ISRCTN18049845 https://doi.org/10.1186/ISRCTN18049845

Trial investigating the effectiveness of mindfulness-based cognitive therapy for life versus stress-reduction psychoeducation programmes in improving the mental wellbeing of healthcare, social care and teaching professionals

Submission date
10/08/2023

Recruitment status
No longer recruiting

Registration date
11/08/2023

Overall study status
Completed

Last Edited
27/05/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Healthcare and other public care staff are considered to have higher levels of stress and are at risk of developing poor mental health due to the challenging nature of their job. High levels of stress and other mental health problems in these groups have been linked with poor outcomes for the person themselves and the wider organisation as well as the quality of care provided. Recognising this problem, the National Institute for Health and Care Excellence (NICE) has recommended Mindfulness-based and Stress Reduction Psychoeducation (SRP) interventions for reducing stress and improving staff wellbeing. SRP uses relaxation techniques to combat the negative consequences of stress. Mindfulness-based approaches combine mindfulness with relaxation, as well as cognitive-behavioural therapy elements in the version of Mindfulness-Based Cognitive Therapy for Life (MBCT-L). MBCT-L develops one's ability to view stress in a positive as well as negative light, promoting a more positive long-term outlook on life. While SRP is being offered as standard care to staff in all regions in England, MBCT-L is a newer approach widely implemented across health and other public care organisations in East Midlands, and in a limited number of other regions across the UK. MBCT-L is currently only offered in some regions. This study will investigate if offering MBCT-L can reduce perceived stress and is more cost-effective than SRP. If so, then MBCT-L may be offered as a form of therapy for NHS and public sector staff.

Who can participate?
Public sector staff, i.e., in healthcare, social care and teaching, accessing well-being programmes through NHS staff communication channels, e.g. through human resource communications, induction days and other staff wellbeing support sources or organisations across NHS sites involved in this study. Recruitment will be facilitated through a study flyer that will be circulated

widely across these sites by email and via other communication channels (e.g., staff communication hub, staff networks/newsletters, Facebook, Twitter, Induction days, etc.)

What does the study involve?
The study consists of a trial to assess whether MBCT-L is superior to SRP in terms of effectiveness. We will recruit 208 staff working in healthcare, social care and teaching sectors through Integrated Care/Wellbeing Hubs across 4 UK public care sites. Participants will be randomly allocated to either an 8-week MBCT-L or a standard usual care 4-week SRP programme. The trial will look at the effects of the two interventions primarily on staff stress at baseline (prior to starting the intervention) and at 20 weeks post randomisation; and secondarily on other mental health aspects too as well as work-related aspects. All participants will be asked to complete outcome assessments at baseline and 6, 12 and 20 weeks after they have been randomised to one of the two programmes. The questionnaires will be completed online independently or over the phone or via Microsoft Teams with a study researcher if so preferred by the participant. The questionnaires will record changes in emotional health and the use of health services over time. Thirty participants who have consented to be contacted about the interview will be emailed towards approaching Week 20 post-randomisation and will be directed to an online link whereby they can access a participant information sheet, followed by a consent form, for the interview study. Upon submitting informed consent, they will be contacted by the research team to arrange an interview via MS Teams.

What are the possible benefits and risks of participating?
Given that healthcare and public care staff are considered to be at risk of developing poor mental health because of the challenging nature of their jobs, this research will provide an additional form of support that may reduce perceived stress. We anticipate some immediate benefits to the public care sectors that already provide such interventions so they make their service provision more efficient. Most importantly, staff working in these organisations will receive help in managing their stress and overall mental health. The interventions are being delivered for the purposes of research and it is not known which if any may be beneficial to participants so there may be no direct benefit to the participants themselves.

Completion of the baseline and follow-up assessments includes asking participants about mental health and associated symptoms. This may evoke emotional difficulty in some participants. A risk and safety management SOP will be put in place to address any risk of harm to self or others.

Where is the study run from?
University of Nottingham (UK)

When is the study starting and how long is it expected to run for?
September 2022 to September 2024

Who is funding the study?
National Institute for Health Research (NIHR) Applied Research Collaborations East Midlands (ARC EM) (UK)

Who is the main contact?
Shireen Patel, shireen.patel@nottingham.ac.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Elena Nixon

ORCID ID
https://orcid.org/0000-0003-4750-7522

Contact details
Assistant Professor in Applied Neuropsychology
Institute of Mental Health, Mental Health and Clinical Neurosciences, C Floor
University of Nottingham
Innovation Park
Triumph Road
Nottingham
United Kingdom
NG7 2TU
+44 (0)115 8230428
Elena.Nixon@nottingham.ac.uk

Type(s)
Scientific

Contact name
Ms Shireen Patel

ORCID ID
https://orcid.org/0000-0002-5537-0717

Contact details
Research Fellow
NIHR Applied Research Collaboration - East Midlands (ARC EM)
Institute of Mental Health
University of Nottingham Innovation Park
Triumph Road
Nottingham
United Kingdom
NG7 2TU
+44 (0)115 8231434
Shireen.patel@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
319606

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 56302, IRAS 319606

Study information

Scientific 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

Study objectives
The hypothesis is that compared to SRP the MBCT-L group will show a greater difference in perceived stress at 20 weeks post-randomisation (primary outcome).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 31/05/2023, East Midlands - Nottingham 1 Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 (0)207 104 8115, (0) 207 104 8063, (0)207 104 8089; nottingham1.rec@hra.nhs.uk), ref: 23/EM/0109

Study design
Randomized controlled superiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual, Telephone

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Mental health

Interventions
Study Design and justification for control arm
The study design is a randomised controlled superiority trial. Researchers will not know

treatment allocation to reduce any bias in outcome data. All participants will receive the same outcome measures so researchers will not know which group the participant is in based on the outcome measures. Participants will be followed-up at 6-, 12- and 20-weeks post-randomisation. In the experimental arm participants receive 8 weekly two-hour sessions of MBCT-L plus a top-up retreat session in Week 9 or 10 depending on whether there is a one-week break (e.g. school break or other holidays). In the control arm, participants receive 4 weekly two-hour sessions of SRP over 4 consecutive weeks, or 5 weeks if there is a one-week break. We will compare the two groups on symptoms and cost-effectiveness.

Sample Size
Our power calculations show we require a sample size of 208 participants to detect a clinically important difference of 5 points on the primary outcome of perceived stress between the two groups; this estimate allows for a 25% loss of data to follow-up. For the interview part of the study which will be carried out at 20 weeks post-randomisation of participants to the intervention, it is estimated based on previous protocols that a total number of 30 participants (15 from each arm) will provide sufficient data for analysis (thematic analysis) which identifies common themes amongst participants' reports.

Stages of the study
Participant recruitment is expected to start in May 2023. The final follow-up of data completion (online survey) is expected to be in July 2024. The same timing applies to the last interview to be carried out. Data analysis will be undertaken in September 2024. Project management meetings will be held every 4-6 weeks. An independent committee will meet 5 times across the two years of the duration of the study to discuss the study's progress. Interim and final reports will be submitted to the ARC EM Scientific Committee which will oversee the conduct and progress of this study. Two Patient and Public Involvement and Engagement (PPI/E) groups have already been recruited and consulted about the study protocol at the time of the funding application and there will be regular meetings/consultations with these groups throughout the trial to aid with recruitment and participant retention techniques, to update on study progress and receive input on any processes or outcomes, as appropriate.

Participant identification
Participants will be directed through existing integrated care services/wellbeing Hubs which are accessed by public sector staff and 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. Eligible participants will be prompted to access the online survey link that will be built on a Research Electronic Data Capture (REDCap) platform through a notification e-mail; once they enter the survey, they will access the Participant Information Sheet, followed by the Consent Form; upon agreed consent, the platform will allow them to proceed to the questionnaire/ quantitative data completion. In the Consent Form, there will also be an option for participants to tick should they wish to be contacted by the researcher(s) later for participation in the semi-structured interview part of the study; and another option to agree to should they wish to be contacted about the results of the study.

Screening/baseline assessment
An adapted screening form will be used that is administered routinely to interested staff who apply for a place on the MBCT-L through the integrated care services offered by the involved Trust providers, 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 study flyer. Questions enquire into any significant life event experience (e.g., bereavement, unresolved trauma) currently causing distress, current diagnosis of a mental health illness by a

GP or other mental health professional and any concurrent or psychotherapy uptake in the next three months. A response of yes to any of the questions will lead to them being excluded. The consultation will be sought by the therapist team with the interested participant in the event of their reporting significant difficulties or issues of potential concern to decide what alternative support would be appropriate.

Following signed consent on the survey, participants will be prompted to proceed with the online completion of the questionnaires/quantitative data. Once these are complete, the project administrator who will be involved in the randomisation will be notified through RedCap to enable the facilitation of participant recruitment on the intervention groups running during each recruitment wave. It will be ensured that participants will be allocated to one of the two interventions within 2 weeks of baseline completion. If this is not possible, staff will be directed to enrol at other MBCT-L or SRP groups, not attached to the trial, which will be running around that time across the involved sites.

The interventions
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. It consists of 8 2-hour weekly sessions to be delivered online (via MS Teams) and a final session which will be a retreat day (0.5 days). The programme will run over consecutively over 9 weeks, or 10 weeks if there is a one-week break (e.g. due to school break or other holidays). The programme will be run in a group-based format. 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 so-called Florence telehealth texting system 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 sites who are part of the teaching team involved in the MBCT-L interventions already being offered to public sector staff through the services.

