RESEARCH PROTOCOL
Pragmatic randomised controlled trial of an intervention to reduce burnout and improve well-being in NHS doctors

Short title of study
CPM Trial 2

Protocol version and date	Research Ethics Committee (REC) reference
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Sponsor organisation	**Controlled trials registration number**
Rotherham Doncaster and South Humber NHS Foundation Trust	ISRCTN14947225

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Contents of the study protocol

1. Synopsis of the study	
Short study title	CPM Trial 2
ISRCTN registration no.	TBC
Study Design	Pragmatic, stepped-wedge randomised controlled trial
Setting	Hospital and community-based NHS providers
Study Participants	GMC registered doctors working in the National Health Service
Primary Objective	To evaluate if a group-based psychological intervention reduces occupational burnout levels in doctors
Secondary Objectives	▪ To assess if the intervention improves subjective well-being ▪ To quantify completion and dropout rates ▪ To investigate predictors of dropout and treatment response ▪ To examine variability in burnout, well-being and job satisfaction according to role and demographic characteristics ▪ To understand participants' experiences of the intervention
Primary outcome	Occupational burnout, measured by the Oldenburg Burnout Inventory (OLBI)
Intervention	An 8-session, 10-week, group-based, psychoeducational intervention based on The Mind Management Skills for Life Programme
Randomization and data collection	Consenting NHS doctors will be randomly assigned to two groups; 1 and 2. Participants in both groups will be asked to complete outcome measures at an initial baseline assessment, after which only participants in group 1 will access an 8-session, 10-week intervention (*controlled phase*). Next, group 2 will access the intervention during an 8-session, 10-week period (*full implementation phase*). Finally, we will collect further outcome measures 6 months after both groups have completed the intervention (*follow-up phase*). Following intention-to-treat principles, participants who do not attend any intervention sessions (and who do not formally withdraw) will be included in the study and will be invited to complete measures.
Planned Sample Size	Minimum recruitment target of 180 participants, expecting 50% attrition, plus approx. 120 non-intervention participants.
Data analysis method	1. Trial data will be summarised using a CONSORT diagram and analyses will be based on *intention-to-treat* principles. 2. The primary analysis will compare between-group differences in OLBI at 10-weeks, using ANCOVA adjusting for baseline OLBI. 3. Secondary analyses: Between-group comparisons will be conducted at each measurement point using ANCOVA adjusting for baseline severity in the relevant outcome measure. 4. Between-group and within-group effect sizes will be calculated using Cohen's d. 5. Completion / dropout rates will be compared between groups using chi-square analysis. 6. Predictors of dropout and treatment response will be examined as a secondary analysis using Elastic Net regularization 7. Variability in burnout, wellbeing and job satisfaction will be examined across groups defined by job role and demographic characteristics using t-tests and appropriate non-parametric tests. 8. Qualitative data will be analysed using thematic analysis.
Study Period	24 months (18 months active study period, plus 6 months analyses and dissemination)

2. Background and rationale

Occupational burnout refers to a state of job-related emotional exhaustion, depersonalisation and reduced personal accomplishment (Maslach, 1982). Burnout is known to be particularly severe in healthcare professionals such as doctors. A 2020 survey by Medscape UK found that the number of doctors experiencing depression and burnout has increased by 68% since 2018, and that many doctors now say they are considering changing careers or retiring early. A systematic review by Williams et al., (2020) found that burnout can have a significant impact on the physical and mental health of doctors. For example, in the 16 studies that examined the link between burnout and depression, they found that burnout was significantly related to depression in six studies. In the seven studies that explored burnout and its link with physical health outcomes three studies supported a relationship between increased burnout and worse physical health outcomes. It is also worthy of note that of five studies looking at the link between burnout and suicidal thoughts, three studies found support for this relationship. For all of these findings, emotional exhaustion seemed to the component of burnout that was most often related to these negative consequences.

