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Evaluation of Mindfulness-Based Cognitive Therapy for Life and a Cognitive Behavioural
Therapy Stress-Management Workshop to Improve Healthcare Staff Stress: Study protocol
two randomized controlled trials

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Abstract

Background: Healthcare workers experience higher levels of work-related stress and higher rates of sickness absence than workers in other sectors. Psychological approaches have potential in providing healthcare workers with the knowledge and skills to recognise stress and to manage stress effectively. The strongest evidence for effectiveness in reducing stress in the workplace is for stress-management courses based on cognitive behaviour therapy (CBT) principles and mindfulness-based interventions (MBIs). However, research examining effects of these interventions on sickness absence (an objective indicator of stress) and compassion for others (an indicator of patient care) is limited, as is research on brief CBT stress-management courses (which may be more widely accessible) and on MBIs adapted for workplace settings.

Methods/Design: This protocol is for two randomised controlled trials with participant preference between the two trials and 1:1 allocation to intervention or waitlist within the preferred choice. The first trial is examining a one-day CBT stress-management workshop and the second trial an 8-session Mindfulness-Based Cognitive Therapy for Life (MBCT-L) course, with both trials comparing intervention to waitlist. The primary outcome for both trials is stress at post-intervention with secondary outcomes being sickness absence, compassion for others, depression symptoms, anxiety symptoms, wellbeing, work-related burnout, self-compassion, presenteeism, and mindfulness (MBCT-L only). Both trials aim to recruit 234 staff working in the National Health Service in the UK.

Discussion: This trial will examine whether a one-day CBT stress-management workshop and an 8-session MBCT-L course are effective at reducing healthcare staff stress and other mental health outcomes compared to waitlist, and, whether these interventions are effective at reducing sickness absence and presenteeism and at enhancing wellbeing, self-compassion,

mindfulness and compassion for others. Findings will help inform approaches offered to reduce healthcare staff stress and other key variables. A note of caution is that individual-level approaches should only be part of the solution to reducing healthcare staff stress within a broader focus on organisational-level interventions and support.

Trial registration: ISRCTN registration number ISRCTN11723441. Registered on 16 June 2017.

www.isrctn.com/ISRCTN11723441?q=&filters=&sort=&offset=3&totalResults=15901&page=1&pageSize=10&searchType=basic-search

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Background

Healthcare workers experience disproportionately high levels of work-related stress. A recent survey in the US found that stress was higher in healthcare workers than in any other industry, with 69% of staff reporting feeling stressed and 17% reporting high levels of stress (Advisory Board, 2014). The picture is similar elsewhere. In the UK, for example, 37% of staff working in the National Health Service (NHS) report feeling unwell due to work-related stress (NHS Survey Coordination Centre, 2017) and NHS staff are more likely to experience work-related stress compared to staff from any other public sector profession, with 61% feeling stressed all or most of the time (Johnson, 2015). Sickness absence is also highest in the NHS of all large public sector organisations (Office for National Statistics, 2017). In addition to the serious personal and economic consequences, high levels of stress in healthcare staff may negatively impact on patient care and safety (Hall et al., 2016). There is therefore a need to find effective ways of reducing healthcare staff stress and interventions based on psychological theory and related psychological therapeutic interventions provide one potential solution.

It is first helpful to clarify what we mean by stress. The transactional theory of stress has arguably been most influential in recent decades (Lazarus and Folkman, 1987, 1984). This suggests that stress is neither a property of situations and nor is it a property of the person. Rather, stress occurs as a transaction, or interaction, between the situation and the person and arises as a consequence of the person's appraisal of the situation. The primary appraisal concerns whether the situation is perceived as a threat to the person, and the secondary appraisal concerns whether the person perceives they have the resources (including personal resources) to cope with the threat (Lazarus and Folkman, 1984). This theory has been applied to a wide variety of contexts, including the workplace (Lazarus, 1995). The transactional theory of stress is potentially helpful in empowering people to identify stress-

related appraisals and choosing how best to respond, even in the context of highly demanding workplace situations. Cognitive behavioural therapy (CBT) and Mindfulness-Based Cognitive Therapy (MBCT) are two psychological approaches which could facilitate increased awareness of stress-related (and other) appraisals, re-evaluation or non-judgmental acceptance of these appraisals and greater awareness of choices available of how best to respond.

A meta-review found that stress-management interventions based on cognitive behaviour therapy (CBT) have the strongest evidence for effectiveness in reducing work-related stress (Joyce et al., 2016). CBT stress-management involves identifying how thoughts (including appraisals), feelings, behaviours and physical sensations interact to contribute to stress, and using this information to identify strategies for preventing or reducing stress. Strategies may include identifying and re-evaluating the accuracy of stress-related thoughts (appraisals), identifying behaviours that contribute to stress and choosing alternative, more helpful behaviours, and identifying strategies to reduce physiological arousal associated with stress. By intervening in this way, the stress-related maintenance cycle between thoughts, feelings, behaviours and physical sensations can be broken and replaced with a stress-relieving maintenance cycle.

There is also growing evidence that MBIs improve in stress in healthcare staff (de Vibe et al., 2013; Eroglu et al., 2014; Geary and Rosenthal, 2011; Song and Lindquist, 2015; Virgili, 2013), including in NHS settings (Marx et al., 2014). Mindfulness is characterised by non-judgemental awareness and acceptance of present-moment experiences (thoughts, feelings, sensations etc.), and greater awareness of helpful behavioural choices available. Mindfulness-based cognitive therapy (MBCT) (Segal et al., 2013) integrates aspects of CBT within an MBI and was originally developed to prevent depressive relapse, for which it has well-established benefits (Kuyken et al., 2016). A recent adaptation for non-clinical

populations draws on the same structure and techniques as MBCT is MBCT for Life (MBCT-L) (Bernard et al., 2017). Adaptations within MBCT-L include a greater focus on wellbeing, appreciation and gratitude, making this better suited in workplace settings.

In summary, there is good evidence that CBT stress-management interventions and MBIs are effective at reducing work-related stress. However, there are some important gaps in the current literature.

