Participant Information Sheet
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IRAS Project ID: 319606

Title of Study: 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 (Mindful Life-Well at Work)

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We would like to invite you to take part in our research study. Before you decide whether you would like to take part, we would like you to understand why the research is being done and what it would involve for you. If you have any questions or concerns after reading this study information sheet, please contact the research team (see in 'Further information and contact details') and one of our team will go through this participant information sheet with you and answer any questions you have. Talk to others about the study if you wish.

What is the purpose of the study?

Public sector employees, particularly in healthcare, social care and teaching services, present with higher levels of stress compared to employees in other work sectors due to the demanding nature of their job. Excessive stress and mental health problems in these work sectors have been exacerbated by the COVID-19 pandemic but have been historically associated with negative wellbeing outcomes for the individual as well as negative work-related outcomes. Mindfulness-Based Cognitive Therapy (MBCT) and Stress-Reduction Psychoeducation (SRP) have both been recently recommended by the National Institute for Health and Care Excellence (NICE) as effective types of wellbeing interventions for healthcare and other public sector employees who are at risk of poor mental health.

SRP interventions employ behavioural techniques to train an individual to combat the negative consequences of stress by engaging in relaxation practices and wellbeing goal setting. MBCT interventions combine the application of Cognitive-Behavioural Therapy (CBT) components with mindfulness techniques to train individuals to reach a relaxed state by paying purposeful attention to the present moment, leading to enhanced coping skills by viewing stress in a positive as well as negative light. While SRP is being offered widely across the UK as standard care to staff accessing wellbeing programmes through Integrated Healthcare Trust services, MBCT-for Life (MBCT-L) is a newly adapted programme for non-clinical populations that is widely implemented across health and public care organisations in England but in a limited number of organisations in other regions across the UK. This trial aims to assess whether online MBCT-L is superior to online SRP in terms of its effectiveness and cost effectiveness, given that the two interventions have not been previously compared.

Why have I been invited?

You are being invited to take part because you are an employee working in the healthcare or social care or teaching sector and have expressed an interest in enrolling on a mindfulness or stress reduction programme delivered through one of the participating Trust sites, 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).
We aim to recruit a total of 208 staff across these sites, with 104 staff being randomly allocated to attend an online MBCT-L programme and the other half an online SRP programme delivered by trained therapists.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be directed in the next form on this online survey to sign an online consent form. You can contact the research team if you have any questions about this part of the study prior to consenting; and also to ask to obtain a copy of this information sheet and consent form should you wish to do so (see in 'Further information and contact details'). If you decide to take part you are still free to withdraw at any time. This will not affect your healthcare, work or legal rights. We will not inform your employer or any other parties of your decision to take part in or withdraw from this study other than the research and therapist team.

What will happen to me if I take part?

Completing questionnaires on online survey

If you decide to take part by signing the consent form, you will be directed to a number of questionnaires on this online survey that we ask you to complete so that we can obtain some information about you, your levels of stress, anxiety, mood, quality of life and other relevant aspects of psychological state or wellbeing; as well as your views on your work engagement and performance. Information involving your personal and work circumstances is essential in order to allow us to perform an analysis based on the trial findings to assess the cost effectiveness of these interventions for the organisations involved. The other questionnaires are largely based on questions which consist of multiple-choice items that you are asked to select from based on which item you believe is mostly applicable to you. The total completion time for this online survey is 30-45 minutes. You can 'save and exit' your responses and return to this online survey at a later time as per your convenience although we ask you to aim to complete it within one week.

Starting the MBCT-L or SRP programme

Once you have completed these questionnaires, the study team will email you with information about the intervention that you have been allocated to, i.e., either to the MBCT-L or SRP programme. Given the nature of this trial, you will be allocated to one of the two interventions randomly by a designated study team, with the research team being blinded to your allocation. In your allocation letter, you will receive the dates of the programme sessions and instructions on how to set up and join MS Teams/Zoom for the first session. It is expected that you will start on the programme within two weeks after you have been randomly allocated to it. The trial duration overall will be 20 weeks after you have embarked on either intervention.