A study by Hall et al., (2020) found that burned out doctors felt they were likely to have decreased empathy and listening skills. Doctors were also more likely to report negative attitudes towards patients, leading to fewer good quality interactions. Finally, doctors reported that they were likely to complete inappropriate referrals, potentially leading to unnecessary investigation and increased emotional distress for patients. Hall et al., (2020) further noted impact on patient safety. They felt issues like a lack of space to think, and inability to approach the patient holistically were likely to cause indirect negative effects on patient safety. Poorer concentration and increased tiredness could also potentially lead to poor decision making. Finally, Hall et al., (2020) note that burnout and mistakes are likely to work in a downward spiral. The more burnt out a doctor is, the more likely they are to make mistakes or have complaints made about them, but also making mistakes or receiving complaints is likely to increase burnout (Hall, et al., 2020). Other studies (not focussed on doctors) show the link between burnout and poorer patient treatment outcomes (Delgadillo, Saxon, & Barkham, 2018), medical errors (Shanafelt et al., 2010), medico-legal cases (Balch et al., 2011), and healthcare related infections (Cimiotti et al., 2012). Burnout can also lead to increased absenteeism and staff turnover (Lee, Lim, Yang, & Lee, 2011; Salvagioni et al., 2017).

A recent examination of staff well-being in the English National Health Service (NHS) concluded that staff shortages related to occupational stress are linked with poor quality of care and poor patient experience (Sizmur & Raleigh, 2018), highlighting the widespread nature of burnout and its impact in the NHS. Burnout in the NHS is a system wide problem with Public Health England estimating the cost of staff absence due to poor health at £2.4 billion per annum. The NHS depends on having a healthy and productive workforce to deliver high quality patient care. The Boorman NHS Health and Well-being 2009 report found that 80% of staff felt that their health and wellbeing had an impact on patient care, but only 40% of staff felt their employer was proactively trying to improve their health and wellbeing. A recent survey of doctors found that around 97% of respondents felt that the NHS has a culture of seeing excessive stress and workload as the norm (Dominic, Gopal & Sidhu, 2021). The gravity of these issues has led to calls for the NHS to make the health and wellbeing of its staff a priority. Their 2015 report 'Work and wellbeing in the NHS: Why staff health matters to patient care' recognises the importance of staff health and wellbeing to both NHS organisations and patients and concludes that our healthcare system's greatest asset is the people who deliver it. As NHS services face unprecedented clinical demand, increasing financial pressures and a patient population with complex care needs, it is often the health and wellbeing of NHS staff that suffers.

Factor in the Covid-19 pandemic, and the outlook is even bleaker. Working during the pandemic has had a great impact on the wellbeing of doctors, resulting in an increase in burnout. Prior to the pandemic in 2020, 32% of doctors reported an impact on their wellbeing, in comparison to 42% of doctors who worked throughout covid (GMC,2021). The doctor's field of work is also something that has an impact on their risk of burnout (GMC,2021). Those with the highest risk of burnout were G.P.s (32%), followed by specialists (18%), doctors in training (11%) and finally SAS and LE doctors (7%).

For these reasons, and given the scale of the problem, the NHS Long Term Plan acknowledges the need to "support improved health and wellbeing of staff and management of sickness absence" (NHS England, 2019, pg. 87).

Approaches to address occupational burnout include individual interventions (e.g., stress management courses, mindfulness courses, cognitive-behavioural coping skills training, communication training) and structural / organisational interventions (e.g., workload redesign, practice delivery changes). Numerous studies have measured the positive effect of such interventions (Lucas et al., 2012, Linzer et al., 2015), although relatively few controlled trials have been conducted with healthcare professionals. A meta-analysis of controlled trials and cohort studies concluded that both individual-focused and organisational strategies can reduce burnout in healthcare professionals by approximately 10% (West, Dyrbye, Erwin, & Shanafelt, 2016). Overall, there is some evidence that both individual and organisational interventions can help to ease occupational burnout, and coping-skills interventions appear to be promising in healthcare staff. Despite this emerging literature, evidence-based interventions to prevent or reduce burnout are not routinely offered to NHS staff. In particular, there is limited research on the efficacy of burnout-focused interventions in doctors working in publicly funded healthcare organisations such as the NHS, who are known to experience particularly high levels of burnout by comparison to other health professionals. Although observational studies indicate that doctors could potentially benefit from burnout-interventions, there are only a few rigorous clinical trials of such interventions, and most are small and underpowered to draw firm conclusions. The present study aims to address this gap in the literature by conducting an adequately powered multi-site randomised controlled trial to test the efficacy of a digitally-enabled intervention for occupational burnout in NHS doctors.