One gap is establishing if benefits extend to reduced sickness absence. Sickness absence is estimated to cost the NHS 2.5% of its entire budget (Quality Watch, 2016). This reduces the budget available for patient care whilst placing an additional strain on staff to cover the duties of the absent member of staff, which in turn may lead to increased levels of stress and greater risk of sickness absence for staff remaining at work. RCT evidence is lacking examining the potential of CBT stress-management and MBIs to reduce sickness absence.

A second gap is in investigating if the benefits of these interventions on healthcare staff stress extend to variables associated with improved patient care. There is evidence from cross-sectional studies that healthcare staff stress is associated with compromised patient safety (Hall et al., 2016), but evidence is limited as to whether interventions such as CBT stress-management and MBIs might have a causal effect on indicators of patient care such as the capacity for compassion for others. Compassion has been defined as a multi-faceted capacity involving the ability to recognize suffering, understand the universality of human suffering, feel for the person suffering, tolerate uncomfortable feelings, and the motivation to act/acting to alleviate suffering (Strauss et al., 2016). Both CBT stress-management and MBCT-L might have an effect on compassion for others (including patients) by increasing awareness of present-moment thoughts, feelings and physical reactions, cultivating understanding of human suffering as universal (as both approaches conceptualise distress

using universal psychological frameworks) and increasing awareness of choices available to act to alleviate suffering.

A third gap is evidence for brief CBT stress-management interventions (Joyce et al., 2016) which may be more readily accessible to healthcare staff in increasingly demanding healthcare settings. Whilst we would advocate giving sufficient time for staff to attend to their own wellbeing, we also acknowledge that many healthcare staff would struggle to attend interventions over several sessions. However, brief CBT stress-management may not be effectiveness in comparison to their longer counterparts (Joyce et al., 2016) and research is needed to assess effectiveness.

Finally, a fourth gap concerns the evidence for MBCT-L. This is a newly developed intervention, designed for non-clinical settings, but we cannot assume that the benefits of MBCT for preventing depressive relapse (Kuyken et al., 2016) will extend to MBCT-L reducing stress in healthcare staff.

This protocol is for two RCTs examining the effectiveness of two interventions for staff working in the NHS: 1) Mindfulness-Based Cognitive Therapy for Life (MBCT-L), and 2) CBT-based stress management. Staff will select one of these two interventions and then will be randomly assigned to either the intervention arm or to the wait-list arm within their preferred choice. Our intention in offering staff a choice between these two interventions is to increase accessibility and choice, acknowledging that no one intervention is likely to meet the needs of all staff.

Given the existing evidence for these interventions is predominantly in stress-reduction, the primary hypothesis is that both interventions will be more effective than waitlist at reducing stress at post-intervention. Secondary hypotheses are that both interventions will be more effective than waitlist at post-intervention at: (1) reducing sickness absence, and (2) improving compassion for others; 3) reducing anxiety symptoms, 4)

reducing depression symptoms, 5) reducing work-related burnout, 6) improving compassion for self, 7) improving wellbeing, 8) reducing presenteeism, and 9) improving mindfulness (for MBCT-L participants only). We also plan to explore participants' experiences of their chosen intervention using thematic analysis of semi-structured interviews.

Methods/Design

Design and sample size

This protocol is for a study of two superiority RCTs with participant preference between the two interventions with 1:1 allocation to either intervention or waitlist within the preferred choice. The randomisation procedure will be web-based and automated; the allocation sequence will be generated and participants randomised using block randomisation by Qualtrics (www.qualtrics.com), the online survey software. Members of the research team involved in the day-to-day management of the study will be blind to block size. Assessments will be completed online by participants at baseline and post-intervention, independent from members of the research team, to reduce risk of bias associated with researcher-administered assessments.

Sample size calculations were conducted using G*Power (Faul et al., 2007). The study aims to have 140 participants giving complete data sets at baseline and post-intervention within each part of the study (i.e. aiming for 140 MBCT-L and 140 CBT study completers). Given the pressures on staff time and the online data collection method, it is conservatively assumed that 40% of participants will fail to complete measures at post-intervention. This means that we aim to recruit 234 participants into each part of the study.

Sample size calculations are based on an estimated medium between-group effect on post-intervention stress outcomes (Cohen's $d = .50$) between the intervention and wait-list arms with 90% power and $p = .05$. For MBCT-L, the estimated medium effect size is based

on between-group post-intervention effects on stress reported in previous trials of MBIs for healthcare staff (de Vibe et al., 2013; Eroglu et al., 2014; Geary and Rosenthal, 2011). For the CBT stress-management workshop it was not possible to estimate the effect directly based on published trials as previous research has evaluated CBT stress-management interventions running over several sessions. We therefore assume that the effect size will be smaller in the current study than the large effect reported in a meta-analysis of multiple-session CBT stress-management interventions in the workplace (Richardson and Rothstein, 2008) and therefore estimate a medium effect size.

Ten participants from the intervention arm of each RCT, who provide complete data sets at baseline and post-intervention and who complete their allocated intervention, will be interviewed about their experiences of their intervention. The sample size for the qualitative interviews is based on recommendations for Thematic Analysis from Braun and Clarke (2006).

Participants

Participants will be members of staff working in one of four NHS trusts in the South of England (three mental health trusts and one community trust) with each trust employing between 2,500 and 5,000 members of staff. Inclusion criteria are that participants: 1) are employed by (or working in an honorary/voluntary capacity for) one of the four NHS trusts, 2) are currently in work (i.e. not currently on sickness absence), 3) have sufficient English language ability to understand intervention information and questionnaire content, and 4) are adults (aged 18 years or older). There are no exclusion criteria.