The MBCT-L programme:
If you have been allocated to the MBCT-L programme, you will be required to attend 8 two-hour weekly group sessions online (via MS Teams/Zoom) plus a half day online practice session. The two-

hour sessions will be group sessions of approximately 8-15 people, who will remain in the same group throughout the programme and will all be participants in this research study. The programme will run over 9 consecutive weeks, or 10 weeks depending on whether there is a one-week break (due to school breaks or other holidays). Weekly session themes will involve teaching on mindfulness-related aspects as well as guided meditation/relaxation practices and group discussions around the taught content and people's experience. There will be 1-2 MBCT-trained therapists delivering these sessions and they will guide you through what is required per session at the appropriate time. You will also be asked to perform daily 30-45 minute home practice outside the formal weekly sessions in order to enhance your practice experience. You will receive text messages via a specially designated text service reminding you about the home practice required for the week and the upcoming session(s) and prompts to flag up any issues that you may experience in relation to your engagement with the trial. These text messages will be sent via Florence which is a simple and easy to use text messaging service to help you manage your health and wellbeing. You can read more about Florence at https://generatedhealth.com/. If you are receiving messages from Florence, or replying to it from the UK you will not be charged for the messages – you can even use Florence if you have a pay-as-you-go phone with no credit. Please ensure that the mobile phone signed up to Florence is only used by you. Once set up, Florence will send you text messages during and after your MBCT-L programme sessions. If, for whatever reason, you decide that you want to stop receiving messages from Florence, you simply need to send "STOP", and Florence will stop sending you messages.

Please note, Florence is automated and is not an emergency service and won't be routinely monitored by the therapists. If you are experiencing a crisis, please contact your GP/clinician directly, dial 999, or access your local NHS urgent mental health helpline.

The SRP programme:
If you have been allocated to the SRP programme, you will be required to attend 4 two-hour weekly group sessions online (via MS Teams). The two-hour sessions will be group sessions of approximately 8-15 people, who will remain in the same group throughout the programme and will all be participants in this research study. The programme will be run over 4 consecutive weeks, or 5 weeks depending on whether there is a one-week break (due to school breaks or other holidays). Weekly session themes will involve teaching around stress management aspects as well as guided meditation/ relaxation practices and group discussions around the taught content and people's experience. There will be 1-2 trained therapists delivering these sessions and they will guide you through what is required per session at the appropriate time. You will also be asked to perform daily 30-45 minute home practice outside the formal sessions in order to enhance your practice experience. You will receive weekly reminders about the week's home practice and the upcoming session(s). You will receive through the therapists prompts to flag up any issues that you may experience in relation to your engagement with the programme.

You will be strongly encouraged by the therapist team on either programme to talk to them about any issues you might be experiencing throughout the programme itself or the duration of the trial; the therapist team will provide or guide you to appropriate support. You are also directed to a number of sources of support further below in the section 'What if there is a problem'.

<u>Repeating questionnaire completion on online survey during the trial</u>

For the purposes of assessing the outcomes of the two interventions, you will be asked to complete a similar online survey to the one that you filled in prior to embarking on the programme at three follow-up time points over the 20-week duration of the trial. You will be sent a link by the research team to the online survey at each of these three time points, specifically 6, 12 and 20 weeks after

you have started on either programme. As for the initial online survey completion, the total completion time for the online survey at each time point is 30-45 minutes. You can 'save and exit' your responses and return to the online survey at a later time as per your convenience although we ask you to aim to complete it within 1 week. Receiving your responses at all these time points will be crucial to the research team for determining any potential changes in how you feel and behave after you have started attending either programme. You will also be asked by the therapists to complete short forms online during the course of either programme, as part of the programme requirements (e.g., e.g. in relation to home practice, etc.).

You are being requested to refrain from attending another wellbeing programme offered through the Integrated Staff Wellbeing (Hub) Trust service or another psychological therapy outside the service during the 20 weeks of the duration of this trial in order to minimise any interfering effects on the assessed outcomes of the MBCT-L or SRP that you will attend. If your circumstances change and you need to do so, please speak to the therapist team on your programme in the first instance or inform the research team (see researchers' contact details in section 'Further information and contact details').

What happens towards the end/after the trial

You will be able to attend the other wellbeing programme that you were not allocated to for the purposes of this trial after the 20 weeks of the trial have ended- so if you are allocated to the SRP programme, after the trial is over you can refer to the Integrated Staff Wellbeing Hub for details on upcoming MBCT programmes to attend, if you wish to do so. The therapist team will be in a position to help you with this.

Towards the end of the trial (around 20 weeks after you have started either programme), the study team will contact you to ask you if you would be interested in taking part in a brief follow-up interview with a researcher to talk about your experience with the programme. Confidentiality in your responses in both the interview as well as the online survey will be ensured (see section on 'Will my taking part in the study be kept confidential?'). You will be directed to an online link for further details about the interview part of the study at that point. However, you will not be contacted about the interview if you have indicated that you do not wish to be contacted about this in the initial consent form that you will sign for partaking in this trial.