3. Objectives and Hypotheses

3.1. Primary Objective

To evaluate if a group-based psychological intervention reduces occupational burnout levels in NHS doctors.

3.2. Secondary Objectives

- To assess if the intervention improves subjective well-being
- To assess if the intervention improves job satisfaction
- To quantify completion and dropout rates
- To explore predictors of dropout and treatment response
- To examine variability in burnout and well-being according to role and demographic characteristics
- To understand participants' experiences of the intervention

3.3. Hypotheses

A) Exposure to the intervention will be associated with significantly lower mean burnout severity by comparison to a waitlist (delayed intervention) control group

B) After the control group is exposed to the intervention, there will be no significant differences in mean burnout level between the two groups (immediate intervention group, delayed intervention group)

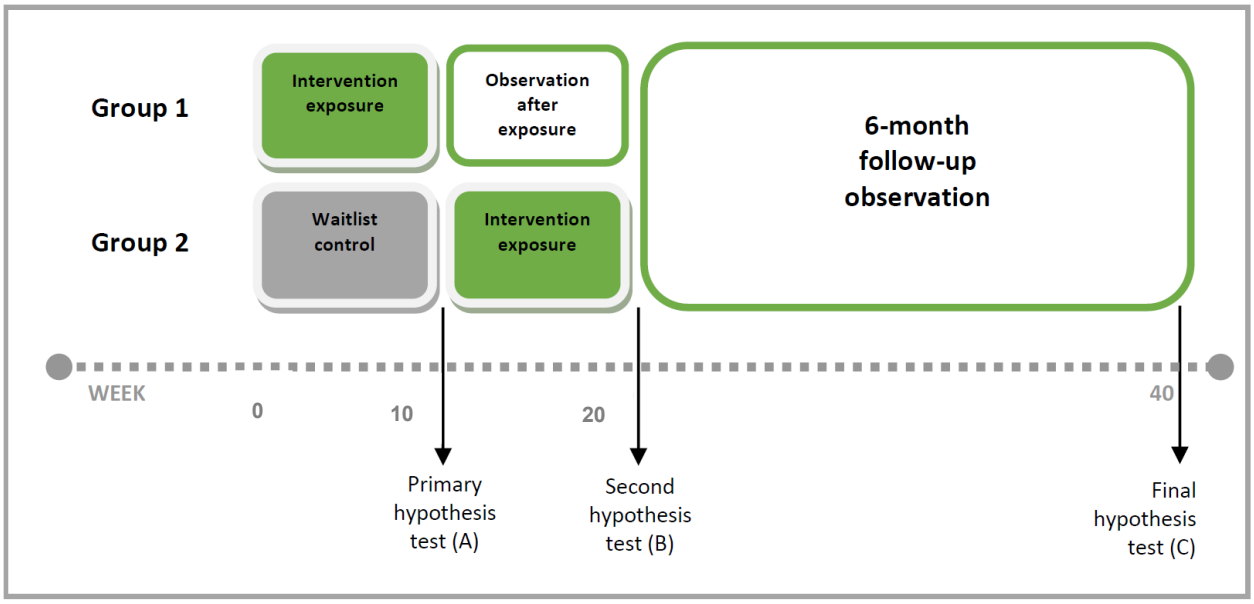
C) Mean burnout severity for all participants at the end of the 6-month follow-up period will be significantly lower than baseline severity (prior to intervention), but not significantly different to end-of-treatment severity, indicating maintenance of gains

4. Study design

This will be a pragmatic, stepped wedge, open-label, randomised controlled trial. Consenting doctors will be randomly assigned to two groups, by a research assistant using a computerized randomization algorithm. The randomisation sequence will be based on random blocks of 10 participants, and

stratification according to participants' employing organisation (trial site). The study will be carried out in three phases, which are illustrated in Figure 1.