Procedure

Recruitment is planned to take place between July and December 2017. The CONSORT diagram showing participant flow through the study is shown in Figure 1. The study will be advertised to all trust staff through adverts placed on intranets and staff

bulletins. In addition, information about the study will be emailed to all staff. Participants consenting to take part in the study will first choose their preferred intervention. Staff can take part in one of the two studies, but not both. This will be checked to ensure that all consenting participants are enrolled in one of the two studies only. Following consent, participants will be sent a standardised e-mail by the research team containing a link to the baseline assessment measures hosted on Qualtrics based on their selected intervention (Time 0). Upon completion of baseline measures, participants will be randomised to their preferred intervention or to the wait list for their preferred intervention. They will be sent a standardised e-mail informing them of their allocation and details of their intervention. After participants have completed their intervention or wait list time period, they will be sent a standardised e-mail asking them to complete post-intervention measures online (Time 1). MBCT-L participants will be sent the link to post-intervention measures immediately after completion of the intervention. CBT participants will be invited to complete post-intervention measures one month after workshop completion. The research team will not be present for any of the online assessments (at baseline and post-intervention); measures will be completed by participants online and in their own time. To promote study retention, where necessary participants will be emailed at weekly intervals for up to four weeks with a reminder to complete their post-intervention assessment. Potential errors with data entry will be minimised as data will be entered by participants online.

Ten participants from each intervention arm, who complete both baseline and post-intervention measures, will be invited to take part in an optional phone interview about their experiences of their preferred intervention.

Interventions

Mindfulness-Based Cognitive Therapy for Life. MBCT-L (Bernard et al., 2017) is an adaptation of MBCT originally developed by Segal, Williams, and Teasdale (2013, 2002).

MBCT was originally developed for people with a history of recurrent depression at risk of depressive relapse and integrates CBT strategies with mindfulness practice and inquiry about practice. MBCT-L was developed to be applicable to the general population across the spectrum of wellbeing and draws on the same structure and techniques as MBCT. MBCT-L is an 8-week group intervention (with a pre-course orientation session) where participants are guided in mindfulness practice and engage with a range of CBT strategies. In this study, each group will be led by one or two MBCT teachers and will consist of up to 15 participants. Each session will take 2 hours and participants will be invited to complete approximately 40 minutes per day of mindfulness practice and other home tasks. Content in the sessions will include guided mindfulness practices, inquiry into experiences following practices, weekly homework review, and teaching/discussion of CBT skills. The teachers leading the groups will have completed MBCT teacher training and will meet MBCT teacher criteria set out by the UK Network of Mindfulness-Based Teacher Training Organisations. Teachers will have completed additional MBCT-L training. Supervision will be provided on at least three occasions per group by a teacher who meets the supervisor criteria set out by the UK Network of Mindfulness-Based Teacher Training Organisations and who has attended a two-day MBCT-L training. Intervention completion is defined as attending at least four of the eight sessions.

Cognitive Behavioural Therapy. This one-day (6 hour) workshop will teach participants CBT approaches to managing work-related stress. The workshop is divided into three broad sections. The first part of the workshop introduces a CBT formulation of work-related stress, drawing on the transactional theory of stress (Lazarus and Folkman, 1987, 1984) and the CBT maintenance cycle highlighting the inter-relationships between thoughts, feelings, physical sensations and behaviours, within work (and other) contexts. Participants will have the opportunity to formulate their own work-related stress experiences within these

frameworks. The second part of the workshop overviews strategies to intervene in the maintenance cycle, with a particular focus on cognitive and behavioural strategies. The third part of the workshop encourages participants to identify SMART goals, drawing on learning from the workshop and making a commitment between participants to progress towards these goals. Each workshop will consist of up to 20 participants and will be facilitated by two mental health practitioners, who demonstrate the following skills and experience between them: 1) a qualified CBT therapist or practitioner psychologist who works with CBT as their primary therapeutic model, 2) experience of facilitating therapeutic workshops or groups, and 3) a senior grade within their NHS trust or a registered mental health professional with significant experience working in their NHS trust. All facilitators will attend a one-day training event led by clinical psychologist and CBT therapist who developed the workshop materials and will receive at least one telephone consultation session. Intervention completion is defined as attending the whole of the one-day workshop.

Measures

Primary Outcome

Stress. The primary outcome measure will be the 7-item stress subscale from the 21-item short version of the Depression, Anxiety, and Stress Scales (DASS-21) (Lovibond and Lovibond, 1995). The stress subscale of the DASS-21 measures the severity of core symptoms associated with stress. Participants are asked to indicate the presence of each symptom over the past week. Responses are given on a 4-point Likert scale, ranging from 0 (never) to 3 (almost always). The DASS-21 stress subscale has been found to have good internal consistency and convergent and discriminant validity (Antony et al., 1998; Henry and Crawford, 2005).

Secondary Outcomes

Sickness absence. Sickness absence data will be obtained from Human Resources departments in the NHS trusts. This will be recorded as the number of sickness absence days taken in the month following the end of the intervention period. Equivalent data from the same one month period in the previous calendar year will be obtained as a baseline measure for each participant. Reasons for sickness absence will not be recorded. This is to respect participant confidentiality.

Compassion for others. This will be measured using the compassion for others scale (Gu et al., n.d.), developed based on the empirically supported five-element definition of compassion as consisting of the ability to recognise suffering, understand the universality of human suffering, feel for the person suffering, tolerate uncomfortable feelings, and the motivation to act/acting to alleviate suffering (Gu et al., 2017; Strauss et al., 2016). Participants are instructed to indicate how true each statement is of them using a 5-point Likert scale, ranging from 1 (not at all true of me) to 5 (always true of me).

Depression. This will be measured using the depression subscale from the short version of the DASS-21 (Lovibond and Lovibond, 1995). The depression subscale of the DASS-21 measures the severity of core symptoms associated with depression. Participants are asked to indicate the presence of each symptom over the past week. Responses are given on a 4-point Likert scale, ranging from 0 (never) to 3 (almost always). The DASS-21 depression subscale has been found to have good internal consistency and convergent and discriminant validity (Antony et al., 1998; Henry and Crawford, 2005).

Anxiety. This will be measured using the anxiety subscale from the short version of the DASS-21 (Lovibond and Lovibond, 1995). The anxiety subscale of the DASS-21 measures the severity of core anxiety symptoms. Participants are asked to indicate the presence of each symptom over the past week. Responses are given on a 4-point Likert scale, ranging from 0 (never) to 3 (almost always). The DASS-21 anxiety subscale has been found

to have good internal consistency and convergent and discriminant validity (Antony et al., 1998; Henry and Crawford, 2005).

