacerbation of a pre-existing illness.

### 2. increase in frequency or intensity of a pre-existing episodic event or condition.

### 3. condition detected or diagnosed after medicinal product administration even though it may have been present prior to the start of the study.

### 4. continuous persistent disease or symptoms present at baseline that worsen following the start of the study.

### There are no anticipated adverse effects.

A Serious Adverse Event (SAE) is any adverse event occurring following study mandated procedures, having received the treatment or intervention that results in any of the following outcomes:

1. Death

2. A life-threatening adverse event

3. Inpatient hospitalisation or prolongation of existing hospitalisation

4. A disability / incapacity

5. A congenital anomaly in the offspring of a participant

### There are no anticipated Serious Adverse Events (SAEs) as a result of this study.

Adverse events (AEs) may occur and may or may not be linked to the intervention. These can include:

* Exacerbated emotional reaction
* Increase in frequency or intensity of a pre-existing (mental or physical) episodic event or illness
* Worsening of symptoms present at baseline following the start of the study

Both interventions (MBCT-L, SRP) are NICE recommended individual interventions to reduce staff stress and burnout. All of the sites in the study already deliver such interventions as part of their staff wellbeing schemes and are hence already procured by NHS providers. These interventions are taken up voluntarily by staff who may or may not present with pathological mental illness symptoms; or physical illness symptoms which might be exacerbated by meditation or relaxation practices, such as chronic pain (e.g., in the back, neck, knee).

Currently, relatively little has been reported on potential adverse effects of MBCT in non-clinical populations. In a recent systematic review [49] of adverse events in meditation practices and meditation-based therapies, including relaxation and MBCT exercises, it was found that adverse effects during or after meditation practices occurred in non-clinical populations associated with meditation practices, particularly anxiety and depression. The overall prevalence of meditation adverse events was 8.3% in 55 studies reporting at least one adverse effect and this percentage is similar to those reported for psychotherapy practice in general.

The structured context of MBCT-L and SRP include psychoeducational materials/resources on how to manage distressing experiences arising during meditation or at other times.

The trained therapists delivering these interventions have a mechanism in place for providing tailored advice and support at any stage; any individuals who meet any of the exclusion criteria on the screening form will be excluded. They will be contacted by a study therapist who will discuss the most appropriate route of support (e.g., referral to MBCT-D [for depression] instead or to other suitable treatments). Participants are prompted once they have embarked on an intervention to report any adverse emotional or physical events/effects to the therapist and/or log any adverse events in-between sessions/throughout the programme. This will trigger a consultation meeting between the participant and the therapist(s) team who will provide advice and refer the participants to further support (within the mental health wellbeing team or to GP) as appropriate. Participants are also prompted to make adjustments during the meditation exercises to reduce any bodily discomfort; and to exert physical effort at a level that is comfortable for them during any body-moving exercises.

Any adverse events will be assessed for seriousness, expectedness and causality. An AE whose causal relationship to the study intervention is assessed by the Chief Investigator in consultation with medical experts of the research team as “possible”, “probable” or “definite” will be reported as an Adverse Event in the CRF and the ARC EM Scientific Committee. Any AEs or SAEs will be documented and reported by the Chief Investigator and where appropriate inform the REC as required and/or make necessary study adjustments.

### Causality

**Not related or improbable**: a clinical event with temporal relationship to trial intervention administration which makes a causal relationship incompatible or for which other treatments or disease provide a plausible explanation**.** This will be counted as “unrelated” for notification purposes.

**Possible**: a clinical event with temporal relationship to trial intervention administration which makes a causal relationship a reasonable possibility, but which could also be explained by other interventions or concurrent disease. This will be counted as “related” for notification purposes.

**Probable**: a clinical event with temporal relationship to trial intervention administration which makes a causal relationship a reasonable possibility, and is unlikely to be due to other interventions or concurrent disease. This will be counted as “related” for notification purposes.

**Definite**: a clinical event with temporal relationship to trial intervention administration which makes a causal relationship a reasonable possibility, and which can definitely not be attributed to other causes. This will be counted as “related” for notification purposes.

With regard to the criteria above, medical and scientific judgment shall be used in deciding whether prompt reporting is appropriate in that situation.