Figure 1. Stepped wedge trial design



Participants in both groups will be asked to complete outcome measures during a pre-intervention baseline assessment (week 0). After the baseline assessment, only participants in group 1 will access an 8 session, 10-week intervention (controlled phase). Next, group 2 will access the intervention during a 10-week period (full implementation phase). Finally, we will collect further outcome measures 6 months after both groups have completed the intervention (follow-up phase). Selected outcome measures (see section '4.3 Measures' for more details) will be completed at each of the measurement points outlined in the above timeline (weeks 0, 10, 20, 44). All measures will be completed online using an industry-standard survey system (Qualtrics), which will be managed by a research assistant.

The end of the study is classed as once the participant has completed the six-month follow-up questionnaire. However, the participants email addresses will be kept for up to six months after this to ensure the research team can disseminate the results of the study. Following this, all personal data will be deleted.

Participants who do not attend at least one intervention session will be classed as part of a 'non-intervention' group. The baseline data for these participants will be retained and, unless they have formally withdrawn, they will be invited to complete the questionnaires at each of the above timepoints so we can include their outcome measures in the primary data analysis, following intention-to-treat principles (see section 5.2).

4.1. Setting and participants

This study will include GMC registered doctors across the broad spectrum of medical specialties, from general practice in community clinics to specialist hospital-based outpatient and inpatient services.

Inclusion criteria

- GMC registered doctors from any areas of specialty and NHS healthcare services, including trainees on rotation in NHS services.
- Working either part-time or full-time in a clinical role.

Exclusion criteria

- Currently accessing or referred to any concurrent psychological intervention delivered by a mental health professional (this specifically refers to talking therapies for mental health problems).
- Doctors that are currently not in active clinical service at the time of recruitment (e.g., on sick leave, maternity leave or suspended for any reason).
- Doctors that work in a purely managerial, supervisory or educational role (e.g., not in clinical practice at the time of recruitment).

4.2. Intervention

This will be a group-based, digitally-enabled (video call) intervention based on the *Mind Management Skills for Life Programme*. This intervention was developed by Professor Steve Peters based on a model of the human mind elaborated in the book called The Chimp Paradox (Peters, 2012). The model is based on developments in neuroscience and psychological theory. It offers practical strategies and skills for the individual to learn how to: (1) gain insight into how their mind is working; (2) understand and recognise their thoughts, behaviours and emotions; (3) better manage themselves to become the person they would like to be. This intervention has been implemented in the world of elite sport, with public sector organisations, in the entertainment sector, in the corporate sector and with individuals over the past two decades. A number of (unpublished) small pilot studies have been conducted using this intervention with groups of NHS staff, both in primary and secondary care. These pilot programmes have shown preliminary indications that the *Mind Management Skills for Life Programme* could lead to improvements in the quality of life and wellbeing of the NHS staff in both their personal and professional lives. A recent randomised controlled trial investigated the effect of the *Mind Management Skills for Life Programme* on burnout and mental wellbeing in a large sample of mental health nurses (N=173), providing evidence that this intervention led to improvements in burnout and wellbeing (Laker et al., 2023). Although these results from a large and adequately powered trial support the efficacy of this intervention, it is not known if such findings might generalise to a population of NHS doctors, whose work demands, and resources are likely to be considerably different to those of participants in the previous trial.

In the proposed trial, this intervention will be delivered by experienced mentors who were trained and supervised by the intervention developer. To safeguard the integrity and transparency of the study, the intervention facilitators and developer are not members of the research team and will have no role in participant recruitment, data collection, data analysis or publication of the study results. All groups will be delivered online via Microsoft teams to groups of up to 30 participants per session. The intervention will consist of eight, ninety-minute interactive sessions, over ten weeks. Each workshop will be structured and delivered using a standardised presentation describing the principles of the model within that session. At specified stages of the presentation, participants will be encouraged to engage in facilitated group discussions consisting of up to 30 people. Participants will receive electronic written and didactic materials which accompany the intervention, to support the transfer of their learning into their daily work and personal life.