Self-compassion. This will be measured using the self-compassion scale (Gu et al., n.d.), developed based on the empirically supported five-element definition of compassion as consisting of the ability to recognise suffering, understand the universality of human suffering, feel for the person suffering (in the case of self-compassion this would be the self), tolerate uncomfortable feelings, and the motivation to act/acting to alleviate suffering (Gu et al., n.d.; Strauss et al., 2016). Participants are instructed to indicate how true each statement is of them using a 5-point Likert scale, ranging from 1 (not at all true of me) to 5 (always true of me).

Wellbeing. Positive mental wellbeing will be measured using the 7-item Short Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS) (Stewart-Brown et al., 2009). The SWEMWBS involves rating items on a 5-point Likert scale ranging from 1 (none of the time) to 5 (all of the time). Participants are asked to rate items based on their experience over the past two weeks. The SWEMWBS has been found to be highly correlated with the long version of the scale and good construct validity (Stewart-Brown et al., 2009).

Burnout. This will be measured using the 22-item Maslach Burnout Inventory – Human Services Survey (MBI-HSS) (Maslach et al., 1981). The MBI-HSS was designed for professionals working in human services such as healthcare and consists of three distinct subscales, emotional exhaustion, depersonalisation, and personal accomplishment. Participants are asked about the frequency with which they have experiences related to the three subscales and items are answered on a 7-point Likert scale, ranging from 0 (never) to 6 (every day). The three subscales of the MBI-HSS has been found to have adequate internal consistency, test-retest reliability, and convergent and discriminant validity.

Presenteeism. This will be measured using the three questions which assess presenteeism from the Institute for Medical Technology Assessment Productivity Cost Questionnaire (iMTA PCQ) (Bouwman et al., 2013). The overall iMTA PCQ is designed to assess and value productivity losses. The three presenteeism questions ask participants: 1) if over the past 4 weeks, they worked whilst experiencing physical or psychological problems (yes/no) and if so, 2) how many days at work they were bothered by these problems and 3) how their performance on these days compared to their performance on normal working days. The third question is measured on a 10-point rating scale, ranging from 0 (on these days I could not do anything) to 10 (I was able to do just as much as I normally do). The first two questions originate from the short form of the Health and Labor Questionnaire (SF-HLQ) (van Rooijen et al., 1996) and the third question from the Productivity and Disease Questionnaire (PRODISQ) (Koopmanschap, 2005). The three questions have been found to have good test-retest reliability (Bouwman et al., 2013).

Mindfulness. This will be measured using the 15-item Five Facet Mindfulness Questionnaire (FFMQ-15) (Baer et al., 2008; Carmody and Baer, 2008). The FFMQ-15 is a short form of the 39-item FFMQ (FFMQ-39) and measures the general tendency to be mindful in everyday life. It includes the same five facets as the long form: Observing, Describing, Acting with Awareness, Non-Judging of inner experience, and Non-Reactivity to inner experience. The factor structure of the FFMQ-15 is consistent with that of the FFMQ-39, there are large correlations between total facet scores of the short and long forms, and the two FFMQ versions do not differ significantly from each other in terms of convergent validity (Gu et al., 2016). Previous research (Baer et al., 2006; Gu et al., 2016; Williams et al., 2014) found that in non-meditator samples, a four-factor hierarchical structure without the ‘observing’ facet provided a superior fit compared to a five-factor hierarchical structure. As it is likely that our current sample has little or no previous meditation experience, ‘observing’

items will be excluded from the total FFMQ-15 score. FFMQ-15 items are rated on a 5-point Likert scale, ranging from 1 (never or very rarely true) to 5 (very often or always true) and will be completed by participants randomised to MBCT-L or waiting list for MBCT-L only.

Intervention Engagement – MBCT-L participants. MBCT-L participants will be asked to report the following at post-intervention: (1) number of MBCT-L sessions attended, not including the orientation session (0-8); (2) average number of days per week engaged in a guided mindfulness practice, not including practice during the group session (0-7); (3) on days when practised, average number of minutes per day of mindfulness practice, not including practice during the group session; (4) ability to bring mindfulness principles into daily life (0-5); (5) ability to actively participate in MBCT-L sessions (0-5); (6) belief in effectiveness of mindfulness in helping to manage stressful situations (0-5); (7) difficulty in finding time to engage in between-session mindfulness practices; (8) satisfaction with the mindfulness teacher leading the course (0-5); (9) levels of comfort with other group members (0-5). 0-5 rating scales are all anchored by ‘not at all’ (0) and ‘extremely’ (5).

Intervention Engagement – CBT participants. CBT workshop participants will be asked to report the following at post-intervention: (1) attendance at CBT workshop (no, yes [part of the day], yes [whole day]); (2) satisfaction with the workshop facilitators (0-5); (3) levels of comfort with other workshop members (0-5). 0-5 rating scales are all anchored by ‘not at all’ (0) and ‘extremely’ (5).

All outcome measures, with the exception of sickness absence data, which will be requested from HR departments at the end of the study, will be administered at baseline and post-intervention. Demographic data (e.g., gender, age, ethnicity, marital status, education level) will be recorded at baseline only and engagement measures will be administered at post-intervention only.

Ten participants from the intervention arm of each RCT, who provide complete data sets at baseline and post-intervention, will be interviewed about their experiences of their intervention by telephone, using an adapted version of the Change Interview (Elliott et al., 2001). A copy of the Change Interview published by Elliott and Rodgers can be found online (2008). This is a semi-structured interview designed to explore people's experiences of psychological interventions, focusing on perceived helpful, unhelpful and missing aspects of the intervention. Each interview will take approximately 30 minutes, will take place over the phone, and will be audio recorded to aid transcription and data analysis.

Planned Data Analysis

The intention in providing two interventions is to increase choice and accessibility. The intention is not to compare the effectiveness of the CBT intervention directly with the MBCT-L intervention and any such comparison would be problematic given the potential for selection bias (i.e. participants preferring MBCT-L may differ in a number of ways from participants preferring the CBT workshop). Intervention preference will be reported as the number and percentage of participants choosing each intervention type, however we would urge caution when interpreting this data as participant preferences may be driven by practicalities (e.g. location and dates of available courses) as much as by intervention preference.