### Reporting of adverse events (AEs)

Participants will be asked to contact the therapist(s) leading their group and/or at the study site immediately in the event of any serious adverse event. Any adverse events will be recorded and closely monitored until resolution, stabilisation, or until it has been shown that the study treatment/intervention is not the cause. The Chief Investigator shall be informed immediately of any serious adverse events and shall determine seriousness and causality in conjunction with the therapists and the medical practitioners who are part of the research team. These will be recorded in the CRF and will instigate further investigation and follow-up as appropriate. The Chief Investigator shall be responsible for all adverse event reporting to the ARC EM Scientific Committee and REC.

**Trial Intervention Related SAEs**

A serious adverse event that is unexpected in its severity and seriousness and deemed directly related to or suspected to be related to the trial treatment or intervention shall be reported to the ethics committee that gave a favourable opinion as stated below.

The event shall be reported immediately of knowledge of its occurrence to the Chief Investigator.

**The Chief Investigator will:**

* Assess the event for seriousness, expectedness and relatedness to the trial treatment or intervention in consultation with the medical experts of the research team.
* If the event is deemed serious, related to the trial intervention and and unexpected shall inform the REC using the reporting form found on the HRA web page within 7 days of knowledge of the event.
* Shall, within a further eight days send any follow-up information and reports to the REC.
* Make any amendments as required to the study protocol and inform the Sponsor and REC as required

### Participant removal from the study due to adverse events

Any participant who experiences a SAE or AE may be withdrawn from the study at the discretion of the Investigator after this has been reviewed by the therapist and research team and the ARC EM Scientific Committee if appropriate.

# ETHICAL AND REGULATORY ASPECTS

## ETHICS COMMITTEE AND REGULATORY APPROVALS

The trial will not be initiated before the protocol, informed consent forms and participant information sheets have received approval / favourable opinion from the Research Ethics Committee (REC), the respective National Health Service (NHS) or other healthcare provider’s Research & Development (R&D) department, and the Health Research Authority (HRA) if required. Should a protocol amendment be made that requires REC approval, the changes in the protocol will not be instituted until the amendment and revised informed consent forms and participant information sheets (if appropriate) have been reviewed and received approval / favourable opinion from the REC and R&D departments. A protocol amendment intended to eliminate an apparent immediate hazard to participants may be implemented immediately providing that the REC are notified as soon as possible and an approval is requested. Minor protocol amendments only for logistical or administrative changes may be implemented immediately; and the Sponsor and REC will be informed.

The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, 1996; the principles of Good Clinical Practice, and the UK Department of Health Policy Framework for Health and Social Care, 2017.

## INFORMED CONSENT AND PARTICIPANT INFORMATION

The process for obtaining participant informed consent will be in accordance with the REC guidance, and Good Clinical Practice (GCP) and any other regulatory requirements that might be introduced. The investigator or their nominee and the participant shall both sign and date the Informed Consent Form before the person can participate in the study.

The participant will receive a copy of the signed and dated forms if requested and the original will be retained in the Trial Master File.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasize to them that consent regarding study participation may be withdrawn at any time without penalty or affecting the quality or quantity of their future medical care, or loss of benefits to which the participant is otherwise entitled. No trial-specific interventions will be done before informed consent has been obtained.

The investigator will inform the participant of any relevant information that becomes available during the course of the study, and will discuss with them, whether they wish to continue with the study. If applicable they will be asked to sign revised consent forms.

If the Informed Consent Form is amended during the study, the investigator shall follow all applicable regulatory requirements pertaining to approval of the amended Informed Consent Form by the REC and use of the amended form (including for ongoing participants).

## RECORDS

### Case Report Forms

Each participant will be assigned a trial identity code number, allocated at randomisation, for use on CRFs other trial documents and the electronic database. The documents and database will also use participants’ initials (of first and last names separated by a hyphen or a middle name initial when available) and date of randomisation. The identifiers used must be robust and able to prevent miss-assignment of data in databases. The identifiers must also allow sufficient identification to prove a person exists, matches the consent obtained (so the identifiers used must be listed on the trial recruitment log) and allows identification of the participant when chasing data queries with participating remote sites. CRFs will be treated as confidential documents and held securely in accordance with regulations.

The investigator will make a separate confidential record of the participant’s name, date of birth, and Participant Trial Number (the Trial Recruitment Log), to permit identification of all participants enrolled in the trial, in accordance with regulatory requirements and for follow-up as required CRFs shall be restricted to those personnel (e.g., the trial administrator) approved by the Chief Principal Investigator or Co-PI and recorded on the ‘Trial Delegation Log.’