4.3. Measures

Primary outcome measure

Occupational burnout will be measured using the Oldenburg Burnout Inventory (OLBI), a 16-item questionnaire designed to assess two facets of burnout, emotional exhaustion (OLBI-E) and disengagement (OLBI-D), including their cognitive and somatic aspects (Demerouti, Bakker, Nachreiner, & Schaufeli, 2001). For both dimensions, four items are phrased positively and four items are phrased negatively (reverse scored). Every item is scored between 1 (strongly agree) and 4 (strongly disagree), and item ratings are averaged into a single index (range = 1 to 4), where a higher score is indicative of increased burnout. Examples of positively and negatively phrased items are: “I can tolerate the pressure of my work very well”; “During my work, I often feel emotionally drained”. A psychometric validation study applying

the OLBI in 2599 adults with a variety of professional backgrounds demonstrated high internal consistency (Cronbach's alpha = .74 to .76 for each subscale) as well as robust convergent, and discriminant validity (Halbesleben & Demerouti, 2005).

Secondary measures

- Participants will also be asked to report basic demographics (age, gender, ethnicity) and generic information about their job role and work setting (speciality, qualified vs. trainee status, hours of clinical work per week).
- The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) is a 14-item questionnaire; each answered on a 1 to 5 Likert scale. Items cover different aspects of eudaimonic and hedonic mental wellbeing and are worded positively. Item scores are summed to produce a total score (range: 14 to 70), where higher scores indicate greater psychological well-being. Psychometric testing has indicated that this measure was valid, reliable and acceptable measure of well-being in adult respondents (Tennant et al., 2007); with good internal consistency (Cronbach's alpha = .89 to .91) and test-retest reliability (.81). This will be collected at each of the measurement points outlined in Figure 1 (weeks 0, 10, 20, 44).
- The Job Discrepancy and Satisfaction Scale is an 8-item scale which captures how satisfied an individual is with their role, their job rewards (e.g., salary and promotion), and job resources (e.g., supervision and working conditions). Items are scored 1-4 and averaged to give the same scale score range with higher values representing greater job satisfaction. A recent study of therapist burnout reported a Cronbach α of .75 (Delgadillo et al., 2018). This will be collected at each of the measurement points outlined in Figure 1 (weeks 0, 10, 20, 44).

Other measures

- The Mental Health Professional Stress Scale is a 42-item measure which captures sources of pressure at work in mental health staff but has also been used in a wider NHS context. It contains seven, 6-item sub-scales with each item scoring 0-4, with higher scores representing a more stressful workplace. Item scores are averaged for each sub-scale and the whole scale to give scores ranging 0-4. The following 6-item sub-scales will be used (total 30-items): workload; client-related difficulties; organisational structures and processes; relationship and conflicts with other professionals; lack of resources. Cronbach's alpha values for these range between .78 and .81 (Cushway, Tyler, & Nolan, 1996). This will be collected at baseline only.
- The Overcommitment subscale of the Effort-Reward Imbalance Questionnaire (Siegrist, Li, & Montano, 2014) is a 6-item scale that captures an individual's ability to separate professional roles from personal life. The effort and reward subscales capture very similar constructs to workload and job satisfaction already provided for by separate measures and so would be superfluous. Items are scored 1-4 with one reverse scored item and averaged to give the same sub-scale score range with higher values representing greater overcommitment to work. Cronbach's alpha is reported as greater than .70 by the authors (Siegrist et al., 2014) and in a recent study of burnout values were .80 or greater and repeatable (Avanzi et al., 2014). This will be collected at baseline (week 0) and at weeks 20 and 40.

4.4. Recruitment, study procedures and data collection

Participant recruitment process

- A principal investigator (PI) will be nominated at each of the participating trial sites, and this person will be responsible for promotion and recruitment tasks described below.
- A promotion and recruitment pack will include: (1) a brief newsletter and (2) a participant information video. These promotional materials will be disseminated to the workforce by the PI via local NHS management mailing lists, via organisational communication teams, and via NHS wellbeing teams, via NHS intranet front page, and via social media campaigns, and other appropriate pathways.

- The PI will also organise attendance at relevant team meetings (e.g., meetings of clinical leaders, managers) conducted remotely (e.g., using MS Teams) to promote the study. The PI may attend one or more of these promotional meetings, but may also delegate attendance to other members of the research team.
- The promotion and recruitment period will last up to twelve weeks. Promotion activities will commence once ethical approvals have been received. The formal electronic consent process (described below) will also be activated once ethical approval is in place. Potential participants will have the opportunity to contact the research team via email to clarify questions, if necessary.
- Promotional materials described above will contain a weblink to an electronic participant information sheet and consent form (when ethical approval has been given). This method will ensure that no paper copies can be lost or misplaced in the post, and will be an efficient way to gather informed consent using an industry-standard and secure online survey system. A sample text for the consent form that will be available electronically is provided in the Appendix. NHS managers and/or team leaders will not be involved in the consenting process, which will minimise administrative burden and the potential for selection biases or the application of undue pressure on potential participants.
- Consenting participants will be randomly allocated to the online intervention groups. Allocation will be carried out by a NHS-based researcher who is independent of the core research team, using a computerized block randomization schedule. Randomisation will be communicated directly to study participants via email within one week of receipt of their electronic consent form. This email will contain further instructions on how participants can register onto an upcoming online workshop anonymously.
- The research team based at Rotherham Doncaster and South Humber (RDaSH) NHS Trust will inform the intervention facilitators when the recruitment target has been met, providing a list of consenting participants after the randomisation process has been concluded. This will ensure CPM facilitators will know how many participants to expect in each of the intervention groups, and how to address them (e.g., the list will include their first names and areas of specialty). A research assistant linked to the RDaSH research team will work closely with the CPM intervention facilitators to coordinate the organisation of the groups.

Organisation of the intervention groups

- Participants will access the intervention using video conferencing software.
- To allow flexibility and to accommodate different working patterns and shifts, participants will have the opportunity to attend one of several available groups (up to four groups will be running simultaneously) which occur throughout different days and times of the week. Participants will receive an email listing the available options, and they will select their preferred schedule.
- After participants select their preferred schedule (e.g., day/time for workshop attendance), details of the sessions, including weblinks, dates and times will be provided via email. Staff will be asked to attend the same session each week to ensure numbers are managed. However, we appreciate that shift patterns need to be accounted for so we will ask participants to notify the research team if they need to change their day on a selected week. We expect that those who agree to take part in the trial will complete eight sessions spread over ten weeks, however we understand that some will be unable to do so, therefore we will consider a participant as having dropped out of the trial if they miss four or more sessions.
- After Group 1 has completed the ten-week, eight session intervention, the second group will have access to the same intervention using the process outlined above in Figure 1.

Data collection and safeguarding procedures

- All participants irrespective of group allocation will be asked to complete the primary and secondary measures described above, at four assessment points, as described in the 'Measures' section above. The measures will be collected by an independent NHS-based research team, who is not involved

directly in the intervention delivery. The researchers will use a secure, web-based, data collection system called Qualtrics.

- The consent and demographic questionnaires will ask for the participant's preferred email address. This is to ensure we are able to contact the participants throughout the study period (e.g., sending email reminders). Once they have completed the consent form we will email the participants a unique participant pseudonym, which cannot personally identify any of the study participants. The participant will then use this pseudonym to identify themselves throughout the rest of the study (i.e., to log in to the Microsoft Teams webinar). The research team will keep a record of the participant's email address and associated pseudonym, so if the participant forgets their code they can contact the team to retrieve these details. Staff in the research team will schedule the MS Teams sessions and will invite participants using their email addresses (this is required for the breakout session facility to be used). All participants' email addresses will be deleted after 2 years, which is a time-scale that we expect will allow sufficient time for the study to be concluded and to enable the research team to communicate all of the relevant results to participants via email.
- The measures will be collected by the research team using a secure, web-based, industry-standard data collection system. Therefore, all data collection will be in electronic form. Participants will receive email reminders (sent confidentially by the research team) at the relevant measurement points (see Figure 1). A maximum of 3 reminder emails will be sent to non-responding participants at each of the measurement points. If participants do not respond after the 3 reminders, we will consider that specific data-point to be missing. To access the survey, each participant will click on the link to access the survey via Qualtrics.
- Pseudonymised qualitative data will be collected using the same Qualtrics survey after all participants had the opportunity to access the intervention (week 20). The purpose of collecting this information is to obtain detailed feedback about the participants' experience of being involved in the study and attending the intervention. We expect that some participants will not have been able to attend any intervention sessions, and therefore we intend to ask them for qualitative feedback to enable us to understand barriers to participation. Therefore, qualitative data will be obtained both from those who attended at least one session of the intervention and those who did not. The qualitative questions are available in the qualitative survey question document.
- The final study dataset will be archived for potential future use in secondary analyses and to contribute to systematic reviews and meta-analyses. The study documents will be stored in a secure NHS network drive, only accessible to members of the research team, which is located behind RDaSH Firewall. This will ensure the security and adequate storage of research data, consistent with NHS and academic codes of information governance and data protection.
- All analyses will be carried out at a University site, and data will be held in a restricted-access drive. The study dataset will be held at RDaSH for 10 years after the conclusion of the study.
- The University of Sheffield will be a data processor, whilst RDaSH will remain the data controller. The University of Sheffield will store anonymised data for 10 years after the conclusion of the study.