Between-group differences at baseline on key demographic variables (age, gender, ethnicity, NHS trust, pay band and years working in the trust) and all outcome measures will be reported for each study. Findings will be reported for both intention-to-treat and per protocol analyses. Hypotheses will be tested using mixed analysis of variance (ANOVA) for each intervention separately, with time (baseline, post-intervention) as the within-group variable and intervention arm (intervention, wait list) as the between-group variable. Post-intervention between-group effect sizes (Cohen's *d*) and 95% confidence intervals will be

reported. Interaction effects will be followed up with within-group t-tests, with Cohen's *d* effect sizes and accompanying 95% confidence intervals for within-group change.

Qualitative data will be transcribed and thematic analysis will be performed in accordance with the Braun and Clarke (2006) protocol. This will involve the researcher leading on the qualitative aspect of the study reading and re-reading transcripts, allocating codes to single units of meaning within each transcript, identifying sub-themes representing lower-order categories of meaning across participants (within CBT/MBCT-L separately) and finally identifying higher-order themes and the relationship between themes and sub-themes (for CBT/MBCT-L separately). This will be conducted under supervision from the lead author. Credibility will be checked through supervision and will be indicated through providing comprehensive extracts from participants to illustrate each theme and sub-theme.

Dissemination

Findings will be written up for submission for publication in a peer-reviewed journal as four papers: 1) reporting on the quantitative findings from the RCT comparing MBCT-L with waitlist, 2) reporting on the quantitative findings from the RCT comparing the CBT-based stress management intervention with waitlist, 3) reporting on the qualitative findings of participating in MBCT-L, and 4) reporting on the qualitative findings of participating in the CBT-based stress management intervention. A lay report of findings will be produced for dissemination to participants and other NHS trust staff.

Discussion

When compared to other professions, healthcare staff experience particularly high levels of work-related stress and sickness absence (Advisory Board, 2014; NHS Survey Coordination Centre, 2017; Office for National Statistics, 2017), with higher levels of stress associated with compromised patient care and safety (Hall et al., 2016). Psychological

approaches based on psychological theory of stress (Lazarus and Folkman, 1987, 1984) provide one solution. Evidence for reducing work-related stress is strongest for CBT stress-management (Joyce et al., 2016) and mindfulness-based interventions (Virgili, 2013). However, effects on objective indicators of stress (such as sickness absence) and on factors associated with patient care (such as compassion for others) is largely unexplored. In addition, potential benefits of brief CBT-based stress management courses and of MBCT-L on healthcare staff levels of staff are unknown.

This is a protocol for two separate RCTs with participant preference examining the effects of two interventions, each compared to wait list, for NHS staff. The first of these is a one-day CBT stress-management workshop and the second is an 8-session MBCT for Life (MBCT-L) course. The primary outcome is stress, as this is the outcome with the greatest evidence for effects. Secondary outcomes include sickness absence, compassion for others, depressive symptoms, anxiety symptoms, compassion for self, work-related burnout, presenteeism, and mindfulness (for MBCT-L participants). Effects on sickness absence would be of particular interest to healthcare employers and would provide an economic incentive to widen access to these interventions. Effects on compassion for others would suggest that benefits to staff might extend to improved patient care and this would lead to further research examining the effects of these interventions for staff on outcomes for their patients. Effects on wellbeing are also important to measure. Whilst the primary outcome in this study is stress, we are interested not only in the potential of the interventions to reduce stress and mental health symptoms, but also of the potential to enhance wellbeing and compassion for self and others. This focus is particularly highlighted in MBIs in the workplace (Good et al., 2016), and in MBCT-L, with its emphasis on cultivating appreciation and gratitude (Bernard et al., 2017).

A limitation of the design is that it will not be possible to directly compare outcomes between the two interventions as participants are not randomised between intervention types. A direct comparison of the two interventions could be explored in future trials, depending on outcomes of the current study. Another limitation is that reasons for sickness absence will not be recorded in order to respect participants' confidentiality. It is also possible that staff may be reluctant to disclose mental health reasons for sickness absence due to concerns about stigma, and that a physical health reason may be given instead. If the interventions have a beneficial effect on sickness absence due to poor mental health this should be reflected in an overall effect on sickness absence. There is also an important note of caution in relation to the interventions being evaluated. Providing psychologically-informed interventions to healthcare staff as a means of reducing work-related stress could contribute to a culture whereby staff are seen as solely responsible for managing their stress, absolving healthcare organisations from responsibility to provide supportive workplaces that do not place excessive demands on their staff. Individually targeted interventions such as CBT stress-management workshops and MBCT-L can be part of a solution to reducing work-related stress in the healthcare workplace. However, we suggest that this should occur in the context of organizational-level interventions to minimise stress, as these may play an additional important role in reducing stress in healthcare workplaces (Panagioti et al., 2017). Within supportive healthcare organisations, our CBT stress-management workshop and MBCT-L have potential to provide staff with the skills to recognise signs of stress in themselves and the skills to act early to prevent stress from escalating, and thereby empowering staff to make choices about how they respond in stressful healthcare workplace settings. **Trial Status**

At the time of manuscript submission, recruitment for this study was ongoing.

SPIRIT Guidelines

Please see Figure 2 for a copy of the SPIRIT figure. The SPIRIT checklist is attached.

List of Abbreviations

ANOVA: Analysis of Variance

CBT: Cognitive Behaviour Therapy

DASS-21: Depression, Anxiety, and Stress Scales (short version)

FFMQ-39: Five Facet Mindfulness Questionnaire (39 item version)

FFMQ-15: Five Facet Mindfulness Questionnaire (15 item version)

HR: Human Resources

iMTA PCQ: Institute for Medical Technology Assessment Productivity Cost Questionnaire

NHS: National Health Service

MBCT: Mindfulness-Based Cognitive Therapy

MBCT-L: Mindfulness-Based Cognitive Therapy for Life

MBI: Mindfulness-Based Intervention

MBI-HSS: Maslach Burnout Inventory – Human Services Survey

RCT: Randomised Controlled Trial

SMART: Specific Measurable Achievable Relevant Time-Limited

SWEMWBS: Short Warwick Edinburgh Mental Wellbeing Scale

DeclarationsEthics approval and consent to participate

This study has been granted ethical approval by the Health Research Authority (HRA) in the UK (IRAS ID 224584). Informed consent will be obtained from all participants through completion of an online consent form. Important modifications to the trial protocol will be submitted for approval from the trial sponsor and HRA.

Confidentiality

_____ Participants will be assigned a unique identification code which will be used to complete assessments and will be used for data files.

Consent for publication

Participants will be asked to consent to their anonymised data to be used in research publications.

Availability of data and material

The datasets created for the current study will be available from the corresponding author on reasonable request.

Competing interests

CS has developed the one-day CBT workshop and WK has co-authored the MBCT-L course. WK is Director of the Oxford Mindfulness Centre and Principal Investigator of several Wellcome Trust and NIHR funded grants examining mindfulness-based programs. Any remuneration for public engagement or consultancy is donated in full to the not-for-profit charity the Oxford Mindfulness Foundation. CS is the Research Lead for the Sussex Mindfulness Centre and has received NIHR funding for research trials evaluating mindfulness-based interventions. CC and AW are employed by Health Education England (Kent, Surrey and Sussex) who have funded this study. All other authors declare that they have no conflicts of interest.

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Authors' contributions

CS designed the study and drafted the manuscript. JG contributed to study design and to drafting the manuscript. NP contributed to drafting the manuscript. CC contributed to

study design. WK contributed to study design. AW contributed to study design. All authors read and approved the final manuscript.

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References

- Advisory Board, 2014. Health care workers may be the nation's most stressed employees [WWW Document]. URL <https://www.advisory.com/daily-briefing/2014/02/13/health-care-workers-may-be-the-nations-most-stressed-employees> (accessed 10.17.17).
- Antony, M.M., Bieling, P.J., Cox, B.J., Enns, M.W., Swinson, R.P., 1998. Psychometric Properties of the 42-Item and 21-Item Versions of the Depression Anxiety Stress Scales in Clinical Groups and a Community Sample. *Psychol. Assess.* 10, 176–181.
- Baer, R.A., Smith, G.T., Hopkins, J., Krietemeyer, J., Toney, L., 2006. Using self-report assessment methods to explore facets of mindfulness. *Assessment* 13, 27–45.
<https://doi.org/10.1177/1073191105283504>
- Baer, R.A., Smith, G.T., Lykins, E., Button, D., Krietemeyer, J., Sauer, S., Walsh, E., Duggan, D., Williams, J.M.G., 2008. Construct Validity of the Five Facet Mindfulness Questionnaire in Meditating and Nonmeditating Samples. *Assessment* 15, 329–342.
<https://doi.org/10.1177/1073191107313003>
- Bernard, P., Cullen, C., Kuyken, W., 2017. MBCT for Life Teacher Manual. Oxford Mindfulness Centre, Oxford, UK.
- Bouwman, C., De Jong, K., Timman, R., Zijlstra-Vlasveld, M., Van der Feltz-Cornelis, C., Tan, S.S., Hakkaart-van Roijen, L., 2013. Feasibility, reliability and validity of a questionnaire on healthcare consumption and productivity loss in patients with a

- psychiatric disorder (TiC-P). *BMC Health Serv. Res.* 13, 217.
<https://doi.org/10.1186/1472-6963-13-217>
- Braun, V., Clarke, V., 2006. Using thematic analysis in psychology. *Qual. Res. Psychol.* 3, 77–101. <https://doi.org/10.1191/1478088706qp063oa>
- Carmody, J., Baer, R.A., 2008. Relationships between mindfulness practice and levels of mindfulness, medical and psychological symptoms and well-being in a mindfulness-based stress reduction program. *J. Behav. Med.* 31, 23–33.
<https://doi.org/10.1007/s10865-007-9130-7>
- de Vibe, M., Solhaug, I., Tyssen, R., Friberg, O., Rosenvinge, J.H., Sørli, T., Bjørndal, A., 2013. Mindfulness training for stress management: a randomised controlled study of medical and psychology students. *BMC Med. Educ.* 13, 107.
<https://doi.org/10.1186/1472-6920-13-107>
- Elliott, R., Rodgers, B., 2008. Client Change Interview Schedule (v5) [WWW Document]. URL <https://drive.google.com/file/d/0B4QhybeF75vseWRYMjlfQVFRWIU/edit>
- Elliott, R., Slatick, E., Urman, M., 2001. Qualitative change process research on psychotherapy: Alternative strategies, in: Frommer, J, Rennie, D.L. (Ed.), *Qualitative Psychotherapy Research: Methods and Methodology*. Pabst Science, Lengerich, Germany, pp. 69–111.
- Erogul, M., Singer, G., McIntyre, T., Stefanov, D.G., 2014. Abridged Mindfulness Intervention to Support Wellness in First-Year Medical Students. *Teach. Learn. Med.* 26, 350–356. <https://doi.org/10.1080/10401334.2014.945025>
- Faul, F., Erdfelder, E., Lang, A.-G., Buchner, A., 2007. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behav. Res. Methods* 39, 175–91.
- Geary, C., Rosenthal, S.L., 2011. Sustained Impact of MBSR on Stress, Well-Being, and

- Daily Spiritual Experiences for 1 Year in Academic Health Care Employees. *J. Altern. Complement. Med.* 17, 939–944. <https://doi.org/10.1089/acm.2010.0335>
- Good, D.J., Lyddy, C.J., Glomb, T.M., Bono, J.E., Brown, K.W., Duffy, M.K., Baer, R.A., Brewer, J.A., Lazar, S.W., 2016. Contemplating Mindfulness at Work. *J. Manage.* 42, 114–142. <https://doi.org/10.1177/0149206315617003>
- Gu, J., Cavanagh, K., Baer, R., Strauss, C., 2017. An empirical examination of the factor structure of compassion. *PLoS One* 12, e0172471. <https://doi.org/10.1371/journal.pone.0172471>
- Gu, J., Kuyken, W., Baer, R.A., Cavanagh, K., Strauss, C., n.d. Compassion Scale (manuscript in preparation).
- Gu, J., Strauss, C., Crane, C., Barnhofer, T., Karl, A., Cavanagh, K., Kuyken, W., 2016. Examining the factor structure of the 39-item and 15-item versions of the five-facet mindfulness questionnaire before and after mindfulness-based cognitive therapy for people with recurrent depression. *Psychol. Assess.* 28, 791–802. <https://doi.org/10.1037/pas0000263>
- Hall, L.H., Johnson, J., Watt, I., Tsipa, A., O'Connor, D.B., 2016. Healthcare Staff Wellbeing, Burnout, and Patient Safety: A Systematic Review. *PLoS One* 11, e0159015. <https://doi.org/10.1371/journal.pone.0159015>
- Henry, J.D., Crawford, J.R., 2005. The short-form version of the Depression Anxiety Stress Scales (DASS-21): construct validity and normative data in a large non-clinical sample. *Br. J. Clin. Psychol.* 44, 227–39. <https://doi.org/10.1348/014466505X29657>
- Johnson, S., 2015. NHS staff most stressed public sector workers, survey finds. *Guard.*
- Joyce, S., Modini, M., Christensen, H., Mykletun, A., Bryant, R., Mitchell, P.B., Harvey, S.B., 2016. Workplace interventions for common mental disorders: a systematic meta-review. *Psychol. Med.* 46, 683–697. <https://doi.org/10.1017/S0033291715002408>

- Koopmanschap, M.A., 2005. PRODISQ: a modular questionnaire on productivity and disease for economic evaluation studies. *Expert Rev. Pharmacoecon. Outcomes Res.* 5, 23–28. <https://doi.org/10.1586/14737167.5.1.23>
- Kuyken, W., Warren, F.C., Taylor, R.S., Whalley, B., Crane, C., Bondolfi, G., Hayes, R., Huijbers, M., Ma, H., Schweizer, S., Segal, Z., Speckens, A., Teasdale, J.D., Van Heeringen, K., Williams, M., Byford, S., Byng, R., Dalgleish, T., 2016. Efficacy of Mindfulness-Based Cognitive Therapy in Prevention of Depressive Relapse. *JAMA Psychiatry* 73, 565. <https://doi.org/10.1001/jamapsychiatry.2016.0076>
- Lazarus, R.S., 1995. Psychological stress in the workplace, *Occupational stress : A handbook*. Taylor & Francis, London, UK.
- Lazarus, R.S., Folkman, S., 1987. Transactional theory and research on emotions and coping. *Eur. J. Pers.* 1, 141–169. <https://doi.org/10.1002/per.2410010304>
- Lazarus, R.S., Folkman, S., 1984. *Stress, appraisal, and coping*.
- Lovibond, S., Lovibond, P., 1995. *Manual for the depression anxiety stress scale*. Psychology Foundation, Sydney. Australia.
- Marx, R., Strauss, C., Williamson, C., Karunavira, Taravajra, 2014. The eye of the storm: a feasibility study of an adapted Mindfulness-based Cognitive Therapy (MBCT) group intervention to manage NHS staff stress. *Cogn. Behav. Ther.* 7, e18. <https://doi.org/10.1017/S1754470X14000300>
- Maslach, C., Jackson, S.E., Leiter, M.P., 1981. *Maslach Burnout Inventory*. Consulting Psychologists Press.
- NHS Survey Coordination Centre, 2017. BRIEFING NOTE: ISSUES HIGHLIGHTED BY THE 2016 NHS STAFF SURVEY IN ENGLAND. Oxford, UK.
- Office for National Statistics, 2017. *Sickness absence in the labour market: 2016*. Newport, UK.

- Panagioti, M., Panagopoulou, E., Bower, P., Lewith, G., Kontopantelis, E., Chew-Graham, C., Dawson, S., van Marwijk, H., Geraghty, K., Esmail, A., 2017. Controlled Interventions to Reduce Burnout in Physicians. *JAMA Intern. Med.* 177, 195. <https://doi.org/10.1001/jamainternmed.2016.7674>
- Quality Watch, 2016. NHS staff sickness absence.
- Richardson, K.M., Rothstein, H.R., 2008. Effects of occupational stress management intervention programs: A meta-analysis. *J. Occup. Health Psychol.* 13, 69–93. <https://doi.org/10.1037/1076-8998.13.1.69>
- Segal, Z.V., Williams, J.M.G., Teasdale, J.D., 2013. *Mindfulness-based cognitive therapy for depression (second edition)*, second. ed. Guilford Press, New York, New York.
- Segal, Z.V., Williams, J.M.G., Teasdale, J.D., 2002. *Mindfulness-based cognitive therapy for depression*. Guildford Press, New York, New York.
- Song, Y., Lindquist, R., 2015. Effects of mindfulness-based stress reduction on depression, anxiety, stress and mindfulness in Korean nursing students. *Nurse Educ. Today* 35, 86–90. <https://doi.org/10.1016/j.nedt.2014.06.010>
- Stewart-Brown, S., Tennant, A., Tennant, R., Platt, S., Parkinson, J., Weich, S., 2009. Internal construct validity of the Warwick-Edinburgh Mental Well-being Scale (WEMWBS): a Rasch analysis using data from the Scottish Health Education Population Survey. *Health Qual. Life Outcomes* 7, 15. <https://doi.org/10.1186/1477-7525-7-15>
- Strauss, C., Taylor, B.L., Gu, J., Kuyken, W., Baer, R., Jones, F., Cavanagh, K., 2016. What is compassion and how can we measure it? A review of definitions and measures. *Clin. Psychol. Rev.* 47, 15–27. <https://doi.org/10.1016/J.CPR.2016.05.004>
- van Roijen, L., Essink-Bot, M.L., Koopmanschap, M.A., Bonsel, G., Rutten, F.F., 1996. Labor and health status in economic evaluation of health care. *The Health and Labor*

Questionnaire. *Int. J. Technol. Assess. Health Care* 12, 405–15.