### Source documents

Source documents shall be filed at the investigator’s site and may include but are not limited to, consent forms, and current medical records.. A CRF may also completely serve as its own source data. Only trial staff as listed on the Delegation Log shall have access to trial documentation other than the regulatory requirements listed below.

### Direct access to source data / documents

The CRF and all source documents, including progress notes shall made be available at all times for review by the Chief Investigator, Sponsor’s designee and inspection by relevant regulatory authorities.

## DATA PROTECTION

All trial staff and investigators will endeavour to protect the rights of the trial’s participants to privacy and informed consent, and will adhere to the Data Protection Act, 2018. The CRF will only collect the minimum required information for the purposes of the trial.. Access to the information will be limited to the trial staff and investigators and relevant regulatory authorities (see above). Computer held data including the trial database will be held securely and password protected. All data will be stored on secure UoN platforms, i.e., in access-restricted password protected online research folders on the University of Nottingham OneDrive. Access will be restricted by user identifiers and passwords (encrypted using a one way encryption method). We will follow the University of Nottingham (sponsor) electronic archiving policy and procedures for all data acquired in the trial.

The following data protection measures will be put in place for the use of video conferencing. Only University of Nottingham/local Trust approved platforms (i.e., Microsoft Teams/Zoom) will be utilised as these platforms are encrypted. In order to ensure confidentiality, Investigators will ensure they are working in an area where conversations cannot be overheard, and the computer screen cannot be observed. Researchers will only use equipment issued to them by the University, they will not use personal accounts or devices to contact participants. Interviews will be recorded on Microsoft Teams to facilitate transcription; interview recordings will be deleted from Microsoft Teams as soon as they are transcribed (either through MS Teams or a university-approved transcription service) and anonymised. The interview recordings will be pseudonymised and any identifying information will be redacted in transcripts . Interview recordings and transcripts will besaved on access-restricted, password-protected online research folders on the OneDrive University of Nottingham. It will be ensured that identifiable data are stored separately from the research data and that Investigators do not have access to the identifiable/randomisation data so as to retain blinding.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

# QUALITY ASSURANCE & AUDIT

## INSURANCE AND INDEMNITY

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS, issued under cover of HSG (96)48. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

The University of Nottingham as research Sponsor indemnifies its staff with both public liability insurance and clinical trials insurance in respect of claims made by research subjects.

## TRIAL CONDUCT

Trial conduct may be subject to systems audit of the Trial Master File for inclusion of essential documents; permissions to conduct the trial; Trial Delegation Log; CVs of trial staff and training received; local document control procedures; consent procedures and recruitment logs; adherence to procedures defined in the protocol (e.g. inclusion / exclusion criteria, correct randomisation, timeliness of visits); adverse event recording and reporting; accountability of trial materials and equipment calibration logs.

## TRIAL DATA

Monitoring of trial data shall include confirmation of informed consent; source data verification; data storage and data transfer procedures; local quality control checks and procedures, back-up and disaster recovery of any local databases and validation of data manipulation. The Trial Coordinator, or where required, a nominated designee of the Sponsor, shall carry out monitoring of trial data as an ongoing activity.

Entries on CRFs will be verified by inspection against the source data. A sample of CRFs (10% or as per the study risk assessment) will be checked on a regular basis for verification of all entries made. In addition the subsequent capture of the data on the trial database will be checked. Where corrections are required these will carry a full audit trail and justification.

Trial data and evidence of monitoring and systems audits will be made available for inspection by REC as required.

## RECORD RETENTION AND ARCHIVING

In compliance with the ICH/GCP guidelines, regulations and in accordance with the University of Nottingham Research Code of Conduct and Research Ethics, the Chief or local Principal Investigator will maintain all records and documents regarding the conduct of the study. These will be retained for at least 7 years or for longer if required. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

The Trial Master File and trial documents held by the Chief Investigator on behalf of the Sponsor shall be finally archived at secure archive facilities at the University of Nottingham. This archive shall include all trial databases and associated meta-data encryption codes.

## DISCONTINUATION OF THE TRIAL BY THE SPONSOR

The Sponsor reserves the right to discontinue this trial at any time for failure to meet expected enrolment goals, for safety or any other administrative reasons. The Sponsor shall take advice from the ARC EM Scientific Committee in making this decision.

## 

## STATEMENT OF CONFIDENTIALITY

Individual participant medical information obtained as a result of this study are considered confidential and disclosure to third parties is prohibited with the exceptions noted above.

