RESEARCH PROTOCOL
UpLift: A randomised controlled trial to improve NHS staff wellbeing

Short title of the study	Sponsorship and funding details
UpLift Trial	*Sponsor organisation:* Rotherham Doncaster and South Humber (RDaSH) NHS Trust *Funders:* MindLife UK and RDaSH NHS Trust
Protocol version and date	**Approval and registration details**
(v3.3) 11/11/2020	*Ethics approval reference:* IRAS 288024 *Controlled trial registration:* [TBC]

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Contents of the study protocol

1. Synopsis of the study	
Short study title	UpLift Trial
ISRCTN registration no.	[TBC]
Study Design	Multi-site randomised controlled trial
Setting	Multiple NHS Trusts in England
Study Participants	Staff that work in the NHS
Aim	To compare the effectiveness of two psychological interventions for occupational burnout in health care professionals
Objectives	▪ To assess changes in occupational burnout and wellbeing ▪ To assess changes in sickness absence ▪ To assess completion and dropout rates ▪ To examine hypothesised mechanisms of change ▪ To examine indicators of App utilisation and acceptability
Primary outcome	Level of occupational burnout, measured 6 weeks after the start of the intervention using the Oldenburg Burnout Inventory (OLBI)
Interventions	Two 6-week, blended-care interventions consisting of online video-based workshops and online self-help tools
Randomization and data collection	Participants will be randomised to one of two groups. They will complete outcome measures at a baseline assessment, after they provide informed consent. All participants will then take part in one of the two 6-week interventions, depending on their group assignment. Outcome measures will be completed online following week 3, week 6, and finally at a 6-month follow-up.
Planned Sample Size	N=240 (120 per group)
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 6-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. Mechanisms of change for each intervention will be explored using Bayesian network models. 7. Indicators of App utilisation and acceptability will be compared between groups using ANOVA.
Study Period	12 months

2. Background and rationale

Currently, the UK National Health Service (NHS) faces unprecedented clinical demand, increasing financial pressures, and a patient population with complex care needs. These challenges increase the risk of occupational burnout in NHS staff, which has been further compounded by the COVID-19 pandemic. The current lockdown and social distancing conditions raise unprecedented risks to the physical and emotional health of NHS staff and their families. Furthermore, many NHS staff have felt unsupported and unprotected, for example due to the lack of adequate personal protective equipment and protracted availability of testing and tracing systems. All of this is likely to undermine the occupational health and wellbeing of NHS staff. In this context, identifying and remediating occupational burnout is a key challenge and priority for the NHS.

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 more severe 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 wellbeing 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 in health care professionals is also associated with poorer patient treatment outcomes (Delgadillo, Saxon, & Barkham, 2018), medical errors (Shanafelt et al., 2010), negligent practice in healthcare-related infection control (Cimiotti et al., 2012) and associated medico-legal cases (Balch et al., 2011).

A recent examination of staff wellbeing in the NHS 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 occupational burnout. Burnout 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. 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). Notwithstanding the recognition that burnout is a major problem, structured and evidence-based interventions proven to enhance occupational health are not routinely available in the NHS.

Approaches to address occupational burnout include individual interventions (e.g., stress management courses) and organisational interventions (e.g., workload redesign, task-focused training). 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 randomised controlled trials (RCTs) 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 rigorous evidence from RCTs in this meta-analysis was not statistically significant. Another meta-analysis of RCTs 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 RCT literature of burnout interventions for mental health workers is smaller, with mixed results, and inconclusive according to a systematic review that lacked a quantitative meta-analysis (Morse, Salyers, Rollins, Monroe-DeVita, & Pfahler, 2012). Two meta-analyses found that organization-directed interventions were the most effective at reducing burnout (Panagioti et al., 2017; Busireddy et al., 2017). Especially the reduction of hours worked, which reduced emotional exhaustion, depersonalization and increased personal accomplishment (Busireddy et al., 2017). However, the reduction of hours this is not always a possible approach to reducing burnout, particularly in the current COVID-19 pandemic. Current