Stress Reduction Programme (SRP): The SRP 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). 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 the 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).

The SRP will be optimised and will explicitly avoid embedding any techniques based on mindfulness or CBT approaches as these are not core or essential elements of a stress-reduction approach. It is also 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 trained wellbeing practitioners who are aware through their practice of the important differences between SRP and MBCT and have previous experience in online delivery of this type of intervention. The same SRP programme will be delivered via MS Teams centrally by the appointed PWPs to randomised participants across all sites in the proposed trial.

Follow up measures
Participants will be asked to complete follow-up questionnaires 6 weeks, 12 weeks, and 20 weeks after they have been randomised to the study. The questionnaires will be completed online independently or over the phone or via Microsoft Teams with a study researcher if so, preferred by the participant. The questionnaires will record changes in emotional health and use of health services over time. Participants can 'save and exit' their responses on the online survey and return to finish completion within a week. Participants who have consented to be contacted about the interview will be emailed towards approaching Week 20 post-randomisation and will be directed to an online link whereby they can access a participant information sheet, followed by a consent form, for the interview study. Upon submitting informed consent, they will be contacted by the research team to arrange an interview via MS Teams.

PPI/E input
The study has been co-designed through PPI/E input. PPI/E representatives have provided input on all patient-facing documents including the participation information sheets and study leaflets. They have helped to shape the design of the study and recruitment processes from the beginning of the design of this trial. They have also reviewed our study questionnaires to ensure that they are suitable. The research team also includes an identified PPI/E Lead who will steer the PPI/E involvement.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Self-rated stress measured using the Perceived Stress Scale-14 (PSS-14) score at 6, 12 and 20 weeks

Secondary outcome measures
1. Self-rated depression measured using the Patient Health Questionnaire-9 (PHQ-9) at 6, 12 and 20 weeks
2. Self-rated trauma measured using the International Trauma Questionnaire (ITQ) at 6,12 and 20 weeks
3. Self-rated mindfulness levels measured using the Five Facet Mindfulness Questionnaire (FFMQ) at 6,12 and 20 weeks
4. Self-rated-personal and occupational burnout measured using the Copenhagen Burnout Inventory (CBI) at 6,12 and 20 weeks
5. Self-rated measure of work engagement measured using the Utrecht Work Engagement Scale-9 (UWES-9), at 6,12 and 20 weeks

6. Health-related quality of life measured using the EuroQol EQ-5D-5L at 6, 12 and 20 weeks
7. Measurement of costs from personal, health and social care perspectives measured using an adapted version of the Client Service Receipt inventory at 6, 12 and 20 weeks

Overall study start date
01/09/2022

Completion date
30/09/2024

Eligibility

Key inclusion criteria
1. In part-time/full-time or honorary/voluntary employment seeking access to well-being support through one of the four sites
2. Currently in work (i.e., not on sickness absence)
3. Aged 18 years or over
4. Competent command of verbal and written English language
5. Access to stable internet connection on a pc/laptop/tablet.

Participant type(s)
Patient

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 208; UK Sample Size: 208

Total final enrolment
260

Key exclusion criteria
1. Concurrently attending or planning to attend a psychological or well-being programme in the next three months. formal psychotherapy uptake;
2. Current diagnosis of a mental health condition from a GP or mental health professional serious current or previous mental health difficulties
3. Experience of recent significant life events currently causing significant distress

These criteria will be picked up by the therapist team who will manually inspect all content on the screening forms and provide alternative/appropriate support if these exclusion criteria are met. The timelines for the occurrence of such events are intentionally left undefined to avoid identifying adverse or other significant events that may not have occurred over the defined period but will still have consequences for the individual.

Date of first enrolment
09/08/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottinghamshire Healthcare NHS Foundation Trust
The Resource, Trust Hq
Duncan Macmillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Nottingham University Hospitals NHS Trust - Queen's Medical Centre Campus
Nottingham University Hospital
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
Tees, Esk and Wear Valleys NHS Foundation Trust
Trust Headquarters
West Park Hospital

Edward Pease Way
Darlington
United Kingdom
DL2 2TS

Sponsor information

Organisation
University of Nottingham

Sponsor details
Research and Innovation E-floor
Yang Fujia Building
Jubilee Campus
Wollaton Road
Nottingham
England
United Kingdom
NG8 1BB
+44 (0)1158467906
sponsor@nottingham.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nottingham.ac.uk/

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/03/2025

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Protocol file	version 4.0	23/01/2024	24/09/2024	No	No
Protocol article		26/05/2025	27/05/2025	Yes	No