Participant confidentiality will be further ensured by utilising identification code numbers to correspond to treatment data in the computer files.

Medical information may be given to the participant’s medical team and all appropriate medical personnel responsible for the participant’s welfare. If information is disclosed during the study that could pose a risk of harm to the participant or others, the researcher will discuss this with the CI and where appropriate report accordingly.

Data generated as a result of this trial will be available for inspection on request by the participating physicians, the University of Nottingham representatives, the REC, local R&D Departments and the regulatory authorities.

# PUBLICATION AND DISSEMINATION POLICY

The trial findings will be disseminated in academic/clinical conferences attended by professional groups and NHS confederation; will be reported to commissioners, NICE, networks of nursing and medical directors of NHS organisations, social care directors and head teachers, HEE and AHSN East Midlands; will also be presented to mental health, occupational health and psychological wellbeing practitioner networks and conferences since these professional groups will be required to staff and deliver these interventions.

We will disseminate our research findings as soon as the results are accepted by a peer reviewed academic publication. A Final Trial Report will be submitted to NIHR ARC EM and the sponsor. Participants in the trial will receive a lay summary of the findings. All proposed publications will be approved by the NIHR prior to publishing and ARC EM will be acknowledged in publications.

# USER AND PUBLIC INVOLVEMENT

# Two PPI groups consisting of 10 members of staff from various areas of the public sector (healthcare, social care and teaching) have been formed, to be involved in the MBCT-L (n=5) and SRP (n=5) arms of the trial respectively. The PPI groups are intended to provide input into all key aspects of the research study, from study design to implementation, evaluation and dissemination. Upon study commencement, quarterly PPI meetings will be held for discussion on the trial progress and consultation at key phases, i.e., progress review on interim recruitment and data collection procedures, data analysis and integration, write-up and dissemination of findings. PPI members will be given the flexibility in deciding how to run their meetings (face-to-face or online) and how to communicate with the research team (e.g., via email, Microsoft Teams or face-to-face). All PPI members will be offered some payment per quarterly meeting attendance/round of provision of feedback and any required travel expenses for face-to-face meetings will be covered. Training and other involvement opportunities in PPI will be offered via affiliated networks and organisations (e.g., Institute of Mental Health Advisory Group, NIHR training and resources, etc.). We have nominated a named PPI Lead (RG) who will organise and coordinate communications and outcomes between the PPI groups and the research team. The PPI Lead will also be invited to attend operational/research meetings (online or face-to-face) throughout the year should they wish/are able to do so and/or will communicate with the research team via email.

A meeting has been held separately with the two PPI groups, who have been consulted about their views on the study design and implementation at this early stage, including their views on the lay summary of the study. Feedback was also received via email by those members who were not able to attend the meeting and subsequently by email for the revisions applied to the proposed research (July 2022).

MBCT-L PPI group feedback:

A lay summary of the proposal was circulated in advance to the five members and a 75-minute session was held via MS Teams, facilitated by EN (on 10/05/22). Two participants were able to attend the meeting and a draft report was circulated to all participants afterwards for further comments from all. All five participants (2 male, 3 female) had experience of attending a MBCT-L intervention. All participants have been employed within the public sector: 4 with the NHS and 1 with the police service. Feedback was also gained on the lay summary included in this proposal as well as on the revised version of the lay summary that was subsequently circulated (July 2022).

The group provided overall positive feedback on the study design expressing the view that the proposed trial is worthwhile. All members having had experience with MBCT-L uptake stated that they had benefited greatly from taking part in the programme. The online delivery was thought to be effective and that it was particularly helpful during the COVID period when face-to-face attendance would have not been possible. They expressed a concern for the importance of having managerial support in attending such programmes and hence indicated a preference for the sessions to take place out of hours to accommodate those members of staff who may not have support by their employer. Participants agreed with the randomisation approach deeming it ‘appropriate’ and ‘necessary’ to asses trial outcomes as well as with the current measures while they commented on how they found that quality of life in general was beneficially affected after having attended MBCT sessions. One participant commented on how MBCT equips individuals with stress-coping skills that last for life while stress-reduction programmes have more transient effects and do not necessarily lead to changes in attitude to life. Some of the other feedback mirrored the qualitative findings from our pilot study in terms of an expressed need for home practices to be kept as short as possible, a need for boosters throughout the programme to keep motivation levels up, and a preference for small groups (n<12). These have been taken into account in the design of the proposed interventions by: having facilitated the production of a shorter version of homework exercises led by the MBCT-L key stakeholder (TS); embedding the Florence texting system for communication/reminders for sessions and home practice in MBCT-L to act as motivation boosters in-between sessions; and keeping an average number of 8 participants (range ~7-12) per intervention group. All 5 participants expressed their interest in remaining on the PPI panel for the duration of the trial.

SRP PPI group feedback:

A 90-minute session held via MS Teams, facilitated by NN (on 11/05/22), followed by circulating the draft report to all participants for further comments. All five participants had experience of Stress Control interventions (one of whom had since commenced a mindfulness-based intervention). All participants had experience of work within the public sector: including teaching, the civil service and the NHS. There were two men and three women, aged between 48-59 years old. A summary of the research was sent in advance, with further explanation at the beginning of the session.

The agreed summary was that all participants thought this was a worthwhile study, even when asked to consider the time and resource commitment it would involve, over several years. All participants commented on how important it was for people to learn how to manage stress related to work, to the point that it might be considered part of ‘induction’ or ongoing annual training requirements. There was discussion about the potential longer-term benefits of mindfulness-based approaches, which were seen as more likely to develop lifelong skills (contrasted to stress reduction). Though there were some specific aspects of stress reduction interventions mentioned positively, including ‘the stress bucket’ and the ‘worry tree’; both cited as helpful ‘learning tools’ or ‘techniques’ that might be ‘simple’ but were valued. There was unanimous agreement on the high level of stress that could be experienced within [public sector] work, with several people commenting on the importance of helping people develop stress-management techniques earlier, rather than later in their career while highlighting how they felt that there was no clear pathway for choosing which intervention would best work for them.

Participants thought this would be a popular study to recruit to. All participants agreed that randomisation was justified, for example so that outcomes weren’t affected by ‘people’s preference for particular approaches’. We had some discussion about session length and number of sessions, with the group coming to the view that these should be kept as close as possible between the two interventions. Participants voiced the idea (unprompted) that regular attendance at stress reduction groups would be made more likely if they were more interactive. Their experience of these groups was that there was little interaction and to the point that they might as well be delivered as a series of pre-recorded videos; and so why were they asked to plan attendance at specific times (with all the inconvenience entailed). Ideas were given as to how increased interactivity could be achieved, for example by asking people about the diaries they’d been asked to keep (on exercise or the gratitude diary), which has been incorporated into the stress reduction programme planned for this study (following subsequent discussion with senior professionals delivering the intervention).

Most participants said they would prefer the groups at the end of the working day, though for some people this was less relevant as they were now ‘freelance’ or had less structure to the working day. One participant said that ‘people wouldn’t want to approach their line manager during the working day, possibly for fear of stigma and there was good agreement with this view. There were no objections to delivery via an on-line platform and all agreed that this would probably be helpful in terms of attendance. These ideas on timing (after the working day) and delivery platform will be taken into account in the delivery of the programme. Participants agreed with the current measures, including PSS and depression/anxiety symptoms. Quality of life was mentioned by several participants with broad agreement as an additional measure. One participant mentioned the importance of life events on understanding outcomes (including the experience of death in close ones), leading to a brief discussion of possibly including a life-events schedule. All other things being equal, participants thought that even a 5% difference (or any significant, above-chance difference) in effectiveness between groups would be important enough to help them make a choice between stress reduction and MBCT-L. Four of the five participants have expressed an interest in continued involvement in the study, including through a PPI panel (through the session and subsequent individual emails).

# STUDY FINANCES

### Funding source

### This study is funded by the National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands (ARC EM).

### Participant stipends and payments

Participants in both trial arms (MBCT-L, SRP) will receive an inconvenience allowance of £15 for completing the trial questionnaires at Week 20. Participants who will also take part in the interviews will receive a further £15 inconvenience allowance upon completion of the interviews at Week 20 post randomisation.

# SIGNATURE PAGES

Signatories to Protocol:

**Chief Investigator:** (name)\_Dr Elena Nixon\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: 06/02/2023\_\_\_\_\_\_\_\_\_\_\_

**Co- investigator**: (name) Shireen Patel\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: 06/02/2023\_\_\_\_\_\_\_\_\_\_\_

**Trial Statistician**:(name)\_\_\_Dr Boliang Guo\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: 06/02/2023\_\_\_\_\_\_\_\_\_\_\_

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