5. Data analysis

5.1. Sample size calculation

Using G*Power to perform a sample size calculation for a between-groups analysis of covariance (ANCOVA), with 80% power, an alpha level of 0.05, and controlling for intake severity to detect an effect size of d=0.6 (based on the CPM 1 trial (ISRCTN34503872) - converts to f=0.30) estimates that at least 45 participants are needed in each group (total sample size of 90).

Accounting for a drop-out rate of 50% (based on the lost-to-follow-up rate at 6-month follow-up in CPM 1), would inflate the total required sample size to a minimum of 180 (90 in each group). This high dropout rate is associated with the busy nature of healthcare, which makes it difficult to retain NHS staff in clinical trials, and hence it is essential to work to a conservative sample size calculation.

For reference, CPM 1 recruited a total of 173 participants (G1=83, G2=90). So, if we were to account for the expected follow-up drop-out rate, we would need to recruit more participants than CPM 1. Therefore, to ensure that the trial is adequately powered and robust to the expected level of attrition, we propose to recruit a minimum of 180 participants and to continue to recruit as many participants as are willing to provide consent within the 3-month recruitment period. In order to ensure the trial recruits to target and is robust to attrition, we will recruit from multiple NHS service providers across England.

5.2. Primary analysis

Trial data will be summarised using a CONSORT diagram and all analyses will be based on *intention-to-treat* principles (e.g., including all available data for participants who never attended intervention sessions, those who attended all sessions, and those who dropped out after a few sessions). Intention-to-treat principles will be followed to minimise well-known biases present in "completer analysis" (e.g., only including data from those who complete the intervention, who may not be representative of the wider population of eligible participants in need for treatment) and to follow best practice principles in healthcare research (White et al., 2011). Missing data will be imputed using an expectation-maximization algorithm, prior to conducting formal analyses.

The primary hypothesis test will be based on comparing mean OLBI (total severity) scores between groups at week 10 (post-intervention), as shown in Figure 1. Mean OLBI scores (dependent variable) will be compared between groups using ANCOVA, adjusting for baseline severity and entering "intervention group" as an independent variable. Adjusted 95% confidence intervals will be calculated around the adjusted mean difference between interventions. The analysis will be conducted using the Statistical Package for the Social Sciences (SPSS) by a researcher who will be blind to the label of the interventions. The primary analysis will be conducted using imputed data, following intention-to-treat principles. Secondary analyses will repeat the above ANCOVA model using per protocol analysis (only including participants that actually started the intervention; and excluding data from those in the 'non-intervention' group) and an unimputed dataset (e.g., completers analysis), to test the robustness and stability of the main analysis.

5.3. Secondary analyses

The analysis described above will be repeated at the 44-week follow-up. In addition, these analyses will be repeated at each of the post-intervention time-points illustrated in Figure 1 (weeks 10, 44), using the OLBI sub-domain scores (*exhaustion*; *disengagement*), the WEMWBS well-being measure, and the JDSS job satisfaction measure, controlling for baseline scores. These between-group comparisons will also be summarised using effect sizes (Cohen's *d*).

Post-intervention measures (weeks 10, 20, 44) will be compared to baseline measures (week 0) within each group, using paired-samples t-tests or an appropriate non-parametric test depending on the distribution of the data. Within-sample pre-post treatment effect sizes will also be computed using the method proposed by Minami et al. (2008).