evidence from meta-analyses of RCTs suggests that emotion-focussed interventions are better at improving emotional exhaustion and depersonalisation (Lee et al., 2016; Dreison et al., 2018; Shin et al., 2014), whereas problem-focussed interventions are better at increasing feelings of personal accomplishment (Lee et al., 2016; Dreison et al, 2018; Shin et al., 2014). *Job crafting* is a novel approach to reduce burnout and to increase job satisfaction by combining individual and organisational interventions (Tims & Bakker, 2010). This approach counts with empirical support from over 100 cross-sectional and longitudinal studies (Lichtenthaler & Fischbach, 2019). Yet, rigorous RCT evidence supporting job crafting to remediate burnout in health care staff is still lacking. 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. However, no specific techniques seem to be more beneficial than others (Maricutoiu, Sava & Butta, 2016) and RCTs of effective interventions typically show small-to-moderate effect sizes in health care staff and particularly in mental health worker populations (Dreison et al., 2018). Evidently, burnout is influenced by multiple risk factors (e.g., organisational factors and individual differences) and therefore different treatment components and intervention models may be effective for different people. To date, there is little understanding of what works for whom in the field of occupational burnout and wellbeing.

This study has been developed as a public health response to the COVID-19 crisis, aiming to support the wellbeing of NHS staff using accessible blended-care interventions that combine video-based workshops with App-based self-help materials. The study will examine the comparative effectiveness of two interventions designed to reduce occupational burnout and to improve wellbeing in NHS staff. One intervention has a well-established evidence base grounded in cognitive behavioural coping skills; the second intervention is novel and has no prior empirical support. The study will compare the effects of the novel intervention relative to the well-established intervention, using a non-inferiority controlled trial design.

3. Objectives and Hypotheses

3.1. Primary Objective

To compare the effects of two group-based, blended-care, psychological interventions designed to reduce the occupational burnout levels of NHS staff.

3.2. Secondary Objectives

- To assess changes in sickness absence.
- To assess completion and dropout rates.
- To examine hypothesised mechanisms of change.
- To examine indicators of App utilisation and acceptability.

3.3. Hypotheses

A) No significant adjusted mean differences will be found when comparing post-treatment outcomes between the two interventions, across any of the outcome measures. Thus, we hypothesise that the novel Job Crafting intervention will have comparable effects to an established intervention based on CBT.

B) Moderate within-group, pre-post treatment effect sizes (~d = .50) will be observed for both interventions in burnout and wellbeing measures.

C) Mean burnout and wellbeing levels at the 6-month follow-up point will be significantly lower than baseline severity (prior to intervention), but not significantly different to end-of-treatment levels, indicating maintenance of gains.

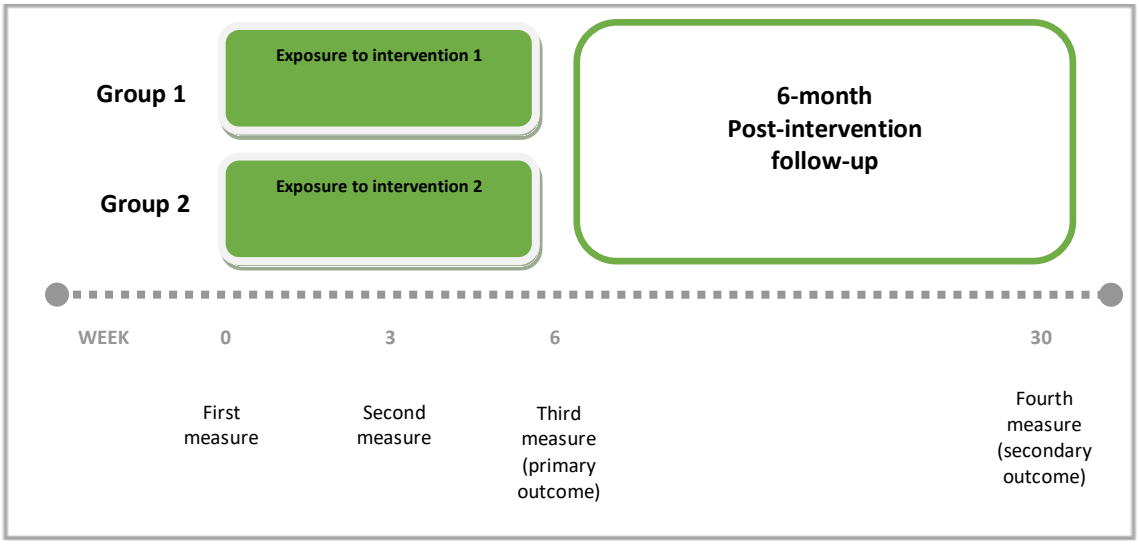
D) The network structure of predictors (mechanisms) of change will be different across both interventions. Self-efficacy, autonomy and neuroticism will be ranked as more important in intervention 1. Organisational stress, over-commitment and relational factors (professional, client, and family-related stress) will be ranked as more important in intervention 2.

4. Study design

This will be a pragmatic, multi-site, parallel group, randomised controlled trial. Consenting NHS staff will be randomly assigned to one of two groups, by a research assistant using a computerized randomisation algorithm. The randomisation sequence will be based on random blocks of 10 participants, and stratification according to participants' employing organisation (trial site) and role (administrative; mental health; other health care roles). Participants will take part in one of the two 6-week interventions, depending on their group assignment. They will complete an online survey with standardised measures at baseline (prior to starting the interventions), after 3 weeks, after 6 weeks (post-treatment,) and finally after 6 months (follow-up). All measures will be completed online using an industry-standard survey system which automatically sends email reminders to consenting participants.

The interventions will be delivered using a "blended care" approach; including weekly online video-conference sessions supported by access to a computerized App with self-help resources related to the content of each weekly session. Both interventions will involve a total of six 1-hour sessions delivered once per week using video-conferencing software that can involve large groups of participants (Microsoft Teams). The trial design and measurement strategy is depicted in Figure 1.

Figure 1. Trial design and measurement time-points



4.1. Setting and participants

This study will involve NHS staff as the primary participants. We will recruit NHS staff from at least three NHS Trusts.

Inclusion criteria

- The study participants will be any staff currently working in the NHS either full-time or part-time.
- Participants will have direct patient contact, either in a clinical capacity or an administrative capacity (receptionists, administrators).

Exclusion criteria

- Staff that are currently not in active service at the time of recruitment (e.g., on sick leave, maternity leave, or suspended for any reason).
- Staff who are on temporary (e.g., bank, agency) contracts.
- Staff whose roles do not involve any direct contact with NHS patients.

- Staff who were a participant in the recent CPM Trial – they are currently in a 6 month follow-up period and we do not want to influence these results
- Staff who are currently accessing or referred to any concurrent psychological intervention delivered by a professional.

4.2. Interventions

Participants will have access to one of two "blended care" interventions which have been developed by our research team with reference to the current evidence-base in the field of occupational burnout. These interventions will involve weekly 1-hour online workshops delivered by psychological professionals, for a total of 6 weeks, which will be supported by an App that integrates educational and self-help tools that are based on the content of each session. The App includes interactive media such as videos, animations and practical exercises that guide participants to apply and practice coping skills covered in each of the 6 sessions. Each session will be delivered in such a way that participants will learn about key concepts in an interactive way (e.g., including group discussions and participation), and will be guided to practice two specific coping skills each week. At the end of each session, participants will be encouraged to use the App, which will guide them to practice key coping skills that will be covered each week. In this way, learning will be followed by practical exercises, increasing the chances of behaviour change and integration of coping skills into daily life. Each of these interventions is based on a different underpinning evidence-base and theory. We expect that both interventions will lead to changes in burnout and wellbeing, but they will do so through different mechanisms, which is consistent with literature in the field that points to multiple interrelated risk factors.

Intervention 1 integrates concepts from cognitive behavioural therapy and positive psychology. The sessions cover specific coping skills that are featured in prior controlled trials that have empirical support from meta-analyses (Lee, Kuo, Chien, & Wang, 2016). These coping skills include individual formulation using the five-areas model; controlled breathing; mindfulness and attention training; cognitive restructuring; problem solving; and the identification and modification of counter-productive behaviours and ineffective coping strategies. The intervention also draws on concepts from the social-cognitive theory of stress (Lazarus & Folkman, 1984) and the *flow state* concept in positive psychology (Nakamura & Csikszentmihalyi, 2009).

Intervention 2 integrates concepts from key theories in the field of occupational burnout: the job demands-resources model (Demerouti et al., 2001), the effort-reward imbalance model (Siegrist, 1996), and the job crafting model (Tims & Bakker, 2010). These theories are used as a conceptual framework to develop coping skills that specifically target empirically-supported risk factors for burnout in mental health care staff, who are known to be at increased risk of burnout (Davis, 2020). These coping skills are designed to mitigate organisational stressors (e.g., imbalance of rewards-effort and demands-resources), relational stressors (arising from professional, client, and family relationships), and psychological stressors (over-commitment).

Potentially participants who work in the same team will be in different intervention groups. To reduce the risk of contamination, the concept of a randomized control trial will be explained to the participant in the participant information sheet and also during the first workshop. This is to encourage participants not to share or discuss materials from the interventions, and therefore we can be sure that any effects that occur from the trial are due to the individual interventions.

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 be asked to provide some demographic information, including age, gender, ethnicity, job role, department, and hours worked for the NHS.
- Participants will be asked to report the number of sickness absence days they have had during the 4-week period period preceding the start of the study, and will self-report any sickness absence days taken during the active study and observation period.
- 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 α = .89 to .91) and test-retest reliability (.81).
- The Job Diagnostic Survey (Hackman & Oldham, 1974) turnover intent single-item will be administered (see below).

Other measures

- The Big Five Inventory-10 (BFI-10; Rammstedt & John, 2007) is a 10-item scale derived from the 44-item measure of personality capturing Extraversion, Agreeableness, Conscientiousness, Neuroticism and Openness. This measure is suitable where limited time is a significant factor and investigations of personality are not the main focus of the study (Rammstedt & John, 2007). An additional item is available to improve the validity of the Agreeableness sub-scale making this 11-items in total.
- 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 General Self-Efficacy Scale - (Schwarzer & Jerusalem, 1995) is a 10-item scale designed to capture an individual’s beliefs about their ability to cope with difficult demands. It has been widely used in burnout research with Cronbach α values ranging from .75-.93 (Shoji et al., 2016). Each item is scored 1-4 and item scores are averaged to create the same range for the scale score with higher scores representing greater self-efficacy.
- The Work-Family Conflict Scale is a 5-item scale designed to capture conflict between work roles and family responsibilities/activities and validation across different samples shows reliable Cronbach’s alpha of .88 – .89 (Netemeyer, Boles, & Mcmurrian, 1996). Items are scored 1-7 and averaged to give the same scale score range with higher values representing greater negative impact of work on family life.
- The Job Diagnostic Survey (Hackman & Oldham, 1974) contains four items relating to job autonomy with both positively and negatively worded questions. Cronbach’s alpha ranges from .68 to .77 (Fields, 2002). Items are scored 1-7 and averaged to give the same scale score range with higher values representing greater autonomy. This subscale was used in a study which

showed lower levels of autonomy related to increased burnout in psychiatrists (Adebayo & Ezeanya, 2011). This will be collected at baseline only.

- 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 baseline only.
- The Job Satisfaction Survey (Spector, 1985), uses 36 items scored 1-4 to describe nine job facets (four items per facet). Cronbach's alpha is reported as .89 (Blau, 1999) and the "Work itself" items will be used which incorporate constructs such as meaning and enjoyment.
- 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).
- The Social Support Scale (House & Wells, 1978) is a six-item self-report questionnaire that captures the level of work-related social support an individual receives from colleagues, supervisors, spouses/partners and friends/family. Participants are asked to indicate how 'true' each statement is using a four-point Likert-scale, ranging from (1) 'not at all' to (4) 'very much'. Higher scores indicate higher levels of perceived social support. Cronbach's alpha values have been reported as 0.84 (Jenkins & Elliot, 2004), 0.89 (Davis, 2020) and 0.85 (Hamaideh, 2011) across diverse population samples.

4.4. Recruitment, study procedures and data collection

Participant recruitment process

- A principal investigator (PI) will be nominated at each of the participating NHS Trusts, 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 poster and (2) a participant information video. These promotion materials will be disseminated to the workforce by the PI via local NHS management mailing lists, via NHS communication teams, and via NHS wellbeing teams, via NHS intranet front page, and via social media campaigns.
- The PI will also organise attendance at relevant NHS 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 four weeks. Promotion activities will commence in August 2020, prior to obtaining ethical approvals. The formal electronic consent process (described below) will 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. The research team will also hold scheduled video-link sessions, which potential participants can attend to ask any questions they may have prior to the deadline for formal consent.
- 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. 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 online intervention groups. Allocation will be carried out by a University-based researcher who is independent of the research team, using a computerized 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 download the App and register onto an upcoming online workshop.

Organisation of the online intervention workshops

- Participants will access one of the two interventions described above; using NHS-approved video conferencing software (Microsoft Teams).
- To allow flexibility and to accommodate different working patterns and shifts, participants will have the opportunity to attend one of the groups (approximately four groups running simultaneously) which occur throughout different days and times of the week. Participants will receive an email listing these four 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 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 six consecutive weeks, however we understand that some will be unable to do so. For this reason, all participants will have access to reading and video materials summarising each session, so that they are able to keep up with the content in case they miss one or more of the video conference sessions. The App content (videos, skills practice instructions, etc.) will be enabled after the end of every weekly workshop session.

Data collection and safeguarding procedures

- All participants will be asked to complete the demographic, primary and secondary measures described above at a baseline assessment time-point (week "0" depicted in Figure 1 above). Participants will then be asked to complete a short version of this electronic questionnaire at subsequent measurement time-points depicted in Figure 1.
- The consent and demographic questionnaires will ask for the participants work 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 UpLift App, as their identifier when they complete the rest of the measures throughout the study), so that their data is completely anonymous when using the UpLift App. The Grounded Research team will keep a record of the participants email address and associated pseudonym, so if the participant forgets their code they can contact us. Staff in the RDaSH IT team will create the MS Teams sessions using participants work email addresses (this is required for the breakout session facility to ne used). IT staff will not have access to any other study data. The participants email address will be deleted when the study has completed.
- 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, using unique participant pseudonyms, which cannot personally identify any of the study participants. Participants will receive email reminders (sent confidentially by the research team) at the relevant measurement points (see Figure 1) prompting them to access the survey via the UpLift Website. To access the survey, each participant will enter their participant ID (an anonymized pseudonym) and a password

of their choice. In this way, the survey software will not collect any identifiable data, and it will have several layers of data protection (password, encryption, no identifiable data stored).
- The final study dataset will be archived for potential future use. The study documents 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 of 5 years after the conclusion of the study.

Incentives for participation

- Participants will be eligible to be included in two prize draws for Amazon shopping vouchers.
- The first prize draw will take place at the end of the intervention phase (week 6 in Figure 1). To be eligible for inclusion in this prize draw, participants should have attended at least four intervention sessions and have completed all three online surveys up to that point. The prize will be a £100 Amazon voucher, and there will be one prize per participating NHS Trust (trial site).
- The second prize draw will take place at the end of the 6-month follow-up phase (week 30 in Figure 1). To be eligible for inclusion in this prize draw, participants should have attended at least four intervention sessions and have completed all four online surveys up to that point. The prize will be a £200 Amazon voucher, and there will be one prize per participating NHS Trust (trial site).
- In accordance with the University of Sheffield's policy for the ethical use of incentives in research, the prize winners will receive their electronic voucher code via email and they will be asked to return a signed receipt via email, which includes their name and work address, which is essential for auditing purposes and for legal reasons.

5. Statistical analysis plan

5.1. Sample size calculation

The sample size to compare two independent means was based on a minimum clinically important difference of 0.15 on the OLBI measure and a standard deviation of change of 0.273. This information was derived from a recent feasibility study by our team in which we collected OLBI measures for participants who accessed an eight-week guided self-help intervention for occupational burnout. Therefore to achieve a power of 90% and level of significance of 5% (two-sided) to detect a difference in means of 0.15, a minimum sample size of 140 (70 in each arm) is required. Expecting a 40% dropout rate, which is a highly conservative estimate compared to the typical 30% dropout rate in psychological interventions, we would need to inflate the recruitment target to a minimum of 240 (120 in each arm). Within psychological research a sample size calculation provides a minimum target of recruitment, and recruiting above this strengthens the findings of the research. Given the current situation with the COVID-19 pandemic, we feel it would be unethical to cap the recruitment at 240 participants, if more are willing to volunteer. There also needs to be the consideration that there may be higher than even the 40% dropout rate we have accounted for, due to the pandemic, so over-recruitment will not be discouraged within this trial.

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 (Schafer & Olsden, 1998), prior to conducting formal analyses.

The primary hypothesis test will be based on comparing mean OLBI (total severity) scores between groups at week 6 (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 in Stata (v15) by a statistician who will be blind to the label of the interventions.

Sensitivity analyses will be performed to assess the robustness of the main findings. This will involve repeating the above analysis including a random intercept for each trial site and additionally introducing "role" as a covariate (admin; mental health; other clinical role) and any other baseline demographics that may be unbalanced between groups.

5.3. Secondary analyses

The analysis (and sensitivity analyses) described above will be repeated at the 30-week follow-up. In addition, these analyses will be repeated at each of the post-intervention time-points illustrated in Figure 1 (weeks 6, 30), using the OLBI sub-domain scores (exhaustion; disengagement), and using the WEMWBS score as an outcome, controlling for baseline scores. These between-group comparisons will also be summarised using effect sizes (Cohen's *d*).

Post-intervention measures (weeks 6, 30) 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).

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 4 weeks 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.

5.4. Exploratory analyses of mechanisms of change

Change scores will be computed denoting changes in theoretical mechanisms measured using the questionnaires listed in pg. 7. These change scores will be computed between time-point 0 and time-point 6, denoting changes within the intervention phase.

Residualized change scores across multiple theoretical mechanisms will be entered into a Bayesian network analysis carried out separately for each intervention group, using the post-treatment (week 6) OLBI as the dependent variable. Each Bayesian network will be trained using a Tree-Augmented Naïve Bayes (TAN) algorithm with adjustment for small cell counts (Friedman, Geiger, & Goldszmidt, 1997). This method offers a data-driven way to model a network of relationships (called *attribute dependencies*) between predictors and their joint influence over a target outcome (post-treatment OLBI). TAN produces a simple and parsimonious network model where each predictor is allowed to depend on one additional predictor, thus modelling multiple two-way interactions. Variable selection will be performed using a 10-fold cross-validation procedure (Rodriguez, Perez, & Lozano, 2010). The resulting treatment-specific network models will be visualised using directed acyclic graphs (Shrier & Platt, 2008), which enable an intuitive interpretation of key mechanisms of change, their relative importance, and their interrelationships.

6. Ethical considerations

6.1. Considerations about informed consent

As the participants of this study will be NHS staff, 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:

- Potential participants will 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 promotional materials described above.
- 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 above. 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.

6.2. Potential for distress

Given the psychoeducational nature of the interventions, 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 their NHS Trust.

7. Risk management

7.1. Risks to participants

See above section.

7.2. Risks to research team

See above section.

7.3. Potential for disclosure

See above section.

8. 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

9. References

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