Virgili, M., 2013. Mindfulness-Based Interventions Reduce Psychological Distress in Working Adults: a Meta-Analysis of Intervention Studies. *Mindfulness* (N. Y). 1–12. <https://doi.org/10.1007/s12671-013-0264-0>

Williams, M.J., Dalgleish, T., Karl, A., Kuyken, W., 2014. Examining the factor structures of the Five Facet Mindfulness Questionnaire and the Self-Compassion Scale. *Psychol. Assess.* 26, 407–418. <https://doi.org/10.1037/a0035566>

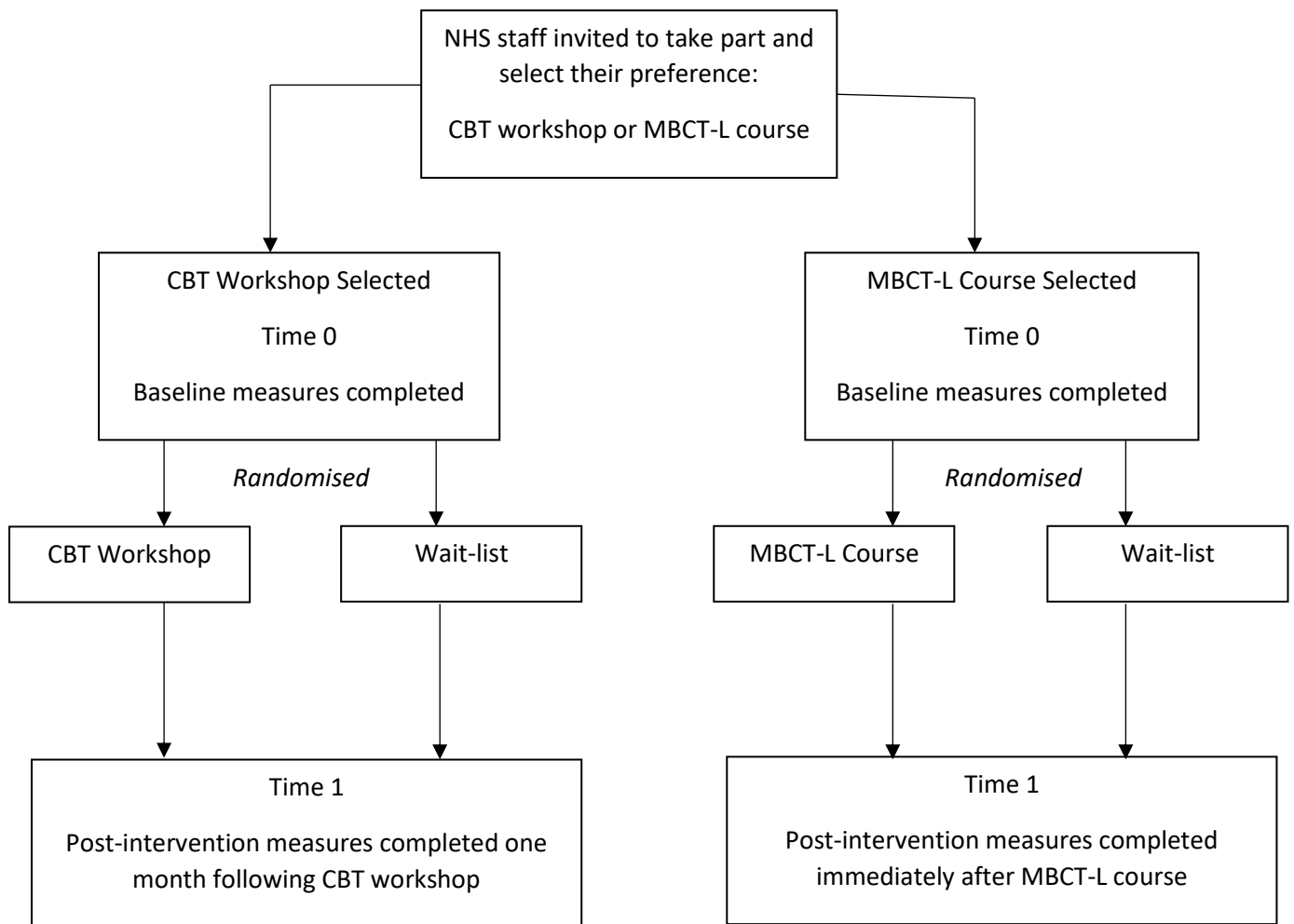


Figure 1: CONSORT flow diagram showing participant flow through the study

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	_____1_____ —
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_____5_____ —
	2b	All items from the World Health Organization Trial Registration Data Set	_____na_____ —
Protocol version	3	Date and version identifier	_____5_____ —
Funding	4	Sources and types of financial, material, and other support	_____24_____ —
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_____1- 2_____
	5b	Name and contact information for the trial sponsor	_____5_____ —

5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_____24_____
5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_____na_____

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	____6- 10_____
	6b	Explanation for choice of comparators	____9- 10_____
Objectives	7	Specific objectives or hypotheses	____9- 10_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	____10_____

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	____11____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	____11- 14____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	____12- 14____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____na____ _
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____13- 14____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	____na____ _
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	____12- 19____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	____12____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	____10- 11____

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_____12_____
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Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_____10_____
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Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_____10_____
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Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_____10_____
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Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_____10,12_____
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	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_____na_____
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Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_____12, 14-19__
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_____12_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_____12_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_____19-20_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_____19-20_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____19-20_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_____na_____

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_____na_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_____na_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_____na_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____23_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_____23- 24_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_____23- 24_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_____na_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_____24_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_____24_____

Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_____25_____
			—
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_____na_____
			—
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_____20_____
			—
	31b	Authorship eligibility guidelines and any intended use of professional writers	_____25_____
			—
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_____na_____
			—
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_____Uploaded_____
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_____na_____
			—

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](https://creativecommons.org/licenses/by-nc-nd/3.0/) license.

Figure 2. Schedule of enrolment, interventions, and assessments

	Enrolment	Allocation	Intervention Period	Close-out
TIMEPOINT		T0		T1
ENROLMENT:				
Informed Consent	X			
Intervention Preference	X			
Allocation		X		
INTERVENTIONS:				
MBCT-L			X	
CBT workshop			X	
ASSESSMENTS:				
Baseline Assessment	X			
Post-intervention Assessment				X