Dropout will be defined as attending less than 4 (half) of the intervention sessions. We will examine predictors of dropout and treatment response (defined as reliable improvement in the OLBI measure), using all available baseline measures as candidate predictors. Reliable predictors of each of these outcomes of interest will be identified using a variable selection method called Elastic Net Regularization (Zou & Hastie, 2005) applied in separate logistic regression models for each dependent variable.

Additional secondary analyses will examine variability in burnout, wellbeing and job satisfaction across groups defined by their job role and demographic characteristics. Between-group comparisons will be made using t-tests (or Mann-Whitney U Tests if the data are not normally distributed).

Qualitative data collected via online surveys after all participants had the opportunity to access the intervention (week 20) will be analysed using thematic analysis (TA). TA will follow the 6-step phase of

analysis proposed by Braun and Clarke (2006). We will triangulate qualitative themes generated via the TA method with baseline survey data in order to explore if the themes vary according to job role (e.g., junior doctors, consultants, etc.) and setting (e.g., community vs. hospital services).

6. Ethical considerations

6.1. Considerations about informed consent

As the participants of this study will be NHS staff, this study does not strictly require NHS research ethics approval. However, it will require Health Research Authority (HRA) approval. We will nevertheless apply for review by an NHS REC, given that this is a clinical trial of a novel intervention, in order to obtain independent scrutiny of the study protocol and relevant recruitment materials and methodology. Our prior clinical trials involving NHS staff as participants have been reviewed by an NHS REC on this basis, given that interventions that affect NHS staff well-being indirectly also affected NHS patients' quality of care.

In order to obtain informed consent from healthcare professionals in line with good practice guidelines, we will take the following steps:

- Planned attendance by members of the research team to clinical team meetings will enable potential participants the opportunity to ask questions, raise concerns and discuss any aspects of the study that they wish to clarify. Potential participants will also be invited to contact a member of the research team if they have any further thoughts or questions after team meetings. Contact details will be provided as part of the Participant Information Sheet (PIS).
- Potential participants will be advised of their right to withdraw from the study at any stage and the right to request their data to be deleted from the study dataset. This will be explicit in the electronic participant information sheet, in the consent form, and will be explained to participants following notification of randomisation. Each participant will receive an electronic copy of the information sheet and consent form via email, for their records.

We will also be collecting fully anonymous data described in section 4.3. Our proposed method for aggregating and analysing fully anonymized data is congruent with the NHS information governance policy and good practice guidelines.

Potential for distress

Given the psychoeducational nature of the intervention, we do not envisage any potential for significant distress or adverse events. Nevertheless, participants will receive the contact details for the chief investigator in the information sheet, if they should wish to make a complaint or to raise any concerns about the intervention or conduct of the study. In the rare event that a participant should become distressed, they will be provided information by the research team about usual sources of psychological and or occupational health support available to employees in NHS Trusts.

Our team is highly experienced at conducting clinical trials of occupational burnout interventions, having involved over 700 participants in randomised controlled trials. To date, we have not encountered any serious adverse events in these studies, and we have been responsive to communicate with and support study participants who have contacted the research team directly with queries or concerns related to occupational wellbeing. This does not mean that adverse events could not potentially occur, but it clearly indicates that they are extremely rare in this context and type of study. In order to be responsive and to follow best practice guidelines for psychological research, we will:

1. Monitor email correspondence from participants on a weekly basis, with recorded delegation of monitoring to more than one member of the research team.

2. Have a senior and clinically-qualified member of the research team nominated to be a point of contact for research team members to consult with if queries and concerns arise during the course of the study. The co-directors of the research team will share this responsibility, both of whom are qualified psychotherapists.
3. Escalate any concerns (even if these are minor) raised by participants directly to the chief investigator within 24 hours.
4. Notify the sponsor organisations' R&D manager, the trial steering group, and the NHS REC about any formal complaints or adverse incidents recorded during the trial.

Risks to participants

See above section.

Risks to research team

See above section.

Potential for disclosure

See above section.

7. Dissemination

After the conclusion of data analysis, we plan to disseminate findings about this study using a variety of forms of communication, including:

- Scientific journal publications
- Newsletter in lay terminology
- NHS Trust communications newsletter and email
- NHS Trust conferences, strategic meetings
- Mental health conferences in the UK and abroad

8. References

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