After the trial has finished and the results have been analysed, you will receive a summary of the trial findings unless you have indicated that you do not wish to do so in the consent form that you will sign for taking part in the trial.

Expenses and payments

Participants will be paid an inconvenience allowance to participate in the trial in the form of a £15 gift voucher. The inconvenience allowance will be paid at the end of the trial following the last follow-up completion of the online survey (at 20 weeks). Participants who will also take part in the follow-up interview will receive another gift voucher of £15 as inconvenience allowance for completing that part of the study too. The inconvenience allowance is not to be treated as an incentive for taking part in this study.

What are the possible disadvantages and risks of taking part?

While it is expected that both MBCT-L and SRP will have a beneficial impact on your psychological wellbeing, some potential adverse effects associated with such programmes have been reported in

non-clinical populations. The overall risk of adverse effects is low and such adverse effects have mainly involved exacerbated emotional reactions during or after meditation practices. Reasons for these occurrences include distress caused by traumatic memories that may resurface or other unpleasant feelings stemming from directing one's attention inwards towards their thoughts and emotions.

Some participants have reported feeling physical discomfort due to the postures involved in meditation/relaxation practices; as per standard practice in such programmes, the therapists will prompt you during the sessions to make adjustments during meditations/relaxation exercises to reduce any physical aches or other bodily discomfort; and to exert physical effort or adopt certain moves at a level that is comfortable for you during such exercises.

Some of the questions you will be asked in the online survey may cause discomfort or you may not wish to answer them. While your full responses will help ensure the completeness of the trial data, you do not have to answer any questions that you do not wish to answer; the online survey platform will flag up any missed answers to you at the end of each questionnaire but, if the lack of response was intentional from your part, the system will allow you to continue to the next questionnaire. If any of the questions cause significant concern or emotional upset, you are prompted to contact the researcher (see contact details in 'Further information and contact details') to inform them of this and to refer to sources of wellbeing support as listed in the section 'What if there is a problem?'.

While there are no other known potential disadvantages associated with taking part in these programmes, adverse events might occur in one's life that may not be related to their participation in the programme/trial. You will be prompted throughout the duration of the programme and after it finishes, throughout the 20 weeks of the trial duration, to report any adverse effects or events: in the weekly session logs as instructed by the therapist team and/or to the therapist team during or outside of the programme duration. A report of any adverse effect or event will trigger a consultation meeting between you and a member of the therapist team who will provide support and direct you to further support if required.

If any adverse reactions persist the therapist team in consultation with the research team may suggest that you discontinue the programme and will discuss with you alternative or further support. Should you wish to withdraw from the programme/trial at any point, you are free to do so (see section 'Do I have to take part?'). Beyond the 20 weeks of the trial duration, you are encouraged to refer to the staff support mental health and wellbeing hub for advice or support and/or refer to other sources of support as listed in the section 'What if there is a problem?'.

What are the possible benefits of taking part?

Wellbeing interventions such as the MBCT-L and SRP have been shown to be effective in reducing stress and improving wellbeing more generally and are hence expected to be of some benefit to you. However, not every psychotherapeutic programme works for everyone and we therefore cannot promise the study will help you. However, the information we get from your participation in this study may help us inform future adaptations in the implementation of such staff wellbeing programmes and guide NHS and other public sector organisations in their decisions about how to best support their staff's wellbeing.

What happens when the research study stops?

After the trial has finished or ended, once any trial results have been analysed, you will receive a summary of these findings unless you have indicated that you do not wish to do so in the consent form that you will sign for taking part in the trial. You can continue to access support through Trust well-being resources after the end of the study, but this will no longer be part of the study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers' contact details are given at the end of this information sheet (see section 'Further information and contact details'). If you remain unhappy and wish to complain formally, you can do this by contacting your local staff support mental health and wellbeing hub.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

If at any point during the duration of your programme or the trial or after the trial has finished you experience distress, as mentioned in section 'What are the possible disadvantages and risks of taking part?', you are strongly encouraged to get in touch with the therapist team who can direct you to appropriate support; and/or refer to the following wellbeing resources for urgent or specialist support:

Resources for further wellbeing support

- Your General Practitioner (GP) services
- Your Occupational Health services
- https://www.samaritans.org/how-we-can-help/contact-samaritan/
- https://www.nightline.ac.uk/want-to-talk/
- https://www.mind.org.uk/

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you at the beginning and during the duration of the trial. This information will be kept **strictly confidential**, stored on a password protected restricted-access database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:
https://www.nottingham.ac.uk/utilities/privacy.aspx

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will

have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Information held securely by the University of Nottingham will be kept confidential and coded. All data and databases will be held on secure University-approved systems that are backed up regularly. Data obtained from you on the online survey (as well as in the follow-up interview) will be identified by a study ID number, from which it is not possible to guess your identity. Only approved members of the research team will be able to access the file which links your study ID with your name, and this data will be held securely in accordance with the systems noted above. Information captured by Florence will include your name, phone number and any information you input via text. This is processed in accordance with Florence Privacy Notice http://generatedhealth.com/privacy. The information will be retained for 5 years. Research data will only be available to the study researchers at the University of Nottingham and will not be shared with anyone else, it will be deleted after 7 years.

Your personal/contact information will be kept by the University of Nottingham for up to 12 months after the end of the study. so that we can e-mail you a summary of the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted) . Your personal information will be kept separately from the research data collected, i.e., from the survey (as well as the follow-up interview) data, and only those who need to will have access to it. Research data will be kept securely and anonymised for at least 7 years after the end of the trial in order to allow inclusion of these data in further/follow-up analyses.

In accordance with the University of Nottingham's, the Government's and our funders' policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it would be necessary to report this to the appropriate persons and/or direct you to appropriate support.

What will happen if I don't want to carry on with the study?

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your healthcare, work or legal rights being affected. If you withdraw entirely from the trial we will no longer collect any information about you but we will keep the information about you that we have already obtained as we are not allowed to tamper with study records and your data may have already been used in some analyses and may still be used in the final study analyses. To safeguard your rights, we will use the minimum personally-identifiable information possible. You may decide to not withdraw from the trial entirely but withdraw from the programme while you are still happy to contribute to the trial by carrying on completing the online survey at the three follow-up time points; or you may wish to carry on with your participation in the programme but withdraw your partaking in the completion of the online survey at the follow-up time points.

If at any point you wish to withdraw, please inform the therapists on your programme or the research team (see researchers' contact details in the section 'Further information and contact details'). The research team will contact you to ask you to complete a form to briefly denote the reason for your withdrawal but completion of this form is non-obligatory.

Involvement of the General Practitioner/Family doctor (GP)

We will not inform your GP of your participation in the study. If at any point during the duration of your programme or the trial or after the trial has finished you experience any distress that may or may not be associated with the trial, as mentioned in sections 'What are the possible disadvantages and risks of taking part?' and 'What if there is a problem?' You are strongly encouraged to get in touch with your GP who can provide appropriate support and refer you to specialist mental health services if necessary.

What will happen to the results of the research study?

The anonymised trial findings will be disseminated to: academic/clinical conferences attended by professional groups and NHS confederation; commissioners, NICE, networks of nursing and medical directors of NHS organisations, social care directors and head teachers, HEE and AHSN East Midlands; mental health, occupational health and psychological wellbeing practitioner networks and conferences.

We will disseminate our research findings to peer reviewed academic journals. A Final Trial Report will be submitted to NIHR ARC EM and the sponsor. You will receive a lay summary of the findings (unless you have indicated that you do not wish to do so in the consent form). All proposed publications will be approved by the NIHR prior to publishing and will be peer-reviewed by assigned panels for the purposes of academic journal publications.

Who is organising and funding the research?

This research is being organised by the University of Nottingham and is being funded by the National Institute for Health Research (NIHR) Applied Research Collaboration East Midlands (ARC EM).

Who has reviewed the study?

All research in health care is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the East Midlands-Nottingham 1 NHS Research Ethics Committee (REC; Ref 23/EM/0109); and has received local Research and Governance (R&D) approval at all Trust participating sites. The study has also been reviewed and is being routinely monitored for progress and conduct by the ARC EM Scientific Committee and an independent Research Steering Committee.

Further information and contact details

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Tim Sweeney, Clinical Lead, Nottinghamshire Healthcare, Nottingham Psychotherapy Unit, 114 Thorneywood Mount, Nottingham; E-mail: Tim.Sweeney@nottshc.nhs.uk

If you remain unhappy and wish to complain formally, you should then contact the Faculty of Medical and Health Sciences Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk