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Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) versus Stress-Reduction Psychoeducation (SRP) for the improvement of mental wellbeing in healthcare and other public sector staff: Protocol for the 'Well at Work' randomised controlled trial

Elena Nixon, Shireen Patel, Priya Patel, James Roe, Neil Nixon, Tim Sweeney, Paul Bernard, Clara Strauss, Michael Craven, Sam Malins, Robert Goodwin, Laurence Astill Wright, Boliang Guo, Richard Morriss

Submitted to: JMIR Research Protocols
on: October 18, 2024

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Abstract

Background: Recently published guidelines by the National Institute for Health and Care Excellence (NICE) have recommended both mindfulness-based and stress-reduction approaches as effective preventative mental wellbeing interventions for healthcare and other public sector staff at risk of poor mental health.

Objective: This trial aims to assess the effectiveness of an increasingly implemented Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) intervention versus a routinely available Stress-Reduction Psychoeducation (SRP) intervention in reducing perceived stress and improving other mental health and work-related outcomes in national healthcare and other public sector service employees.

Methods: The trial is a multi-site, single-blind, parallel-group, two-arm superiority Randomised Controlled Trial (RCT). Recruitment, interventions and assessments will be conducted remotely, via online digital platforms. We will recruit 260 healthcare and other public sector staff in 26 intervention groups across the UK to be delivered through existing integrated care or wellbeing hub services or other human resource staff wellbeing channels affiliated with the participating National Health Service (NHS) Trusts. Participants will be randomly allocated in a 1:1 ratio to either the MBCT-L or SRP. Primary and secondary outcomes will be collected at 6, 12 and 20 weeks following randomisation. The primary outcome will be change on the Perceived Stress Scale-14 (PSS-14) from baseline to 20 weeks post randomisation. Demographic, intervention-related and health economic data will also be collected. Adverse events will be recorded. Data analysis will involve multilevel modelling and will be conducted on an intention-to-treat basis. A sub-study will involve online semi-structured interviews post 20 weeks randomisation with a sub-sample of participants (n=30). Transcribed data will be subjected to thematic analysis for eliciting qualitative outcomes on perceived wellbeing and work-related changes post intervention, and drivers and barriers to intervention uptake and acceptability.

Results: Recruitment of participants commenced on August 29th, 2023. The target recruitment of 260 participants was reached 30th April 2024. Follow up outcome data collection was completed 30th September 2024 and data analysis is underway. Thirty qualitative interviews have been conducted.

Conclusions: Findings will be made publicly available and will inform future refinements in intervention suitability and implementation for public care staff wellbeing. Clinical Trial: ISRCTN18049845

(JMIR Preprints 18/10/2024:67695)
DOI: https://doi.org/10.2196/preprints.67695

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Title: Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) versus Stress-Reduction Psychoeducation (SRP) for the improvement of mental wellbeing in healthcare and other public sector staff: Protocol for the 'Well at Work' randomised controlled trial

Authors

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Abstract

Background

Mindfulness-based and stress-reduction interventions have been recommended by the National

Guidelines for Health and Care Excellence (NICE) in England and Wales as effective preventative mental wellbeing interventions for healthcare and other public sector staff at risk of poor mental health.

Objectives

This trial aims to assess the effectiveness of an increasingly implemented Mindfulness-Based Cognitive Therapy-for Life (MBCT-L) intervention versus a routinely available Stress-Reduction Psychoeducation (SRP) intervention in reducing perceived stress and improving other mental health and work-related outcomes in national healthcare and other public sector service employees.

Methods

The trial is a multi-site, single-blind, parallel-group, two-arm superiority Randomised Controlled Trial (RCT). Recruitment, interventions and assessments will be conducted remotely, via online digital platforms. We will recruit 260 healthcare and other public sector staff in 26 intervention groups across the UK to be delivered throughhuman resource staff wellbeing provision channels affiliated with the participating National Health Service (NHS) Trusts. Participants will be randomly allocated in a 1:1 ratio to either the MBCT-L or SRP. Primary and secondary outcomes will be collected at 6, 12 and 20 weeks following randomisation. The primary outcome will be change on the Perceived Stress Scale-14 (PSS-14) from baseline to 20 weeks post randomisation. Demographic, intervention-related and health economic data will also be collected. Secondary outcomes will involve assessments of wellbeing, mental health state, and work-related engagement and performance. Adverse events will be recorded. Data analysis will involve multilevel modelling and will be conducted on an intention-to-treat basis. A sub-study will involve online semi-structured interviews post 20 weeks randomisation with a sub-sample of participants (n=30). Transcribed data will be subjected to thematic analysis for eliciting qualitative outcomes on perceived wellbeing and work-related changes post intervention, and drivers and barriers to intervention uptake and acceptability.

Results

Recruitment of participants commenced on August 29th, 2023. 29/08/2023, The target recruitment of 260 participants was reached 30th April 2024. Follow up outcome data collection was completed 30th September 2024 and data analysis is underway. Thirty qualitative interviews have been conducted.

Conclusions

Findings will inform future recommendations on intervention suitability and implementation for public care staff wellbeing.

Trial Registration

ISRCTN18049845

Keywords: healthcare NHS staff; digital intervention; staff well-being; mindfulness based cognitive therapy; therapy; stress reduction psychoeducation; randomized controlled trial

Introduction

Public sector employees present with higher levels of stress compared to those in other job sectors, with healthcare and public care staff in particular experiencing disproportionately high stress levels [1, 2]. Stress levels in public sector employees have been further exacerbated by the COVID-19 pandemic which has reportedly imposed additional stressors in the workplace, especially in healthcare staff [44; 45; 46]. 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 employees in human health, social care and education sectors in the United Kingdom (UK) [1]. Excessive stress and mental health problems such as anxiety and depression in public sector staff have also been broadly associated with further negative individual-level outcomes, such as 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 [3-5]. Mindfulness-based and stress-management training are two approaches that have been recently recommended by the National Institute for Health and Care Excellence (NICE) [6] as effective psychotherapeutic interventions to be delivered in the UK in either online or face-to-face group modality to healthcare or other public care employees at risk of poor mental health.

While a broad range of organisational- and individual- level wellbeing interventions are currently being offered in National Healthcare Service (NHS) Trusts and other public sector workplaces, stress reduction psychoeducation (SRP) is a standard usual care group programme offered widely and in various formats across all geographical regions in England (UK) to healthcare staff, as well as to other public sector staff accessing psychotherapeutic interventions through their organisational wellbeing services affiliated with NHS Trusts. Mindfulness-based Cognitive Therapy-for Life (MBCT-L) [7] is a newer, third-wave intervention, which is becoming increasingly implemented in NHS and other public sector services. MBCT-L borrows its premises from the standard MBCT variant [8, 9], the latter being a NICE-recommended treatment option for recurrent as well as mild-to-moderate acute depression [10], while it is also included in the clinical guidelines as a relapse prevention option in other countries too [11-13]. Importantly, 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 populations, including healthcare workers; as evidenced in previous work [14-18], including a recent RCT which showed moderate to large effects on healthcare staff wellbeing derived from MBCT-L as compared to a wait-list control [19]. SRP and MBCT-L approaches are increasingly being implemented across the NHS Trusts in the UK in online formats, particularly post-COVID, and in acknowledgement that digital modalities can overcome main barriers to intervention uptake and adherence [21]. However, MBCT-L is currently being offered as a workplace psychological programme through Trust wellbeing services in a limited number of Trusts across the UK. Notably, MBCT-L is a longer-duration programme,

commonly lasting 8 weeks, or 9 weeks if a practice (retreat) day is included, as opposed to SRP, the duration of which can vary between 4 and 6 weeks. Furthermore, MBCT-L requires for its delivery more skilled staff, i.e., specifically MBCT-trained staff, whereas SRP programmes can be delivered by classically trained CBT practitioners, psychological wellbeing practitioners (PWPs) or other healthcare staff trained in supporting people with common mental health problems in managing their conditions.

SRP and MBCT-L approaches differ in their conceptual and practical premises; whereas SRP relies on behavioural stress-reduction techniques coupled with wellbeing and goal setting [20], MBCT-L is an enhanced approach that combines both stress reduction and cognitive therapy elements in one programme, embedding mindfulness practice too [7]. Thus, a presumed advantage of MBCT-L over SRP approaches is that the former teaches foundational coping skills that do not only alleviate transient stress but cultivate a long-term change in one's attitude to stress and promote a more positive outlook to stressful experience and life more generally.

However, the two approaches have not yet been compared to one another in terms of their effectiveness as workplace interventions in improving stress and other wellbeing aspects and job-related outcomes. The reviewed study findings of the recent NICE guidance [6] indicated larger effects of face-to-face mindfulness-based approaches on stress and other mental health and job-related outcomes than stress-reduction interventions, 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 public sector populations which included healthcare staff. Very low-quality evidence suggested that such mindfulness interventions may improve job stress in such populations. Further, the reviewed mindfulness-based studies seemed to rely on mindfulness-based stress reduction (MBSR) approaches - largely without cognitive elements embedded - while some of the reviewed SRP studies also included cognitive elements in their content and exercises. 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 which included healthcare staff. Low and very low-quality evidence hinted that a stress management approach might be effective in improving stress and mental health symptoms in these populations.

Study rationale

The NICE review did not include any online mindfulness-based studies while the included stress management interventions were delivered either face-to-face or online. All five mindfulness-based and all five stress-management studies included in the NICE review had a wait-list or usual care as a comparator, or no wellbeing comparator intervention. Only one of stress-management studies was based in the UK while there were no UK-based mindfulness-based studies. Finally, while the NICE review consolidated some qualitative data assessing barriers and facilitators to intervention uptake, it only included one qualitative study and this involved another type of intervention, i.e., digital Cognitive Behavioural Therapy (CBT) [6]. The findings of this study indicated that there are a number of positive aspects of the digital modality of such a wellbeing 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 given intervention.

Therefore, in light of the lack of online mindfulness-based studies in the NICE review and a lack of studies comparing directly mindfulness-based and stress-reduction psycho-education approaches, the proposed superiority trial will assess the effectiveness -and cost effectiveness- of the two approaches; and in light of the lack of qualitative studies exploring the acceptability or effectiveness of either approach, the present study will also aim to gather in-depth qualitative data from a subsample of participants to enquire into their perceived impact of the intervention in terms of post-intervention changes in their wellbeing and work performance, as well as barriers and

facilitators in their uptake and acceptability of such interventions, and in their engagement throughout the programme course. The overarching research question is: Does MBCT-L demonstrate superior efficacy to SRP in reducing perceived stress and improving mental health and work-related outcomes among public sector employees? The findings of the study are expected to fill in the aforementioned gaps in the existing research and are intended to inform NHS and other public sector organisations on how to best invest in their future resource provision to retain and support their staff at risk of poor wellbeing.

Methods

Aim, design and setting of the study

The proposed 'Well at Work' study is a single-blind, multi-site, parallel-group, two-arm superiority RCT that will aim to assess the clinical and cost effectiveness of MBCT-L versus SRP in healthcare and other public sector staff seeking to access wellbeing support through human resource channels of staff wellbeing provision affiliated with the participating NHS Trusts. The primary objective of the trial will be to determine if there is a difference in change on the primary outcome on the perceived stress scale (PSS-14 [25]) between the two intervention groups from baseline to 20 weeks post randomisation. The secondary objectives will be to assess differences in change in any of the secondary mental wellbeing and work-related outcome measures between the two arms from baseline to each follow-up time, i.e., at 6, 12 and 20-weeks post randomisation. Recruitment, interventions and assessments will be conducted remotely, via online digital platforms utilising videoconference and electronic technologies.

Qualitative study: A sub-study will involve online semi-structured interviews to be conducted at 20 weeks post randomisation with a sub-sample of participants from each arm to gather qualitative data for in-depth insights into participants' perceived changes post intervention, and their experience and views in relation to intervention uptake and acceptability.

The Well at Work study is hosted by the University of Nottingham in the United Kingdom which is the sponsor of the study, and will be mainly based across four public care (NHS) sites over three geographical regions in the United Kingdom, i.e., Nottingham University Hospitals NHS Trust and Nottinghamshire Healthcare NHS Foundation Trust (East of England); Sussex Partnership NHS Foundation Trust (South of England); and Tees, Esk and Wear Valleys NHS Foundation Trust (North of England). The online MBCT-L intervention will be offered across all four NHS Trust sites while 9 additional NHS Trust sites will also be participating in the trial: Lincolnshire Partnership NHS Foundation Trust; Lincolnshire Community Health Services NHS Trust; Derbyshire Community Health Services NHS Foundation Trust; York & Scarborough Teaching Hospitals NHS Foundation Trust; South Tyneside & Sunderland NHS Foundation Trust; Leicestershire Partnership NHS Trust; Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust; South West London & St George's Mental Health NHS Trust; and Northern Care Alliance NHS Foundation Trust. These additional sites will be channelling interested staff to one of the main four Trust sites delivering the interventions. Given the online intervention delivery format, the trial aims with this approach to achieve wide geographical coverage and outreach across healthcare and any other public sector staff across the United Kingdom seeking wellbeing support through their organisations that is offered through the participating NHS Trust sites.

Patient and Public Involvement and engagement (PPIe): A PPIe group consisting of members of staff working in the public sector has been formed and consulted on the design of the study. The PPIe group is intended to provide input into all key aspects of the trial throughout its duration, from conceptualisation to implementation, evaluation and dissemination.

Reporting of the protocol is according to SPIRIT guidelines (please refer to Multimedia Appendix 1).

Sample selection

Potential participants will be directed to the study through existing integrated care services, wellbeing hubs and other human resource channels which are accessed by staff working in healthcare

as well as other public sectors, e.g., social care and teaching, through the NHS Trust sites participating in the trial. Communication of study information will be facilitated through a study flyer that will be circulated widely across the participating sites by email and via other communication channels, including staff communication hubs, staff wellbeing websites, staff networks/newsletters/social media (e.g., Facebook, X) and staff induction or other events.

Staff expressing an interest in the study will be directed to an online link facilitated via Research Electronic Data Capture (REDCap) [22, 23] tools hosted at the University of Nottingham, which will include a Participant Information Sheet (PIS) with information about the study, followed by an eligibility screening form. The contact details of the study researchers will be provided in the PIS should any interested participants wish to ask any questions. Upon completion of the eligibility form, eligible participants will be emailed a link to a participant consent form on the REDCap platform. In the consent form, participants will also be asked to indicate if they would be willing to receive information at a later stage about the qualitative sub-study. Following provision of informed consent on REDCap, participants will be directed on the platform to the survey containing the baseline assessment questionnaires.

Inclusion criteria

Participants must meet all the following criteria to be eligible for participation in the trial:

1. Aged 18 years or over

2. In part-time/full-time or honorary/voluntary employment seeking access to wellbeing support through one of the participating sites

3. Currently in work (i.e., not on sickness absence)

4. Have competent command of verbal and written English language

5. Have access to stable internet connection on a pc/laptop/tablet

Exclusion criteria

Interested participants meeting any of the following criteria will not be eligible for inclusion in the

trial:

1. Current diagnosis of a mental health condition from a General Practitioner or mental healthcare professional

2. Experience of significant life event(s) currently causing significant distress

3. Concurrently attending or planning to attend a psychological or wellbeing intervention within the subsequent three months

Screening: Exclusion criteria will be flagged up in the screening form and interested participants deemed as ineligible will be contacted by the trial practitioner/facilitator team to verify their eligibility; if exclusion criteria are confirmed, interested participants will be signposted to alternative available support as appropriate, e.g., to a MBCT-for Depression (MBCT-D) programme run routinely at each of the involved sites if participants experience high levels of depression. As this is the mechanism already in routine place for staff recruitment on these interventions through Trust wellbeing services, we will not add any measure threshold exclusion criteria.

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Sample size

With reference to the trial primary outcome, 5 points on the PSS-14 will be considered as the minimum clinically important difference. Assuming a two-tailed 0.05 significance level with 90% power (using ANCOVA) and SD=7.7, and assuming that the correlation between baseline and follow-up is 0.2 and the correlation among follow-up measures is 0.7, a total of 76 participants will be needed to estimate the treatment effect from baseline at 20 weeks post randomisation. Assuming the average group size is 8, ICC=15% and attrition rate is 25% (considering potential loss to follow-up), the final sample size was inflated to 208 participants to be randomly recruited in 26 groups (1:1 ratio) across all the recruitment sites. However, upon monitoring follow-up rates after about a third of participants were randomised, it was highlighted by a blinded independent statistician that the follow-up rate was approximately 62% and group size was about 10. Therefore, the trial management group decided to update the sample size with 85% power to mitigate the loss to follow-up. A substantial amendment was submitted, and ethical approval was received for the sample size to be increased to 260 in total, in 26 groups.Ethics, oversight and monitoring

The trial has been granted ethical approval by the Research Ethics Committee (REC; East Midland-Nottingham 1) and Health Research Authority (HRA) & Health and Care Research Wales (HCRW) Committee (Ethics Reference: 23/EM/0109) and has received favourable approvals by the Research and Development (R and D) governance bodies of the participating Trust sites. The study has also been reviewed by the NIHR ARC-EM Scientific Committee as part of the funding application.

The trial will be overseen by an independent ARC EM Scientific Committee. The members of the committee will be drawn externally from outside the institutions that the research team currently work to ensure its independence of the research team. It will serve the function of a Trial Steering Committee (TSC) and a Data Monitoring Committee (DMC). The trial will be reviewed every 6 months through reports to this committee and presentations of progress to the committee by the study team. The data monitoring committee will review safety data and periodically review the conduct of the study. The steering committee takes responsibility for the scientific validity of the study protocol, assessment of study quality and conduct and for the scientific quality of the final study report. The sponsor and the investigators participating in the trial bear the final responsibility for the conduct of the trial. 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.

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All participants will sign the participant consent form. Participants will be informed in the PIS that entry into the trial is entirely voluntary and that their healthcare, work and legal rights will not be affected by their decision. It will also be explained that they can withdraw at any time during the trial (including at follow-up) but that in the event of their withdrawal data collected up to that point cannot be erased and may still be used in the final analysis. It will also 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 (intervention) 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. 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.

Randomisation and blinding

Once participants have consented on the REDCap platform, they will be randomly allocated in a 1:1 ratio to either the MBCT-L or SRP intervention. The online format and delivery of the interventions allows the allocation of participants to take place across the participating sites; this is expected to facilitate timely and sufficient recruitment within and across the intervention groups running at any sites, until the two intervention groups are full in each recruitment wave throughout the trial. Randomisation will be conducted via a web-based randomisation system set up by a Clinical

Decision Support System (CDSS) supported by the University of Nottingham. The randomisation system will ensure that all the researchers involved in the outcome assessments (SP, PP, JR) remain blind to intervention allocation. Participant allocation to either intervention arm will be solely facilitated by a project administrator who will manage the randomisation system independently of the research team and following specified standard operating procedures. The study statistician will also be blinded to treatment allocation, In the event of inadvertent unblinding, the details of the unblinding incident will be recorded in the study log, relevant sponsor and monitoring committees will be informed (e.g., the University Sponsor, the Research Ethics Committee, the ARC-EM Scientific Committee) and the extent and impact of the unblinding will be assessed. All participants will receive the same outcome measures to complete on the survey so that researchers/outcome assessors will not know by the measurements which group the participant is in. . In view of the nature of the interventions, participants cannot be blinded; they 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 intervention delivery (e.g., dates and times, requirements for online attendance, joining instructions, etc.).

Interventions

The two interventions that participants will be randomised to, i.e., the MBCT-L or the SRP, will be delivered online via a videoconference platform, i.e., via Microsoft Teams, taking place in a group format, once a week and at different times and days allowing participants to indicate (at consent) which group times they would opt for if they were to be randomised to either intervention. The sessions on either intervention will not be recorded. There will be 3 recruitment waves in total, with the interventions starting at various time points during a given recruitment wave; with both intervention arms starting in the same week in each recruitment wave to allow synchronised data collection. For an outline of recruitment, consenting, randomisation and assessment processes, please refer to the CONSORT Flowchart (Figure 1).

Please insert Figure 1 here

The MBCT-L intervention: MBCT-L integrates conventional cognitive therapy 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 [7]. The programme includes 8 online weekly sessions lasting approximately 2 hours as well as an online practice day lasting approximately 6 hours. MBCT-L 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) and in a group-based format of an average of 8 participants recruited per group. Content includes weekly session-theme teaching/discussions and guided meditation practices (e.g., breathing practice, body scan, etc.); as well as everyday homework practices lasting 30-45 minutes. Participants will receive frequent automated text reminders about their upcoming sessions and homework/home practices via an automated text messaging service provided by a Generated Health system, Florence [24]. The programme will be delivered by approximately 8 trained MBCT practitioners/facilitators across the main Trust sites, who are part of the teaching team involved in the MBCT-L interventions already being offered to public sector staff through the NHS Trust services; and who have been trained under, and use the same, MBCT training protocol [7].

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 the application of this learning to everyday life -including work- to respond more effectively to stress and enjoy the positive aspects of life.

The SRP intervention: The SRP will be delivered in 4 online weekly sessions lasting

approximately 2 hours and running over 4 consecutive weeks, or 5 weeks if there is a one-week break (e.g., school break or other holidays). The programme will run as it is currently being offered as standard care across Nottinghamshire and across all the other regions in England, through NHS Talking Therapies (formerly known as 'Improving Access to Psychological Therapies'; IAPT), or Trust or other healthcare services. Its content is focused on psychoeducation around wellbeing and stress management, combined with relaxation strategies [20]. Specifically, the programme consists of sessions focused on areas of stress, wellbeing and goal setting; sleep hygiene; anxiety and depression; behavioural activation; 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 daily for approximately 30 minutes; and through diary activity (e.g. behavioural activation diary). They will receive e-mail reminders for completing these and for attending the upcoming sessions.

Recognising that SRP programmes can vary in their content and format or structure in how they are being offered across NHS Trusts and other organisations in the United Kingdom, 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 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 when groups are delivered by experienced facilitators. The programme will be delivered by a total of 3 experienced facilitators (2 PWPs and 1 psychiatrist) across the SRP groups recruited across all sites ensuring consistent intervention delivery across all participating NHS sites.

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Intervention compliance: Intervention adherence and/or compliance rates, i.e., session attendance, and any other data specific to the intervention where applicable, will be collected electronically via a password protected MS Online Form as per routine therapy protocol during the MBCT-L/SRP intervention. Retention rates and turnover by randomised group will be determined after the first recruitment wave. We will consider participants as compliant if they have attended 50% of the sessions on either intervention. Participants will not be allowed to continue with the intervention if they have missed the first couple of sessions on either intervention arm. Participant attendance will be recorded by the facilitators on either intervention as per routine practice and will be reported to the project administrator who will monitor attendance and will contact participants if they have missed the first and/or second session. Home practice adherence will not be monitored/recorded; as per routine practice, participants will be strongly encouraged to engage in home practice outside the formal weekly sessions but potential lack of daily commitment to practice should not affect participants' session attendance. Practitioners/facilitators will prompt participants to complete their daily home practice in-between intervention sessions and remind them of the upcoming intervention session(s).

Outcome Assessments

Consented participants will be required to complete the outcome assessments via online surveys through REDCap which will contain the 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. Participants in both arms will receive the same outcome measures. Participants will be able to save their responses and return to the survey to complete their assessments at a later point. For both incomplete baseline and follow-up surveys, participants will receive 3 automated e-mail reminders through REDCap asking them to complete the survey. If the survey is still incomplete, the research team may then send out one further personalised email reminder from the study email address.

Primary outcome

The primary outcome will be change on the Perceived Stress Scale-14 (PSS-14; see below [25]) score from baseline at 20 weeks post randomisation. The PSS-14 was selected as the primary outcome measure as it is a well-validated and internationally used self-report scale of perceived stress and has been widely used in previous trials, assessing changes in stress levels in diverse populations, including public sector workers.

Secondary outcomes

All secondary outcome measures used in the trial are also widely recognized as valid and effective scales in assessing the severity of mental health problems in various populations, including healthcare workers. Although these measures are relatively brief to administer, they present with limitations due to their reliance on self-report, which can entail biases such as recall bias and may not index the full complexity of an individual's experience of stress or poor wellbeing.Secondary outcomes will all be collected at 6, 12 and 20-weeks post randomisation, These standardised measures have been commonly used in intervention studies to assess changes in wellbeing, mental health state, and work-related satisfaction, engagement and performance.

- Perceived Stress Scale-14 (PSS-14; [25]: 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). PSS-14 assessment at 6 and 12 weeks will be treated as secondary outcome.

- Generalised Anxiety Disorder scale-7 (GAD-7; [26]): 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; [27]): 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; [28]): a brief measure of Post-Traumatic Stress Disorder (PTSD) and complex PTSD (CPTSD); respondents are asked 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, think about themselves and relate to others.
- Five Facet Mindfulness Questionnaire (FFMQ; [29]): items assess five aspects of mindfulness and their impact on wellbeing; participants are required to rate statements on a 5-point scale from 1 (never or very rarely true) to 5 (very often or always true) on facets of mindfulness relating to describing, observing, non-reacting, acting with awareness, and non-judging.
- Copenhagen Burnout Inventory (CBI; [30]): 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’. The 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.

- Utrecht Work Engagement Scale- 9 item (UWES–9; [31]): 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).

Economic evaluation

We also plan to conduct an economic evaluation will be from a NHS and personal social services perspective.

Measures of cost effectiveness

Primary measure of cost-effectiveness: Incremental Cost-Effectiveness Ratio (ICER) per QALY gained for the MBCT-L vs SRP interventions.

Secondary measures: ICER per reduction in Perceived Stress Scale-14 (PSS-14 for MBCT-L vs .SRP).

The following outcome data will be collected:

- Health-related quality of life (HRQoL) outcomes will be collected at baseline and at 6-, 12- and 20-weeks post randomisation. These will be measured via the widely used EuroQol 5 Dimension 5 Level (EQ-5D-5L [32]).
- A health economics assessment adapted from the Client Service Receipt Inventory (CSRI; [33]), 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, 6 weeks preceding data collection at 6 weeks follow up, 6 weeks preceding data collection at 12 weeks follow up and 8 weeks preceding data collection at 20 weeks follow up. It is intended that the data gathered from these measures will be utilised for a cost effectiveness analysis subject to trial outcomes should MBCT be superior to SRP.

Other data acquisition

We will aim to collect demographic data including information about protected characteristics (e.g., age, gender, ethnicity, pregnancy, marital status, highest qualification, religion, sexual orientation, disability, first language, caring responsibilities, refugee and asylum seeker status). We will also gather job-related information on job sector, job title, duration in post, monthly salary, presenteeism, absenteeism, turnover intention, and service usage (including wellbeing programmes, primary care, outpatient appointments, inpatient appointments, private therapy and medication); and where available, practitioner/facilitator feedback data. Data will also be collected on recruitment uptake/rate, session attendance, compliance to treatment, any adverse events, attrition/drop-out rates (mid intervention and loss to follow-up), and reasons for attrition and/or non-compliance, including diversion and inclusion barriers to intervention uptake and implementation.

Qualitative study: A subsample of 30 participants (n=15 in each intervention arm) will be recruited for the qualitative study post 20-week randomisation (within an 8-week data collection window). The semi-structured interviews will enquire into participants' perceived changes post intervention and their experience and views in relation to intervention uptake and acceptability. They will be conducted online via MS Teams and will be video and/or audio recorded for transcription purposes, depending on the participant preference as to whether the camera is kept on during the interview or is switched off with only the mic on).

Qualitative study - 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 levels of work satisfaction, engagement and performance (i.e., beneficial impacts, adverse effects).
- Nature of wellbeing support sought and 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.

Dissemination

We will report the trial findings and recommendations on the digital intervention product refinements to our PPIe group and other stakeholders, scientific audiences, the NHS confederation, NICE, networks of nursing and medical directors of NHS organisations, social care directors, Academic Health Science Network (AHSN)- East Midlands, NHS England (previously known as Health Education England), and professional wellbeing practitioner groups who will be required to staff and deliver these interventions.

Adverse events (AEs)

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 in practice. The trained practitioners/facilitators delivering these interventions have a mechanism in place as routine practice for providing tailored advice and support at any stage. Participants are prompted once they have embarked on an intervention to report any adverse events (AEs), emotional or physical events/effects, to the practitioner/facilitator. This will trigger a consultation meeting between the participant and the therapist(s) team who will provide advice and refer the participant to further support, as appropriate (within the mental health wellbeing team, General Practice or Mental Health Services). Participants are 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. Participants are also signposted in the PIS to available wellbeing support

resources they can access outside the trial.

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; and worsening of symptoms present at baseline following the start of the study. 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 AE in the study log and the ARC EM Scientific Committee. Participants are being asked to contact the practitioner leading their intervention group and/or at the study site immediately in the event of an AE. Any AEs 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 AEs 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 study log and will instigate further investigation and follow-up if/as appropriate. The Chief Investigator shall be responsible for all adverse event reporting to the ARC EM Scientific Committee and Ethics Committee Board.

Data management plan

Source data will include participant demographic, consent, assessment data logged by participants and/or the research/study team on the REDCap data capture system; and any other supplementary data logged by the research/study team. Source data will also include participant interview transcripts. Access to the research data will be limited to assigned trial staff and researchers to allow trial-related monitoring and/or audits and ensure compliance with data management regulations. All data will be stored on secure University of Nottingham 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). Research data will be anonymised by allocating a unique trial specific number and/or code in the database. It will be ensured that identifiable data will be stored separately from research data and that and that the researchers do not have access to the identifiable/randomisation data in order to retain blinding.

Interview data and use of video conferencing: Only University of Nottingham approved platforms (i.e., Microsoft Teams) will be utilised for the conduct of interviews as these platforms are encrypted. To retain privacy and confidentiality, researchers will ensure they are working in an area where conversations cannot be overheard, and the computer screen cannot be observed. Researchers 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. The interview recordings will be pseudonymised and any identifying information will be redacted in transcripts. Interview recordings and transcripts will be saved on access-restricted, password-protected online research folders on the OneDrive University of Nottingham.

The trial will follow the University of Nottingham (Sponsor) electronic data management policy and procedures in accordance with the Data Protection Act 2018.

Analyses

Statistical method

All analysis will be conducted on an intention-to-treat (ITT) basis; a description of the planned ITT and sensitivity analyses for both primary and secondary outcomes conforming to the Estimand framework [34] has been provided (see Multimedia Appendix 2). After exploratory analysis, multilevel modelling will be implemented to quantify the treatment effect estimate and its precision over the follow-up times with treatment implementation group and each participant as higher-level analytical unit, baseline measure, allocation status, follow-up time and interaction of follow-up ×

allocation as covariates with fixed effects. A similar analytic approach will be used to quantify the treatment effects on all secondary outcomes. Missing values will be explored and imputed using a multiple imputation approach under missing at random assumption for missingness mechanism [35]. 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. The latest available version of STATA will be used for data analysis. A detailed trial Statistical Analysis Plan (SAP) setting out the proposed analyses has been published at: https://doi.org/10.6084/m9.figshare.28164743.v1

Economic analysis

The initial estimates of cost-effectiveness will require a basecase analysis before exploring the impact of uncertainty. To perform the basecase analysis, firstly each individual participant within the trial will have an estimated intervention cost, a healthcare cost, a QALY score based upon their EQ-5D-5L responses, and a PSS-14 score. Secondly, using Ordinary Least Squares Regression, incremental costs, QALYs, and PSS-14 scores will be estimated for MBCT-L vs. SRP. These incremental values will then be used to estimate the ICER per QALY gained and ICER per PSS-14 reduced. The basecase analysis will use data from all participants who report complete data, however, a secondary analysis using all participants will be conducted, with missing data controlled for using multiple imputation [35].

The basecase analysis will not include any productivity costs (i.e. due to absence off work), as per National Institute of Health and Care Excellence Guidelines [47]. A secondary analysis will be conducted whereby productivity costs will also be included, using a similar approach as the basecase analysis. All analyses will be conducted using the latest version of STATA. Please refer to Multimedia Appendix 3 for a detailed Economic Analysis Plan.

Qualitative data analysis

Based on the expected nature of the data as per previous studies, thematic analysis is intended to be applied to the transcribed data from the semi-structured interviews. The analytical approach is anticipated to be reflexive, guided by key principles of the grounded theory framework and the guidelines by Braun and Clarke following their 6-step thematic analysis methodological approach [38, 39]. The latest version of N-Vivo software will be used for coding. The process of codebook development will be adopted until code agreement has been reached, and a reflexive log will be kept to document coders' personal reflections and observations emerging during the coding and thematic analysis process [39] and to be utilised as a tool for minimizing potential bias in interpretation. A codebook example will be provided following the guidelines of Boyatzis [48] illustrating how codes were generated from participant quotes and how codes in turn led to the derivation of themes and subthemes. Inter-rater reliability between two raters will likely be determined based on the formula suggested by Miles and Huberman [49] which is suitable for small-scale participant samples; and is defined as the number of agreements / number of agreements + disagreements, with 75% being the minimum percentage to indicate adequate levels of agreement [50].

Preprint JMIR Publications

Results

Recruitment of participants commenced on August 29th, 2023. The target recruitment of 260 participants was reached 30th April 2024. Follow up outcome data collection was completed 30th September 2024. We anticipate data analysis to be complete by December 2024.

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Discussion

There has been increasing recognition of the importance of wellbeing in the public sector workplace and how it is associated with individual as well as work-related outcomes [3-5]. In light of the disproportionate high rates of psychological distress in healthcare, public care and other employees in the public sector [1, 2], wellbeing support provision offered within organisational settings is conducive to maintaining a healthy and effectively productive workforce. The overall aim of this trial is to determine whether an online mindfulness-based variant, MBCT-L, is superior to an online stress-reduction approach, SRP, in reducing perceived stress and improving other mental health and job-related outcomes in healthcare and other public sector employees. Both interventions are recommended by NICE as effective psychotherapies for improving psychological wellbeing in public sector employees at risk of poor mental health in the context of individual-level therapies that can reduce stress levels and improve general psychological wellbeing. While the two approaches differ in their nature, structure and programme duration, the present study is the first to directly compare these two types of interventions for their effectiveness and cost effectiveness being delivered in online modalities. Beyond the primary outcome of perceived stress, the trial will secondarily assess intervention change on other aspects of mental wellbeing (e.g., anxiety, depression, post-traumatic stress and burnout) that have been found to be affected in these cohorts; as well as on work outcomes related to work engagement, satisfaction and performance, which are factors linked to presenteeism, absenteeism and turnover in the workplace [3-5].

The trial will also collect additional data through the online survey which will include, among other data, information on work engagement and turnover intention, absenteeism and previous uptake of wellbeing support within or outside the work settings, to allow us to describe the mental health state and needs of the given cohort. The NICE committee also stressed the potential resource impact for rolling out such interventions in the workplace sectors. We will aim to also

perform a budget impact analysis to inform on intervention cost in practice although this will depend on the outcomes of the trial in terms of intervention clinical and cost effectiveness.

While NICE recognises that organisational-level and managerial-level policies and practices are important to address work-related issues, particularly in ensuring equality and work satisfaction, the committee has highlighted that local commissioners and healthcare providers have a responsibility towards enabling staff at risk of poor wellbeing to take up such wellbeing interventions in the workplace, within a supportive organisational culture and climate [6]. This is of particular importance given the long-term impact of the COVID-19 pandemic on public care staff and considering its particular impact on individuals from BAME and/or deprived socio-economic backgrounds [40]. Preliminary reports from the NHS CHECK study, one of the largest UK ongoing cohort studies launched during the pandemic to longitudinally investigate the psychosocial impacts of COVID-19 on NHS staff, indicated that women, younger staff and nurses faced poorer mental health outcomes than other healthcare staff; and that NHS staff from ethnic minorities faced significant workplace inequalities leading to negative health outcomes [41]. The trial will collect information on protected characteristics as well as recruitment uptake, session attendance and compliance to treatment, attrition and/or drop-out rates and reasons for attrition and/or non-compliance; including barriers to intervention access or uptake and engagement that may reflect equality, diversion and inclusion (EDI) issues, that will be explored in more depth in the semi-structured interviews in the qualitative sub-study.

Considering that interventions that are perceived to tackle mental health can be heavily stigmatised in some cultures [42], a limitation to this study might be the potential lack of engagement by individuals of certain sociocultural backgrounds. We will emphasise in the trial that both interventions are intended to help people cope more effectively with stress in the workplace and busy personal lives in an attempt to address such stigma. Advertising will be wide and will be aimed to reach all staff groups within the target cohort. We will keep engaging in discussions with PPI

representatives and NHS Trust Equality and Diversity or wellbeing champions about any particular approaches within the set study design that may help to engage staff from different ethnic groups. Our lead therapist team has also examined the content of the interventions involved in the trial to ensure that they are culturally sensitive to equality and diversity issues but anticipated qualitative input by participants on their experience with and acceptability of the interventions in the semi-structured interviews will input into the refinement of the interventions toward improved future practice. Along similar lines, the inclusion in this study of selected NHS sites across the UK represents a limitation to the study design and the representativeness of the data. The measures used in the trial may also pose a challenge to the interpretation of results given their self-report nature and potential biases in recall or response bias.

A further shortcoming integral to the endpoint of assessing the superiority of MBCT-L is the lack of its wide availability across the Trusts in the UK, compared to the readily available SRP programmes. To overcome this limitation, and utilising the digital intervention modality, we have adopted a study design that allows Trusts in the UK where MBCT-L is not available to partake in the trial as 'channelling' sites, allowing the recruitment of eligible staff on either of the two interventions delivered through the four main Trust sites in the trial. It is hoped that this approach will also help mitigate for potential low recruitment rates or loss to follow-up.

Possible unintended outcomes might include adverse effects following engagement with the interventions. Currently, relatively little has been reported on potential adverse effects of MBCT in non-clinical populations. However, in a recent systematic review of adverse events in meditation practices and meditation-based therapies, including relaxation and MBCT exercises [43], it was found that adverse effects during or after meditation practices occurred in non-clinical populations too and were 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 and SRP include psychoeducational materials and resources on how to manage distressing experiences arising during meditation or at other times while there is a mechanism in place in the trial for the participant to consult the therapist in the event of excessive discomfort or distress or to be directed to other wellbeing support. The trial will log any adverse effects reported during the intervention period and at follow-up while there are plans in place for reviewing these and the conduct of the trial with the NIHR ARC EM scientific committee as well as the external steering committee; and for terminating a participant's engagement in the trial or terminating the trial, should the criteria for doing so be fulfilled.

Conclusions

The outcomes of this trial are expected to inform NHS and other public care services as to which intervention might be more effective to be commissioned for provision to their staff who access such wellbeing interventions through Trust integrated care pathways or other organisational wellbeing resource channels. We aim to also inform NICE in light of its review findings that did not include any evidence of online MBCT nor any studies comparing the effectiveness of MBCT versus SRP approaches. In terms of impact, we hope there may be some immediate benefits not only to the staff receiving the interventions but also to those NHS services and other public care areas that already provide these interventions in the UK and internationally so that they can refine their practice.

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Acknowledgements

This study is funded by the National Institute of Health and Care Research (NIHR) Applied Collaboration East Midlands (ARC EM) (Grant No. 1.19). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

The development and funding of this research was supported by the National Institute of Health and Care Research (NIHR) Applied Collaboration East Midlands (ARC EM). The NIHR ARC EM Scientific Committee provided expert advice and feedback on the trial design and conduct. We thank the PPIe group for their ongoing input into the design of the study, as well as other key aspects of the trial. We acknowledge the contribution and support of all the practitioners/facilitators involved in

delivering the interventions in the trial, besides the co-authors Paul Bernard, Tim Sweeney and Laurence Astill Wright: Kathryn Feenan; Sonia Moratto; Karen Hoyle; Elinor Morgan; Jo Etherington; Jiva Masheder; Nicky Mouat; Ferhana Girach; and Laura Martin in the initial stages of the trial. Our thanks also go to Robert Marx, from the Sussex Partnership NHS Trust, for participating in the initial study conceptualisation stages. We are also grateful to Julie Moss, our senior study administrator, for her support with allocating participants to groups, setting up the Florence text messaging system and general administrative support throughout the study. Special thanks also to Yvonne Price for providing overall project management support. In addition, we wish to thank Daniel Simpkins for his senior data management support in setting up and managing participant surveys and randomization through the REDCap platform. We also thank all participating sites for helping us to set up the trial to recruit participants, including Emily Budden and Joanna Pooley for screening potential participants.

Conflicts of interest

The authors have read the journal's policy and have the following competing interests: Richard Morriss is the lead of the NIHR ARC EM Mental Health and Well-being Theme, supported by the Nottingham NIHR Biomedical Research Centre, the NIHR HealthTech Research Centre Mental Health (MindTech) and a NIHR Senior Investigator Award; Laurence Astill Wright is supported by the Wellcome Trust; Paul Bernard is co-author of the MBCT-L programme. Elena Nixon, Shireen Patel, Priya Patel, James Roe, Neil Nixon, Tim Sweeney, Clara Strauss, Michael Craven, Sam Malins, Robert Goodwin, and Boliang Guo: all declare no conflict of interest.

Abbreviations

JMIR: Journal of Medical Internet Research
MBCT-L: Mindfulness-Based Cognitive Therapy-for Life
NHS: National Healthcare Service
NICE: National Institute for Health and Care Excellence
RCT: randomized controlled trial

SRP: Stress-Reduction Psychoeducation

Multimedia Appendices

Multimedia Appendix 1. SPIRIT checklist

Multimedia Appendix 2. Estimand framework

Multimedia Appendix 3. Economic Analysis Plan

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Supplementary Files

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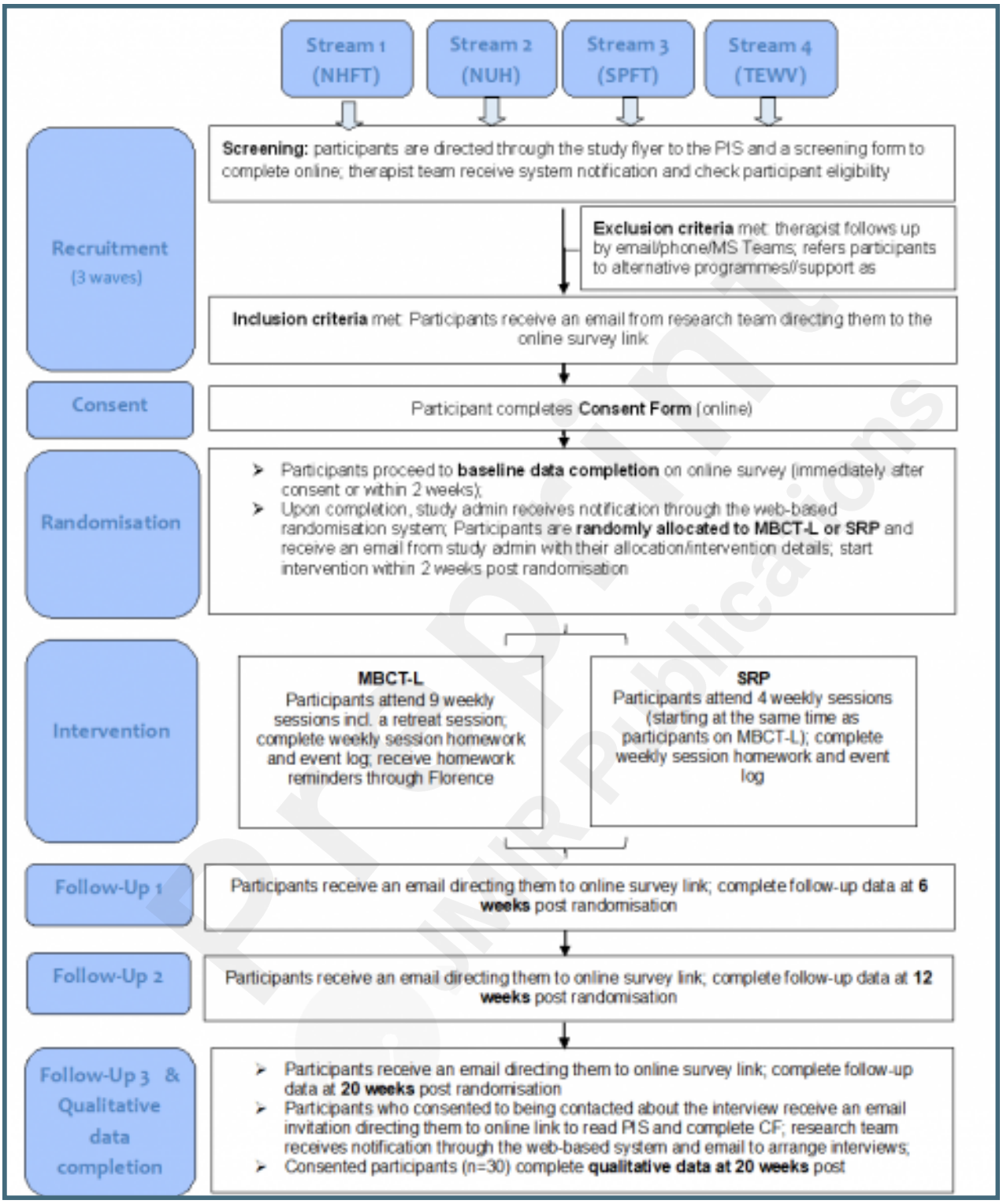
Stream 1 (NHFT)
Stream 2 (NUH)
Stream 3 (SPFT)
Stream 4 (TEWV)
Recruitment (3 waves)
Screening: participants are directed through the study flyer to the PIS and a screening form to complete online; therapist team receive system notification and check participant eligibility
Exclusion criteria met: therapist follows up by email/phone/MS Teams; refers participants to alternative programmes//support as
Inclusion criteria met: Participants receive an email from research team directing them to the online survey link
Consent
Participant completes Consent Form (online)
Randomisation
Participants proceed to baseline data completion on online survey (immediately after consent or within 2 weeks);
Upon completion, study admin receives notification through the web-based randomisation system; Participants are randomly allocated to MBCT-L or SRP and receive an email from study admin with their allocation/intervention details; start intervention within 2 weeks post randomisation
Intervention
MBCT-L
Participants attend 9 weekly sessions incl. a retreat session; complete weekly session homework and event log; receive homework reminders through Florence
SRP
Participants attend 4 weekly sessions (starting at the same time as participants on MBCT-L); complete weekly session homework and event log
Follow-Up 1
Participants receive an email directing them to online survey link; complete follow-up data at 6 weeks post randomisation
Follow-Up 2
Participants receive an email directing them to online survey link; complete follow-up data at 12 weeks post randomisation
Follow-Up 3 & Qualitative data completion
Participants receive an email directing them to online survey link; complete follow-up data at 20 weeks post randomisation
Participants who consented to being contacted about the interview receive an email invitation directing them to online link to read PIS and complete CF; research team receives notification through the web-based system and email to arrange interviews;
Consented participants (n=30) complete qualitative data at 20 weeks post

Figures

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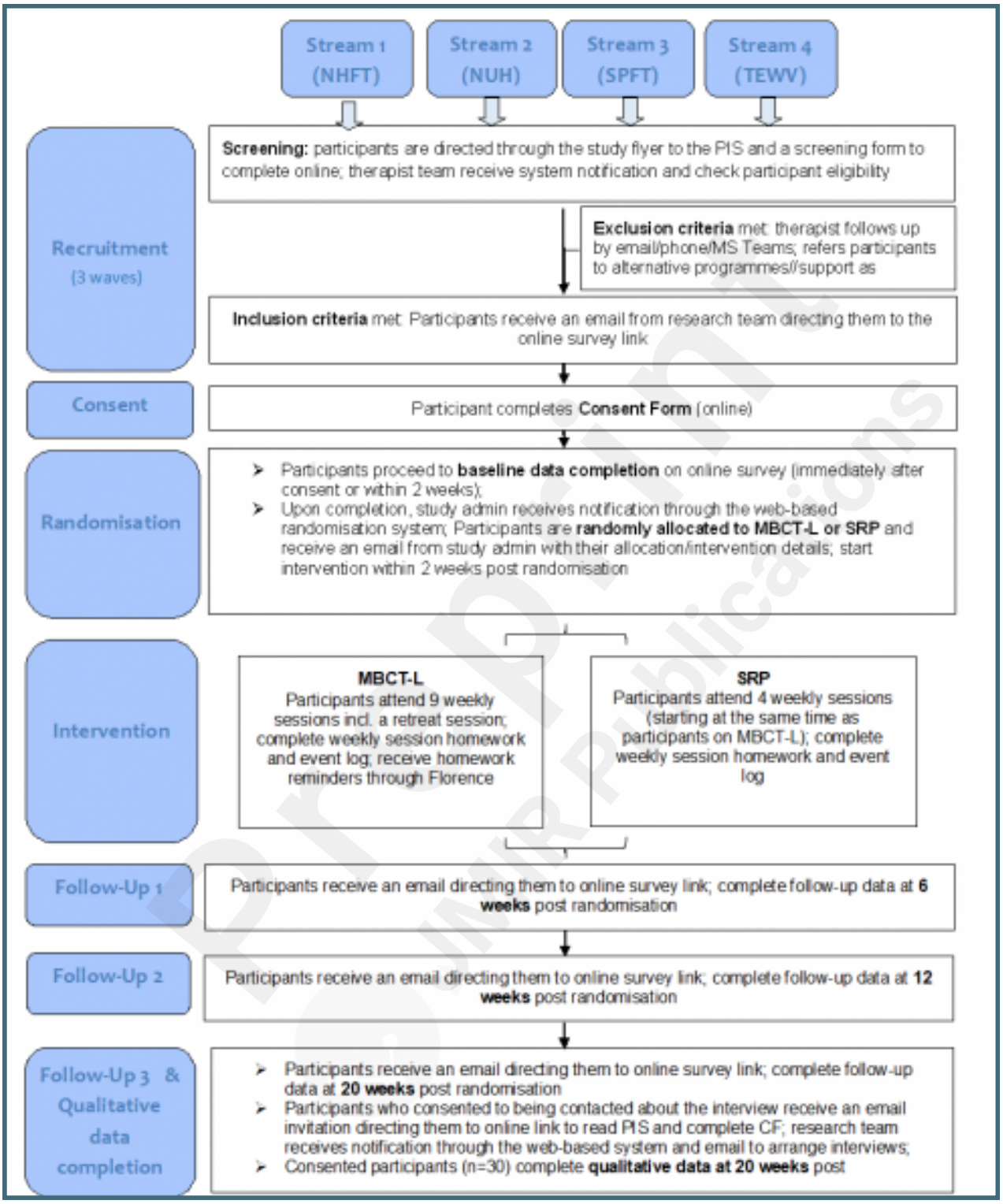
CONSORT Trial Flowchart.



Multimedia Appendixes

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SPIRIT Checklist.
URL: http://asset.jmir.pub/assets/aad42362f188e5ab0c434c2c4bc940fd.docx

Estimand Framework.
URL: http://asset.jmir.pub/assets/587d74f768a4d4b3949df07320b58e30.docx

Economic Analysis Plan.
URL: http://asset.jmir.pub/assets/18f655bd14061c5041df1956cc06577e.docx

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TOC/Feature image for homepages

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Feature image for homepage from study flyer.