RESEARCH PROTOCOL

Pragmatic randomised controlled trial of an intervention to reduce burnout and improve well-being in healthcare professionals

Short title of study
CPM Trial

Protocol version and date	Research Ethics Committee (REC) reference
(v6) 18.03.20	20/WA/0029
Sponsor organisation	**Controlled trials registration number**
Rotherham Doncaster and South Humber NHS Foundation Trust	ISRCTN34503872

Research team

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Contents of the study protocol

1. Synopsis of the study	
Short study title	CPM Trial
ISRCTN registration no.	TBC
Study Design	Pragmatic, stepped-wedge randomised controlled trial
Setting	Adult Community Nursing services across the geography of Rotherham Doncaster and South Humber NHS Foundation Trust
Study Participants	Registered nurses that work in the National Health Service
Primary Objective	To evaluate if a group-based psychological intervention reduces occupational burnout levels in a cohort of nurses
Secondary Objectives	▪ To assess if the intervention improves subjective well-being ▪ To assess if the intervention reduces self-reported sickness absence ▪ To quantify completion and dropout rates
Primary outcome	Occupational burnout, measured by the Oldenburg Burnout Inventory (OLBI)
Intervention	An 8-week, group-based, psychoeducational intervention based on The Chimp Paradox Model
Randomization and data collection	Consenting NHS staff 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-week intervention (*controlled phase*). Next, group 2 will access the intervention during an 8-week period (*full implementation phase*). Finally, we will collect further outcome measures 6 months after both groups have completed the intervention (*follow-up phase*).
Planned Sample Size	Minimum recruitment target of 192 participants, expecting 30% attrition.
Data analysis method	1. Trial data will be summarised using a CONSORT diagram and analyses will be based on *intention-to-treat* principles. 2. Between-group comparisons will be conducted at the end of each phase using ANOVA. 3. The primary analyses will examine between-group differences in occupational burnout (OLBI) severity over time (after each of the 3 phases, post-baseline). 4. Secondary analyses will involve comparing between-group differences in each of the OLBI burnout dimensions (exhaustion, disengagement), and in measures of subjective well-being and personal goal attainment. 5. We will also quantify and report intervention completion / dropout rates, and self-reported days on sickness leave.
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 acute in healthcare professionals, and especially in mental health workers, affecting around 40% according to a recent meta-analysis (O'Connor, Muller, Neff, & Pitman, 2018). Previous studies have demonstrated that burnout has a negative impact on psychological well-being and physical health (Salvagioni et al., 2017). Burnout is also associated with poorer job performance (Taris, 2006), and increased absenteeism and staff turnover (Lee, Lim, Yang, & Lee, 2011; Salvagioni et al., 2017). Furthermore, increased burnout not only has adverse consequences for healthcare professionals, but is also associated with 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).

A recent examination of staff well-being in the English National Health Service concluded that staff shortages associated with occupational stress are associated 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 National Health Service (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. The importance and impact of these issues has led experts, including The Royal College of Physicians (RCP), to call for NHS organisations to prioritise the health, wellbeing and engagement of staff. Their 2015 report '*Work and wellbeing in the NHS: why staff health matters to patient care*' outlines the fundamental importance of staff health and wellbeing to both NHS organisation 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. 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 assessed the remedial or preventive effect of such interventions, 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 physicians by approximately 10% (West, Dyrbye, Erwin, & Shanafelt, 2016). Although cohort studies generally indicate beneficial effects of these interventions, the more stringent pooled effect size from randomised controlled trials in this meta-analysis was not statistically significant. Another meta-analysis of randomised controlled trials found that cognitive-behavioural coping skills significantly reduced overall burnout in nurses, with maintenance of effects up to 1-year follow-up (Lee, Kuo, Chien, & Wang, 2016). The literature of controlled investigations of burnout remediation interventions for mental health workers is smaller, with mixed results, and inconclusive according to a systematic review which lacks a quantitative meta-analysis (Morse, Salyers, Rollins, Monroe-DeVita, & Pfahler, 2012). Overall, there is some evidence that individual and organisational interventions can help to alleviate occupational burnout, and coping-skills interventions appear to be particularly promising in healthcare staff. In spite of this emerging literature, evidence-based interventions to prevent or remediate burnout are not commonly or routinely available to NHS staff.

The Chimp Paradox model (CPM) is a mind management approach created by Professor Steve Peters, a Consultant Psychiatrist (Peters, 2012). The model is based on developments in neuroscience. 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. The model 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. The CPM was first published in 2010 and has now sold over 1 million copies worldwide and was ranked The Sunday Times Number 1 Business Book from 2014 to 2017. A number of (unpublished) small pilot studies have been conducted using the model with groups of NHS staff, both in primary and secondary care. These pilot programmes have shown preliminary indications that the CPM could lead to improvements in the quality of life and wellbeing of the NHS staff in both their personal and professional lives. However, to date, rigorous and experimental support for this model is lacking. The CPM was developed in order to help individuals understand themselves better and help them to achieve personal success. We aim to assess whether system-wide implementation of the model amongst a cohort of NHS staff, and the collective impact on individuals, could translate to reduced burnout, improve wellbeing and reduce sickness absence.

This study aims to assess if access to a group-based intervention based on the CPM may lead to changes in occupational burnout and well-being in healthcare professionals. This will be the first experimental test of this intervention in the NHS.

3. Objectives and Hypotheses

3.1. Primary Objective

To evaluate if a group-based psychological intervention reduces occupational burnout levels in healthcare professionals.

3.2. Secondary Objectives

- To assess if the intervention improves subjective well-being
- To assess if the intervention improves personal goal attainment
- To assess if the intervention reduces sickness absence
- To quantify completion and dropout rates

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

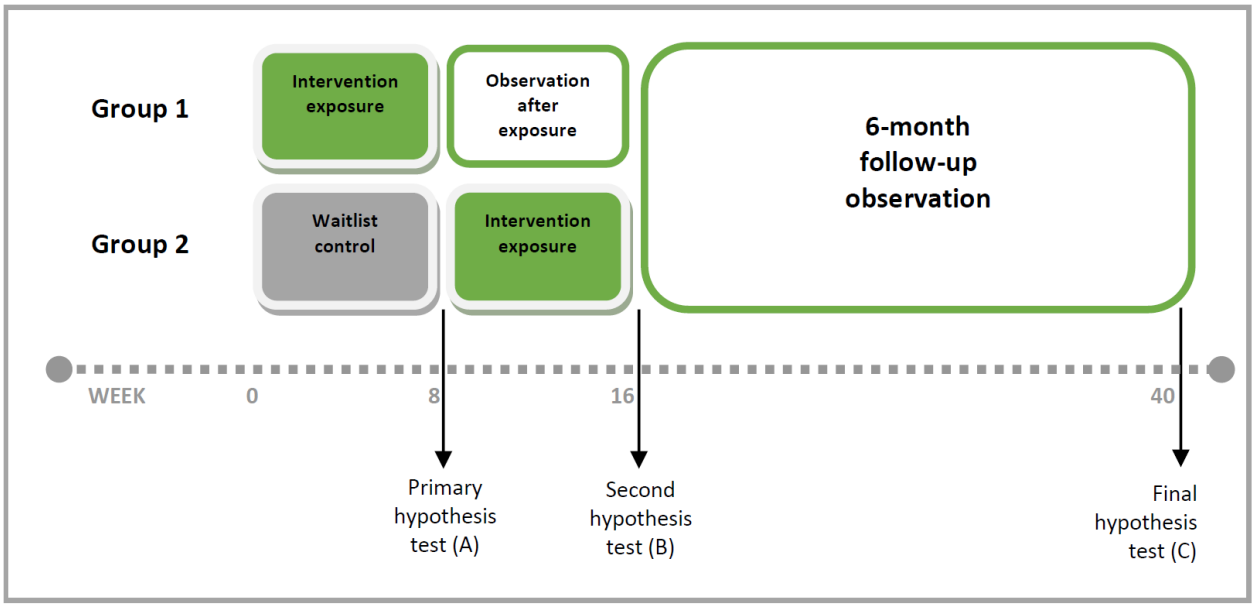
B) After the control group is exposed to the intervention, there will be no significant differences in mean burnout level between the two groups (immediate intervention group, delayed intervention group)

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 NHS staff will be randomly assigned to two groups, by a research assistant using a computerized randomization algorithm (applying a simple 1:1 randomization schedule). The study will be carried out in four 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-week intervention (controlled phase). Next, group 2 will access the intervention during an 8-week period (full implementation phase). Finally, we will collect further outcome measures 6 months after both groups have completed the intervention (follow-up phase). The outcome measures will be completed continuously at each of the measurement points outlined in the above timeline (weeks 0, 8, 16, 40). All measures will be completed online using an industry-standard survey system (Qualtrics – which automatically sends email reminders to consenting participants), which will be managed by a research assistant.

4.1. Setting and participants

This study will be conducted with registered nurses working in community based services across all four care groups in Rotherham Doncaster and South Humber NHS Foundation Trust (RDaSH). The services provide planned and unplanned home-based care and community clinic-based care for children and adults. The specialist services may include one or more of the following: holistic assessment, case management, treatment and symptom management for acute and chronic conditions, mental health care, medicines administration, palliative care and end of life care, wound care management, and other health and educational interventions.

Inclusion criteria

- The study participants will be nursing staff currently working in Rotherham Doncaster and South Humber NHS Foundation Trust (RDaSH), either full-time or part-time.
- All participants will be RDaSH employees and hold an active professional registration with the Nursing and Midwifery Council (NMC).
- aged 18+

Exclusion criteria

- Currently accessing or referred to any concurrent psychological intervention delivered by a professional.
- Nurses that are currently not in active service at the time of recruitment (e.g., on sick leave, maternity leave or suspended for any reason).

4.2. Intervention

The planned intervention is the delivery of a standardised series of group-based workshops amongst a cohort of NHS nurses that consent to participate. The workshops will provide these study participants with an understanding of the Chimp Paradox Model (CPM) and help facilitate them in acquiring the skills required to apply the model to themselves in their world. All groups will be delivered at a meeting room based in the NHS to minimise travel time for participants. If there are any obstacles that prevent participants from accessing the groups in person (such as health problems, policy changes, transportation problems, etc.), these will be facilitated online using video-conference technology in a way that preserves the participatory nature of the intervention.

The workshop series will consist of eight, ninety-minute interactive sessions, one week apart. Each standardised workshop will be delivered and facilitated by a member of the Chimp Management team. 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 small group discussions consisting of 6-8 people.

In addition to attendance at the workshops, study participants will all be given a copy of The Chimp Paradox book as a reference source. They will be requested to read particular chapters between the sessions and asked to spend some time contemplating key areas covered that week. This is to allow for continuous learning; specifically, the development of insight, acquisition of skills and application of these skills to themselves. Sessions 1-4 will introduce the basic principles of the CPM and sessions 5-8 will cover: communication, success, happiness and leadership.

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

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).

Participants will be asked to report the number of sickness absence days they have had during the 6-month period preceding the start of the study, and will self-report any sickness absence days taken during the active study and observation period.

Participants will also be asked to report basic demographics (age, gender, ethnicity) and generic information about their work setting (adult services, children’s services, inpatient vs. outpatient care).

4.4. Recruitment, study procedures and data collection

Participant recruitment process

- The RDaSH NHS Trust research team will promote the study using usual channels of communication with staff: newsletter circulated via email from the NHS communications team, via the staff intranet front page, and via posters placed in communal areas (i.e. cafeterias, meeting rooms, hospital corridors). A standard promotional leaflet will be promoted through these methods (see Appendix).
- Potentially eligible participants will receive copies of the study information sheet in three ways: (1) via email from the research team; (2) printed copies distributed to the team base and placed in staff inboxes; (3) printed copies distributed by a clinical studies officer at local team meetings.
- Potential participants will have the opportunity to contact the research team to clarify questions, if necessary, prior to the deadline for providing consent to participate (within 2 weeks). They will be asked to provide consent electronically using an online consent form which will be accessible through a weblink embedded in the information sheet. 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 survey system (Qualtrics). An sample text for the consent form that will be available electronically is provided in the Appendix. The promotional material will clearly indicate the deadline for application to participate. 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 immediate intervention group (group 1), or the waitlist control (delayed intervention) group. Allocation will be carried out by the research team, using a computerized randomization schedule, and will be communicated directly to study participants via email within a week of the application to participate deadline.
- The research team based at RDaSH NHS Trust will inform the CPM intervention facilitators when their 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. 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 attend the sessions which will take place at St Catherine's House in Doncaster on the site of the RDaSH Trust Headquarters. To allow flexibility, staff will have the opportunity to attend one of the groups (n=4 groups running simultaneously) which occur throughout the week. Sessions will be held on a Tuesday lunchtime and Tuesday evening and Thursday lunchtime and Thursday evening. Details of the sessions, including exact location, dates and times will be provided via email to the consenting participants by email following the outcome of the randomisation process. Staff can attend any one of the sessions as long as they complete one session per week. We expect that those who agree to take part in the trial complete one session for each of the 8 consecutive 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 the Group 1 have completed the eight-week intervention, the second group will attend the sessions and complete the same intervention using the process outlined above.

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 illustrated in Figure 1 (weeks 0, 8, 16, 40). The measures will be gathered by an independent researcher, who is not involved in the intervention. The researcher will use a secure, web-based, data collection system called Qualtrics.

Therefore, all data collection will be in electronic form, using unique participant pseudonyms, which cannot personally identify any of the study participants, or identify their random allocation.

- At the time of attendance at their initial group intervention session, participants will be asked to complete a brief checklist where they will report basic demographics and generic information about their role (see Appendix 3). These paper-based surveys will be entirely anonymous (no names, pseudonyms or identifiers), in order to protect participants' confidentiality. Participants will be asked to deposit their survey into a box, which will be managed by a member of the research team, who will then transcribe the results onto a spreadsheet, which will be safely stored in a secure network drive. The only reason to collect these data is to enable the research team to provide basic aggregated sample characteristics (e.g., mean age and standard deviation, % of people from a minority ethnic group, etc.) This will enable us to assess if the study sample is broadly representative of the wider NHS workforce or not.
- The dataset will be stored in a secure University network drive, only accessible to members of the research team, which is located behind The University of Sheffield 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 the University for a minimum of 5 years after the conclusion of the study.
- Participants will be contacted by email two weeks after randomisation has been completed to request that they complete an anonymised electronic survey gathering basic information for descriptive purposes (e.g., role, age, gender, years/months of experience, qualifications, etc.). As described above, all survey-based information will be securely stored using fully pseudonymised data files located in a password protected network drive at the University of Sheffield, only accessible to members of the research team.

5. Data analysis

5.1. Sample size calculation

A sample size calculation was performed using the method described by Cohen (1992). There is no precedent for this type of trial in this setting, so it is not known whether exposure to the CPM intervention may be associated with small, moderate or large effects on measures of occupational burnout or well-being. We have therefore followed conventional sample size calculation methods described by Cohen (1992), expecting a moderate effect size as a conservative assumption. In order to detect a moderate effect size using between-groups ANCOVA, with 80% power, and an alpha level of 0.05, and controlling for intake severity, we estimate that at least 67 participants are needed per group. This would yield a minimum sample size of 134. Expecting a 30% dropout rate, which is common in studies of psychological interventions, we would need to inflate the recruitment target to 192.

5.2. Primary analysis

Trial data will be summarised using a CONSORT diagram and all analyses will be based on *intention-to-treat* principles. Missing data will be imputed using an expectation-maximization algorithm, prior to conducting formal analyses.

The primary hypothesis test (A) will be based on comparing mean outcome measures between groups at week 8, as shown in Figure 1. Mean OLBI scores will be compared between groups using analysis of covariance (ANCOVA), controlling for baseline severity.

Sensitivity analyses will be performed to assess the robustness of the main findings. This will involve repeating the comparison of means whilst controlling for any potential site-effects (systematic differences in burnout between NHS services), introducing a site variable as a random effect.

5.3. Secondary analyses

ANCOVA (and sensitivity analyses) described above will be repeated at each of the time-points illustrated in Figure 1 (weeks 0, 8, 16, 40), using the OLBI (total score; then separate domain scores), and using the WEMWBS as an outcome, controlling for baseline scores. Outcomes at 6-months follow-up (pooled for both groups) will be compared to outcomes at the baseline assessment, using paired-samples t-tests (or an appropriate non-parametric test depending on the distribution of the data).

We will carry out an exploratory analysis of sickness absence, by comparing the mean number of sickness absence days reported by all participants for the 6 months preceding the start of the study, and the mean sickness absence days reported during the 6-month follow-up period after both groups completed the intervention. This within-group comparison will be carried out using a paired-samples t-test (or an appropriate non-parametric test depending on the distribution of the data).

6. Ethical considerations

6.1. Considerations about informed consent

As the participants of this study are NHS staff participating due to their NHS role, this study does not strictly need NHS research ethics approval. However, it will require Health Research Authority (HRA) approval, and we are nevertheless seeking a proportionate review by an NHS REC in order to obtain independent scrutiny of the study protocol and relevant recruitment materials and methodology.

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 PIS, consent form and will be explained to participants following notification of randomisation.

We will also be collecting fully anonymous data described in section 4.3. We consider that 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 CPM 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 RDASH NHS Trust.

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

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